



JACARDI

Joint action
cardiovascular diseases
and diabetes

JACARDI methodological framework

JACARDI Work package 5
Deliverable 5.1



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Glossary of Acronyms

Acronym	Description
JACARDI	Joint Action on CARdiovascular diseases and DIabetes
WP	Work package
WP1	Work package 1: Project management and coordination
WP2	Work package 2: Communication and dissemination
WP3	Work package 3: Evaluation
WP4	Work package 4: Sustainability
WP5	Work package 5: Methodological framework and integrative approach
WP6	Work package 6: Health literacy and awareness of CVDs and diabetes
WP7	Work package 7: Data availability, quality, accessibility and sharing
WP8	Work package 8: Screening high-risk population and individuals
WP9	Work package 9: Integrated care pathways
WP10	Work package 10: Patients' self-management
WP11	Work package 11: Labour participation of people living with NCDs, in particular with CVDs and diabetes
JA	Joint action
EU	European Union
EC	European Commission
ICT	Information and communication technology
JANFP4Health	Joint Action of National Focal Points for Health
CVDs	Cardiovascular diseases
NCDs	Non-communicable diseases
GDPR	General data protection regulation
WP6-11 leadership teams	Leadership teams of Work package 6 to 11
NFP	National focal point
FDA	Finnish Diabetes Association
NGO	Non-governmental organisation
IHI	Institute for Healthcare Improvement
SWOT	Strengths, weaknesses, opportunities, and threats

DG SANTE	Directorate-General for Health and Food Safety
NIJZ	National Institute of Public Health Slovenia
THL	Finnish Institute for Health and Welfare
JADECARE	Joint Action on implementation of digitally enabled integrated person-centred care
GA	Grant agreement
Q&A	Questions and answers
PreventNCD	Joint Action Prevent Non-Communicable Diseases
HADEA	European Health and Digital Executive Agency
CARE4DIABETES	Joint action to improve and foster health in the EU Member States by reducing the burden of type 2 diabetes
SMART	Specific, Measurable, Achievable, Relevant, Time-Bound
PDSA	Plan-Do-Study-Act
JRC	Joint Research Centre
PR	Public relations
AI	Artificial Intelligence
WHO	World Health Organization
CFIR	Consolidated framework for implementation research

Glossary of Terms

Term	Description
Activity	Activities are directly influenced by the project; together with outputs, they are “what the project does.” Activity is the insight needed to bring about the desired outcomes and how these insights will be gained. ¹
Best practice	A best practice is a relevant policy or intervention implemented in a real-life setting that has been favourably assessed in terms of adequacy (ethics and evidence) and equity, as well as effectiveness and efficiency related to process and outcomes. Other criteria are important for the practice’s successful transferability, such as a clear definition of the context, sustainability, intersectionality, and participation of stakeholders ² .
Cardiovascular diseases	Cardiovascular diseases are a group of disorders of the heart and blood vessels. They include coronary heart disease – a disease of the blood vessels supplying the heart muscle; cerebrovascular disease – a disease of the blood vessels supplying the brain; peripheral arterial disease – a disease of blood vessels supplying the arms and legs; rheumatic heart disease – damage to the heart muscle and heart valves from rheumatic fever, caused by streptococcal bacteria; congenital heart disease – birth defects that affect the normal development and functioning of the heart caused by malformations of the heart structure from birth; and deep vein thrombosis and pulmonary embolism – blood clots in the leg veins, which can dislodge and move to the heart and lungs ³ .
Capacity-building	In health promotion, for example, capacity-building is developing knowledge, skills, commitment, partnerships, structures, systems, and leadership to enable effective health promotion actions. Capacity-building is intended to strengthen and complement existing capabilities and sustain and amplify health outcomes through health promotion. It involves actions to improve health through advancing knowledge and skills among frontline practitioners, expanding support and infrastructure for health promotion in organisations, and developing cohesiveness and partnerships for health in communities ⁴ .
CFIR	The Consolidated Framework for Implementation Research is a determinants framework designed to describe barriers and facilitators to implementation outcomes.
Co-design	Meaningful, participatory, and inclusive involvement of all relevant stakeholders, including persons with lived experience (i.e., end-users or end-beneficiaries), professionals, and other pertinent groups of designing products, services, and policies. Sometimes, it is also referred to as co-creation.
Context Analysis	Context Analysis seeks to understand the relevant background conditions, stakeholders, policies, and trends within which the project operates. In

¹ Belcher et.al., 2020. A refined method for theory-based evaluation of the societal impacts of research. Published by Elsevier B.V.

² European Commission. Guide for submitting Best and Promising Practices to the Public Health Best Practice Portal. March 2023

³ WHO.Fact Sheets. June 2021. Available at: [https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds))

⁴ Health promotion glossary of terms 2021. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0IGO

	JACARDI, the Context Analysis aims to assess the current state of preventing and managing cardiovascular diseases (CVD) and diabetes in all countries participating in the project. The assessment includes the availability of governance and financing and how service delivery, as well as the capacity for the prevention and management of CVD and diabetes, deviates from an ideal state. Therefore, the aim is to identify specific gaps at the national level that justify the selection and implementation of Best Practices and other practices or elements of these by the pilot sites.
Critical reflection	A continuous, life-long process of acknowledging our limitations in knowledge and challenging our biases, prejudices, stereotypes, and our position of power in relation to others.
Culture of collaboration and consensus-seeking	It is considered one of the cornerstones for building up sustainable pilots. Culture is understood as a set of beliefs, values, behaviours, perceptions, and local conventions that strongly influence pilot implementation and its sustainability. Understanding and operating in concordance with the local culture, collaboration, and consensus-seeking across all stakeholders are recognised as imperative features of the local environments and a basis for ensuring pilot continuity. ⁵
Diabetes	Diabetes is a chronic metabolic disease characterised by elevated levels of blood glucose (or blood sugar), which, over time, leads to severe damage to the heart, blood vessels, eyes, kidneys, and nerves. The most common is type 2 diabetes, usually in adults, which occurs when the body becomes resistant to insulin or doesn't make enough insulin. Type 1 diabetes, once known as juvenile diabetes or insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin by itself ⁶ .
Diversity	The presence of different characteristics or social dimensions within a group, organisation, or community. Social dimensions include age, gender, race, ethnicity, sexual orientation, socioeconomic status, physical and cognitive abilities, religious beliefs, and cultural background.
End-user/End-beneficiary	The individual, community, or organisation, i.e., relevant stakeholder, will ultimately use or benefit in some way from the developed product, service, or measure.
Equity	The fair treatment and equal distribution of resources and opportunities across individuals or social groups (e.g., based on social, economic, demographic, and geographic characteristics).
Impact	Impact reflects higher-level project aims outside of project influence. It is the result of a deliberate chain of activities and conditions by which the potential impact that the project is aiming for could be realised. Underlying all this is the belief that engaging with stakeholders throughout the project and the activities increases the chance for productive interactions, leading to impact. ⁷
Inclusion	Securing material resources, abilities, and rights for equal and meaningful participation in society and decisions concerning oneself.

⁵ JADECARE project.

⁶ WHO: *Health Topics*. Available at: https://www.who.int/health-topics/diabetes#tab=tab_1

⁷ Belcher et.al., 2020. A refined method for theory-based evaluation of the societal impacts of research. Published by Elsevier B.V

Inclusive and accessible communication	Principles and practices that ensure the suitability of information for everyone, regardless of their abilities (including digital skills), gender, background, or life situation. It considers that the language and/or visuals used do not reinforce prejudices, stereotypes, or discriminatory views toward specific individuals or social groups.
Multidimensional assessment	In JACARDI, the framework for multidimensional pilots' assessment will ensure the collection of complete, high-quality quantitative and qualitative data to allow the multidimensional assessment of a wide range of pilot outcomes within and across countries. In summary, developing an assessment framework aims to bring structure, objectivity, and consistency to evaluating pilots' outcomes, ultimately contributing to improving activities/practices and advancing knowledge in a particular field.
Other practices	In JACARDI, "other practice" refers to evidence-based practices and interventions resulting from previous projects or actions that have yielded promising results but are not yet recognised as Best Practices by the European Commission.
Outcome	Outcome are in indirect influence of the pilot, "Who the project works with and through". Outcomes relate to changes in behaviour, relationships, actions, and activities of stakeholders resulting from the exchange of knowledge and the uptake of the pilot outputs. They identify who has to do what differently to achieve the desired impact. Changes can be: Instrumental: plans, decisions, behaviour, practices, actions, policies; Conceptual: changes to knowledge, awareness, attitudes, and emotions that contribute to the understanding of issues and reframing debates; Capacity-building: technical and personal skills and expertise; Network: number and quality of relationships and trust; Knowledge culture: attitudes towards knowledge exchange and impact itself. ⁸
Output	Outputs are the tangible products as a result of the activities. Together with activities, they are under direct influence of the project, they are "What the project does". Usually expressed as nouns, tangible and can be counted (15 trainings). ⁹ In the JACARDI methodological framework, we also refer to them as pilot project results.
Ownership of sustainability	It is considered one of the cornerstones for building up sustainable pilots. Each pilot consists of various interventions; accordingly, different governance structures are responsible for its continuity. Holders of sustainability, including high-level policy individuals, managers and champions, regional/local health organisations and departments, and/or integrator companies that engage in various formal and informal networks, must be present at different levels to facilitate the sustainability of the pilots ¹⁰ .
Persons with lived experiences	Individuals and communities who have first-hand experience on the given subject and who are the end-users or end-beneficiaries for the planned

⁸ Belcher et.al., 2020. A refined method for theory-based evaluation of the societal impacts of research. Published by Elsevier B.V

⁹ Belcher et.al., 2020. A refined method for theory-based evaluation of the societal impacts of research. Published by Elsevier B.V.

¹⁰ JADECARE project

	actions. From the perspective of JACARDI, the lived experiences of relevance are living with or being affected by diabetes and/or cardiovascular diseases.
Pilot	A pilot or a pilot project is a small-scale, preliminary initiative implemented to test the feasibility, effectiveness, and potential impact of a proposed solution or intervention in a real-world setting. It serves as a precursor to larger-scale initiatives, providing valuable insights and evidence to inform policy decisions and future actions.
Policy environment	It is considered one of the cornerstones for building up sustainable pilots. The pilots are to be grounded in the national and/or regional policy frameworks where they are embedded: health strategies, policies, and funding mechanisms, among others. Furthermore, vertical solid linkages between relevant institutions and networks, including top-down and bottom-up connections, that assure the systemic funding and continuity of pilots are to be established. ¹¹
Scalability	Assessing the scalability of a pilot involves evaluating its potential for expansion and replication to reach a larger population or be implemented in different settings. As it is usually mentioned together with transferability – transferability, on the other hand, refers to the extent to which the findings and outcomes of the pilot can be applied to other settings, populations, or contexts beyond the original pilot environment.
Situation analysis	Situation analysis involves a comprehensive assessment of the current state or conditions related to the project's focus area or target population. The aim of the situation analysis is to gain a clear understanding of the existing situation, identify key issues or problems, assess strengths and weaknesses, and identify opportunities for intervention or improvement. This analysis serves as a foundation for pilot implementation planning, objectives setting, and strategy development.
SCIROCCO	The Scirocco self-assessment tool is used to identify the maturity of the health and social care systems for the adoption and scaling up of integrated care or best practice solutions.
Social determinants of health (SDH)	Social determinants of health (SDH) are the non-medical factors that influence health outcomes. Conditions in which people are born, grow, live, work, and age are shaped by the distribution of wealth, power, and resources at global, national, and local levels. In the context of the JACARDI project, ethnicity/migrant origin are considered as independent social determinants of health and to be in complex interaction with other social determinants of health.
Socioeconomic (or social) position (SEP)	Socioeconomic (or social) position (SEP) is a broad concept related to the factors that produce stratification within a society and define the position of an individual according to hierarchies of wealth, power, prestige, and access to resources. It is often incorrectly used interchangeably with the narrower concept of socioeconomic status (SES), measured as a combination of education, income, and occupation.

¹¹ JADECARE project

Stakeholder Board	An advisory board consisting of different individuals, groups, institutions, organisations, or other entities that show an interest in the activity, program, intervention, or policy relevant to your field are either directly or indirectly affected by the planned or implemented actions, decisions, or outcomes; or are important advocates for continuation and potential scalability of results when JACARDI ends. Persons with lived experiences should be included in the stakeholder board, and it must be ensured that their participation is equitable to that of experts, professionals, and policymakers.
Sustainability	In this context, this term reflects expectations from the European Commission that a project produces results and outcomes that will be further used after the financing of the project ends, i.e., the long-term exploitation of JACARDI's results and potentially an impact. Within JACARDI, therefore, we execute activities and nurture conditions by which the potential impact of JACARDI could be realised. Sustainability in JACARDI is operationalised at the pilot level, at the level of the six thematic areas covered by WP6-11, and at the level of JACARDI as a consortium of partners supported by corresponding products.
SWOT analysis	SWOT (strengths, weaknesses, opportunities, and threats) analysis is a method for identifying and analysing internal strengths and weaknesses and external opportunities and threats that shape current and future operations and help develop strategic goals.
SQUIRE 2.0	Standards for Quality Improvement Reporting Excellence guidelines are intended to guide authors reporting on systematic, data-driven efforts to improve healthcare quality, safety, and value.
Transferability	Transferability refers to the extent to which the findings and outcomes of the pilot can be applied to other settings, populations, or contexts beyond the original pilot environment.
WP6-11 leadership teams	WP6-11 leadership teams include WP leaders, WP co-leaders, Task leaders, Task co-leaders, and all those WP members that, by the JACARDI grant agreement, support the design, implementation, monitoring, and reporting of pilots, including sustainability perspective.

Keywords

Methodology, implementation, evidence-based practices, implementation science, cardiovascular disease, diabetes, best practices, EU, joint action

Configuration Management: Document Location

The latest version of this document is stored in <[JACARDI Teams](#)>. ¹²

¹² This link is only accessible to people who already have access to Teams (JACARDI partners).

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Executive summary

Joint Action on CARdiovascular Diseases and diabetes (JACARDI) aims to support 21 European countries in reducing the burden of cardiovascular diseases and diabetes. 143 pilots across 18 countries target six thematic areas: health literacy and awareness, integrated care pathways, data availability, quality, accessibility and sharing, screening high-risk populations and individuals, patients' self-management, and labour participation.

Overview of the activities: In JACARDI, all 143 pilots across all thematic areas will follow a harmonised methodological approach based on the JACARDI methodological framework. The framework integrates several theoretical concepts: country-level context analysis, learning from best practices and other appropriate practices, the sustainability principle and equity and diversity principle as transversal principles, multidimensional assessment, capacity-building, communication and dissemination, and reporting using the standardised guidelines. Applying the principles of implementation science, the integrated conceptual framework was transformed into methodological guidance for application at the pilot level, consisting of Steps I to XV. The Steps cover pilot design, implementation, monitoring, reporting, assessment, and the integration of sustainability, as well as equity and diversity in all stages. This methodology supports a harmonised and efficient approach across all thematic areas of Work packages 6 to 11 after being adapted to the specifics of the thematic area.

Methodology applied: The JACARDI methodological framework is the result of seven different teams working on seven tasks across two work packages, a dozen meetings before JACARDI started, a process within JACARDI run by a board including participants from all work packages (Implementation board) to discuss and agree on all elements of the JACARDI methodological framework including feasibility in eight consensus meetings and sixteen discussion webinars and complemented by internal revision of advanced draft by 25 individuals. Collaboration, consensus-seeking, and searching for synergies were the main values supporting this work to translate the theory into as many concrete steps as possible. Learnings from the experiences in past Joint Actions that had implementation at the core of their work were taken on board in total. The external revision was kindly provided by Juha Koivisto from THL, Finland.

Outcomes and findings: This document, with its seven Annexes, covers the theoretical concepts with the aim of showing their compatibility and the primary goal of presenting their applicability at the pilot level. The implementation science principles and tools translate theory into the methodological guidance to be used at the pilot level. The first six steps cover planning the pilot and its actions. Steps VII and VIII cover the first implementation period, at the end of which an intermediary analysis will be performed to determine the potential adaptation of the pilot and its actions to increase its efficiency and better address the actual needs. In Step IX, the adapted pilot action plan is developed and implemented during the second implementation period (Step X). After the second intermediary reporting (Step XI), the results will be interpreted, and the Final implementation report will be finalised in Step XII. Steps XIII to XV support pilots in conveying the essential messages to key stakeholders in an effective way and involving them in developing a sustainability action plan. This plan covers actions for up to two years after the funding of JACARDI ends and supports further uptake of JACARDI pilot results, outcomes, and key findings in the same setting, in other settings, or are transferred to other populations, programs, or policies.

In conclusion, the JACARDI methodological framework will support 143 JACARDI pilots across six thematic areas. The results, outcomes, and key findings, including implications for future updates after

JACARDI ends, will be reported in the Final implementation report. Each pilot will define the Sustainability action plan with key stakeholders, who will take over the activities after the financing ends to facilitate the long-term impact of JACARDI. Lessons learned will be included in the Roadmaps, presenting the future developments per each of the thematic areas and into the overall JACARDI Sustainability plan, supporting its impact in the long run.

1. Introduction

1.1 Purpose and scope of the document

Joint Action on CARdiovascular diseases and Diabetes (JACARDI) aims to support European countries in identifying and implementing effective policies and actions to reduce the burden of CVDs and diabetes and improve citizens' health and well-being.

The **purpose** of this deliverable is to support the European countries participating in JACARDI in pilot design, preparation, implementation, monitoring, reporting, and assessment, including the development of sustainability action plans with planned activities for a two-year after JACARDI ends, ensuring a harmonised and efficient approach for all Joint Action (JA) activities, organised in 11 work packages (WPs)¹³. The transversal aspects, reflected in all steps of the common methodology, are the sustainability lens (assuring long-term exploitation of JACARDI's results) and the equity and diversity lens (covering social and commercial determinants and cultural and ethnic diversity).

The **objective** of the document is to present a clear and complete description of the JACARDI methodological framework¹⁴. It integrates several theoretical concepts (country-level context analysis, learning from best practices and other appropriate practices, the sustainability principle and the equity and diversity perspective as transversal principles, multidimensional assessment, capacity-building, communication and dissemination, and reporting) into a single conceptual framework. Applying implementation science principles, the integrated conceptual framework was transformed into methodological guidance for the application at the pilot level, consisting of Steps I to XV. The Steps cover pilot design, implementation, monitoring, reporting, assessment, and sustainability, ensuring a harmonised and efficient approach across all thematic areas of WP6-11.

This document also includes guidance materials, checklists, and generic templates.

The **intended audience** of this methodological guide is primarily leadership teams of Work packages 6 to 11 (WP6-11 leadership teams) and members of the JACARDI core pilot teams who guide the pilot's work, as well as other members of the JACARDI's competent authorities and associated entities. Furthermore, the developed methodology can be used to design and implement evidence-based actions on the prevention and management of CVDs and diabetes as well as other NCDs. This document brings a hands-on perspective on improving practices, including exchanging best practices. Thus, it can also be used by participants of other JAs with the same approach, targeting NCDs in EU4Health (such as Joint Action Prevent Non-Communicable Diseases and Cancer (PreventNCD)) and other projects (such as European partnership on transforming health and care systems) to generate debate and encourage convergence.

Other JACARDI products will complement this deliverable by presenting methodological guidance adapted to the specifics of WP6-11's thematic areas.

¹³ All JA activities are organised through the mandatory four WPs (WP 1: Project management and coordination, WP2: Communication and dissemination, WP3: Evaluation, and WP4: Sustainability, one additional transversal WP on the development of a common methodological framework and integrative approach (WP5), and six technical WPs (WP6: Health literacy and awareness of CVDs and diabetes, WP7: Data availability, quality, accessibility and sharing, WP8: Screening high-risk populations and individuals, WP9: Integrated care pathways, WP10: Patients' self-management and WP11: Labour participation of people living with NCDs, in particular with CVDs and diabetes.

¹⁴ Framework as "a system of rules, ideas, or beliefs that is used to plan or decide something", i.e. in our case a system of concepts.

1.2 Structure of the document

This document is organised into several chapters and annexes, each providing a thorough overview of the JACARDI methodological framework and its development process. Below is the overview of the content of each chapter:

CHAPTERS	CONTENT
Executive summary (link)	Provides a concise summary of the document, emphasising the key points, including the overview of the JACARDI methodological framework, its development process, and conclusions and main recommendations.
Introduction (link)	Outlines the purpose and scope of the document, discusses its structure, and explains its relation to other works within the project. It also provides a list of applicable and reference documents.
Development process of the JACARDI methodological framework (link)	Describes the rationale behind the framework's development, including the generic principles, essential elements, supporting tools, and a general timeline.
JACARDI methodological framework (link)	Provides a meticulous description of the framework itself, covering the country-level context analysis, identification of best and other practices, integration of transversal principles (equity and diversity, sustainability), multidimensional pilot assessment, and detailed steps for its execution - from team formation to celebrating and co-creating the way forward of JACARDI and its pilots (Steps I-XV). Key aspects like capacity-building, communication and dissemination, and reporting are also addressed.
Conclusions and recommendations (link)	Summarises the key findings and provides recommendations for future development of the JACARDI methodological framework.
Annexes (link)	Includes detailed descriptions of key elements of the JACARDI methodological framework, including templates and additional guidance. Contains: <ul style="list-style-type: none"> • Annex I: Detailed description of selected implementation science approaches • Annex II: Methodological and explanatory framework for equity and diversity integration in JACARDI • Annex III: Inclusive and accessible communications guidelines (WP2)

	<ul style="list-style-type: none"> • Annex IV: Methodological framework for country-level context analysis, and best and other practices identification • Annex V: Methodological framework for multidimensional pilot assessment • Annex VI: Methodological guidance: Steps I to XV templates • Annex VII: Final implementation report and Sustainability action plan guidance and templates
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Table 1. Chapters' content overview

1.3 Relation to other work in the project

By its nature, the topic of this deliverable calls for intensive communication across tasks and WPs, collaboration, development of common understanding across different fields of expertise, search for synergies, and integration of all elements to a single cohesive methodology, applicable and feasible for pilots. We believe this was an essential part of the development process and is described in Chapter 2 ([link](#)). We also think this product may be an important product of JACARDI to be presented and discussed in synergy meetings with other Actions, initiatives, and projects, as mentioned elsewhere.

1.4 Applicable and reference documents

The JACARDI methodological framework is based on the principles of implementation science and proven tools designed and deployed in other JA.

By systematically integrating research findings into healthcare policies, programs, and practices, implementation science ensures that evidence-based interventions are effectively adapted to local contexts. This approach maximises the impact of public health initiatives across diverse European Union (EU) countries, addressing variability in healthcare systems and population needs. By grounding the project in implementation science, the framework becomes more adaptable, scalable and sustainable. In this context, reference frameworks used in the development of the JACARDI methodological framework include:

Model for improvement¹⁵, developed by the Institute for Healthcare Improvement (IHI), is a simple yet powerful framework for accelerating improvement and has been used successfully in many industries, including thousands of healthcare organisations in numerous countries, to improve countless different processes and outcomes.

The scaling-out methodology¹⁶, developed by the Biosistemak Institute for Health Systems Research of the Basque Country, Spain, promotes the replication of Good Practices (complex interventions consisting of several components, defined as being the parts that make the whole intervention and, in isolation or combination, can generate the power of the intervention) across European countries to enhance the transition of healthcare systems to digitally enabled, integrated, person-centred care.

¹⁵ <https://www.ihi.org/resources/how-to-improve>

¹⁶ <https://ijic.org/articles/10.5334/ijic.8605>

CFIR¹⁷ (Consolidated Framework for Implementation Research) provides a framework of constructs arranged across five domains that have been associated with effective implementation and can be easily customised to diverse settings and scenarios. It promotes consistent use of constructs, systematic analysis, and organisation of findings from implementation studies. The objective of CFIR is to provide researchers with a framework in which they can select the most relevant constructs in the particular field of their study and use them to diagnose the context of the implementation, evaluate the progress of this process, explain the results and improve the quality of the initiatives.

SWOT¹⁸ and SWOT-action planning. The SWOT analysis methodology is an analytical method that is used to identify and categorise significant internal (Strengths and Weaknesses) and external (Opportunities and Threats) factors faced either in a particular area, such as an organisation, or a territory, such as a region, nation, or city. This analysis allows revealing key enablers/positive forces and actual/potential barriers that need to be recognised and possibly addressed for the implementation of pilot project. It also enables participants to share their vision, make judgments in a structured way, build a common perception of the situation, and develop a sense of ownership of the pilot project.

Theory of change¹⁹-action planning helps to identify solutions to effectively address the causes of problems that hinder progress and guide decisions on which approach should be taken, considering comparative advantages, effectiveness, feasibility and uncertainties that are part of any change process.

JADECARE Sustainability framework²⁰ identifies three core elements of sustainability for building up sustainable pilot projects: (1) sustainable practices are to be grounded in the health strategies and policy frameworks, with strong top-down and bottom-up connections; (2) holders of sustainability are needed to be present at different levels, facilitated by formal and informal networks; (3) culture of collaboration and consensus-seeking is an essential value and engagement of partners is an unwritten rule.

SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence)²¹ guidelines for reporting are intended as a guide to authors reporting on systematic, data-driven efforts to improve healthcare quality, safety, and value. It was designed to increase the completeness and transparency of reporting of quality improvement work and has contributed to the development of this body of literature by providing a guide to authors, editors, reviewers, educators, and other stakeholders.

SCIROCCO Maturity model²² is an online participatory self-assessment tool that helps stakeholders to understand (1) the local context and conditions for delivering integrated care in health and social care, including its strengths and weaknesses; (2) the readiness level of a country, region or organisation to adopt and scale-up integrated care; (3) the actions that more progressive regions have taken to be successful and enable information sharing, twinning, and coaching to overcome barriers and accelerate results in demand-driven innovation.

¹⁷ <https://cfirguide.org/>

¹⁸ <https://wikis.ec.europa.eu/display/ExactExternalWiki/SWOT+analysis+-+strengths%2C+weaknesses%2C+opportunities+and+threats>

¹⁹ <https://unsdg.un.org/sites/default/files/UNDG-UNDAF-Companion-Pieces-7-Theory-of-Change.pdf>

²⁰ JADECARE Deliverable 4.3 Characteristics of JADECARE practices, leading to sustainability and integration in national policies, available at <https://www.jadecare.eu/resources/>

²¹ https://www.squire-statement.org/index.cfm?fuseaction=Page_ViewPage&PageID=471

²² https://scirocco-exchange-tool.inf.ed.ac.uk/en_gb/login/?redirect_to=https%3A%2F%2Fscirocco-exchange-tool.inf.ed.ac.uk%2Fen_gb%2F

Additional details on the underlying methodologies are provided in Annex I. In addition, the methodological framework uses proven tools that have been designed and deployed in other JA.

JA CHRODIS²³ launched a comprehensive portal for health topics, focusing on providing well-founded information on chronic diseases, prevention, and healthy ageing. This portal offers user-friendly resources and best practices in healthcare. By promoting health literacy and supporting policymakers, they aimed to improve people's quality of life and reduce the burden of chronic diseases to finally become a trusted source for all health-related questions.

JA CHRODIS PLUS²⁴ identified solutions, tools, and good practices that improve the care of people with chronic diseases and that can be adapted to the casuistry of various national and local settings across Europe. The key areas of the JA were integration into national policies, health promotion, disease prevention, multimorbidity care model, fostering the quality of care, and employment and chronic diseases.

JADECARE²⁵ aimed to reinforce the capacity of health authorities to successfully address important aspects of health system transformation, in particular, the transition to digitally enabled, integrated, person-centred care. To achieve this goal, JADECARE supported the transfer four evidence-based Good Practices selected by the Steering Group on Health Promotion and Prevention and Management of Non-Communicable Diseases of the European Commission (EC), from original healthcare systems to other 21 healthcare systems across Europe.

CARE4DIABETES²⁶ aims at reducing the burden of non-communicable diseases (NCDs) by providing a multidisciplinary lifestyle treatment intervention for type 2 diabetes with the potential to support Member States to promote new evidence-based policies and actions on patient empowerment, health promotion in people with type 2 diabetes, and cost-effective management of the disease while improving the efficiency of health investments. For this means, the JA aims at transferring and implementing an identified evidence-based best practice across 12 Member States.

SCIROCCO Exchange²⁷ was the EU Health Programme Funded Project aiming to improve the capacity of healthcare authorities to adopt and scale up integrated care. Building upon the preliminary achievements of the B3 Action Group on Integrated Care (of the European Innovation Partnership on Active and Healthy Ageing) that first developed the concept of the B3 Maturity Mode, the Scirocco Maturity Model was further refined, tested, and supported by a validated online self-assessment tool for integrated care.

²³ <https://chrodis.eu/>

²⁴ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/projects-details/31061266/761307/3HP>

²⁵ <https://www.jadecare.eu/>

²⁶ <https://c4djointaction.eu/>

²⁷ <https://www.sciroccoexchange.com/>

2. Development process of the JACARDI methodological framework

2.1 Introduction with rationale

The burden of NCDs in Europe is increasing. The four main NCDs – cardiovascular diseases (CVDs), cancer, diabetes, and chronic respiratory diseases- are responsible for approximately 75% of all deaths in the European region²⁸ and are **the leading cause of avoidable premature deaths**²⁹. It has been estimated that almost 63 million people in the EU live with CVDs, which is also the leading cause of death in this region. At the same time, the number of adults with diabetes has almost doubled over the last decade, reaching 32.3 million in 2019^{30,31}. The scale and impact of the NCDs **require an integrated and coordinated response across Europe**, which has been recognised also by the EC in 2021³².

JACARDI emerged from this need. The EU-funded project supports 21 European countries in identifying and implementing evidence-based policies and actions adapted to the needs of the local context to reduce the burden of CVDs and diabetes and related risk factors at both individual and societal levels while assuring health systems sustainability and equity. By doing so, JACARDI raises awareness of related risks and the acceptability of innovative lifestyle interventions. Thus, it contributes to achieving the objectives of the EU4Health Programme, which prioritises the reduction of NCDs and the improvement of EU citizens' health and well-being. From a broader perspective, it also contributes to the United Nations Sustainable Development Goals by reducing premature mortality from NCDs through prevention and treatment.

By the end of 2027, **143 evidence-based pilots** will be implemented in **18 out of 21 participating European countries** in six thematic areas of CVDs and diabetes and their risk factors that cover the entire patient journey:

- Health literacy and awareness of CVDs and diabetes
- Integrated care pathways
- Data availability, quality, accessibility, and sharing
- Screening high-risk population and individuals
- Patient's self-management
- Labour participation of people living with NCDs, in particular with CVDs or diabetes

Moreover, a country-level context analysis will be conducted to identify the needs of the European countries in these areas, allowing core pilot teams to assess if their pilot responds to these needs and align it to be more efficient in this respect. In addition, this information will facilitate policy responses across EU countries and at the EU level and support the development of roadmaps within the thematic areas underpinning further developments after the end of JACARDI.

²⁸ As defined by the [World Health Organization](#) (WHO).

²⁹ World Health Organization, Regional Office for Europe. Noncommunicable diseases in 53 countries: WHO/Europe presents new visual data tool. Available at: <https://www.who.int/europe/news/item/05-01-2022-noncommunicable-diseases-in-53-countries-who-europe-presents-new-visual-data-tool#:~:text=NCDs%20are%20by%20far%20the,of%20deaths%20across%20the%20Region>.

³⁰ European Commission. Healthier Together EU Non-Communicable Diseases Initiative. June 2022. Available at: https://health.ec.europa.eu/system/files/2022-06/eu-ncd-initiative_publication_en_0.pdf

³¹ Institute for Health Metrics and Evaluation (IHME). GBD Compare. Seattle, WA: IHME, University of Washington, 2017. Available from <http://vizhub.healthdata.org/gbd-compare>.

³² [Healthier together - EU non-communicable diseases initiative](#)

Two significant challenges had to be overcome in developing the JACARDI methodological framework. Firstly, each element of the common framework³³ is based on a specific scientific or evidence foundation, frequently having its own theoretical concepts already in place. For example, health economics is a complex, research-based, transdisciplinary science with clear theoretical concepts and tools, and it is clear what “good health economics studies” look like; approaches to study equity and diversity are well defined, several guidance documents exist on how to tackle the field of inequalities in health; assessment of the context at country level is defined by several golden standard principles; reporting of implementation experience has its own guidelines (SQUIRE 2.0), etc. In JACARDI, all this knowledge and different concepts had to be glued together to form **a single conceptual framework**. This common conceptual framework stems from all ideas and rules represented in individual frameworks (presented in Annexes) and overcomes potential overlaps or antagonisms.

The second challenge was that the “recipients” of all those ideas and rules were core pilot teams, with their defined resources, a mix of skills and expertise, availability, and interest. There are so many sciences, and all target the same teams at the same time! It was inevitable to glue individual theoretical concepts together by applying principles of implementation science, as described above. In addition, implementation science has also helped develop a practical, concrete methodology that converts theory (conceptual framework) into practice. In addition to methodological guidance, several templates were created.

As a result, the JACARDI methodological framework integrates several theoretical concepts into a single conceptual framework. Applying the principles of implementation science, the integrated conceptual framework was transformed into common methodological guidance for application at the pilot level, consisting of Steps I to XV. The Steps cover pilot design, implementation, monitoring, reporting, assessment, and sustainability, ensuring a harmonised and efficient approach across all thematic areas of WP6-11 (*Figure 1. JACARDI methodological framework*).

JACARDI methodological framework specifies the generics to be applied in pilots to assure efficient implementation and reduce the risk of failure; supports consistency, coherency, and harmonisation; supports comparability of outcomes across settings; brings insights into contextual considerations; supports a multidimensional assessment of outcomes; and facilitates the sustainability and scalability of successful pilots across the EU. Moreover, the common methodology considers equity and diversity in the work of pilot projects from the beginning, thus better meeting the needs of the increasingly diverse population in the EU and supporting the reduction of health inequalities in the region.

³³ Country-level context analysis, learning from best practices and other appropriate practices, sustainability principle, as well as equity and diversity perspective as transversal principles, multidimensional assessment, capacity-building, communication and dissemination, and reporting

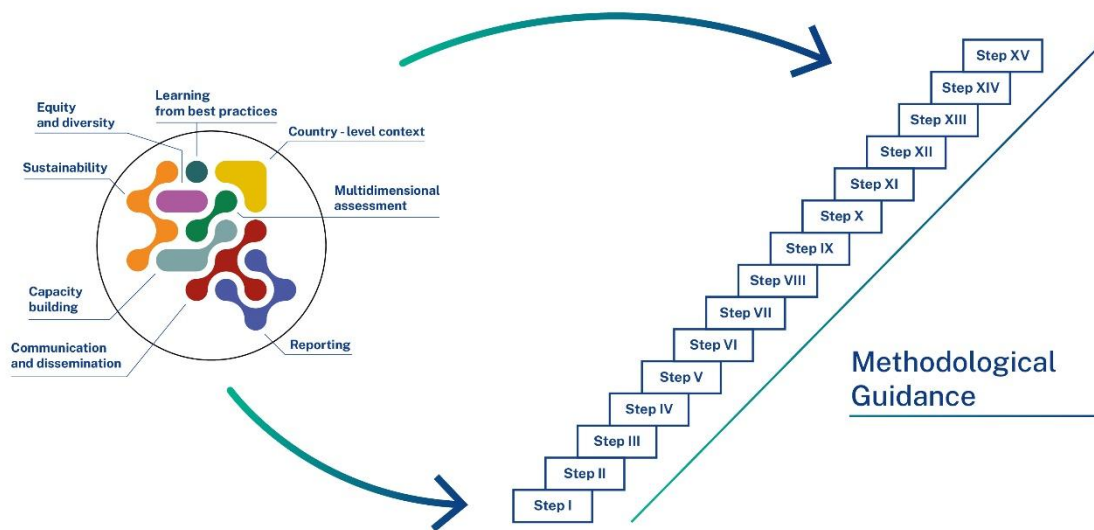


Figure 1. JACARDI methodological framework

The JACARDI methodological framework (Figure 2. Visual explaining how all frameworks are interrelated) includes:

- Country-level context analysis:** The rationale behind conducting a context analysis at the European and country levels arises from the necessity of considering the broader context when implementing a pilot. The analysis aims **to map the state of the art at national and European levels, identifying the current situation** and how the pilots respond. Since this information becomes available to core pilot teams after deciding on their general objectives, specific objectives, and pilot implementation plans, they can still use it during the intermediate reporting. They can adjust their pilots (pilot implementation plans) at that stage. The core pilot teams also benefit from the results of this mapping when developing the final implementation report (Step XII). Moreover, they are essential when developing the sustainability action plan (Steps XIII to XV).
- Best and other practices identification:** The reason for identifying successful practices and interventions, or single elements of these, that have been already implemented across Europe lies on **the idea that only relevant and appropriate practices should be implemented** by pilot sites and that each pilot project should have a robust evidence-based rationale at its basis. This approach aims to ensure that the implemented pilots are effective, efficient, transferable, and sustainable, encompassing participation and intersectoral collaboration and an equity approach following the criteria from DG SANTE evaluation of Best Practices³⁴. In particular, the core pilot teams can scan the context in other settings where practices (or part of them) relevant to their pilot have already been implemented and learn from them.

³⁴ https://health.ec.europa.eu/document/download/bd368be6-cb3d-4d95-9e06-aff855d8931_en

- **Sustainability perspective:** From this perspective, the JACARDI methodological framework materialises the expectations from the EC that the effect of the project will not vanish when the project ends. In JACARDI, sustainability is integrated into the activities of the core pilot teams from the very beginning and supported by several approaches. Generally, it aims to help pilots focus on the policy environment, key stakeholders, and their active engagement, as well as collaboration and consensus-seeking as an umbrella principle. During the last three Steps, each pilot will, in collaboration with key stakeholders, develop a sustainability action plan covering two years after the end of JACARDI.
- **Equity and Diversity perspective:** Reducing health inequalities is a major health goal, yet social inequalities in health persist. More effective and sustainable health promotion measures require consideration of increasing population diversity from formulating the objective to implementation, ensuring the sustainability of actions, and scaling up. Meaningful engagement of the communities we aim to serve ensures that the measures are acceptable and meet the needs of the beneficiaries. When the principles of diversity inclusion are applied from the outset, the need for costlier, targeted, and tailored corrective measures is likely to decrease. The application of diversity and inclusivity principles does not necessarily require additional resources. It needs a shift in perspective – applying the equity and diversity lens to the activities being done anyway.

In JACARDI, the equity and diversity perspectives are **cross-cuttingly integrated in its methodological framework and actions**. Integration of equity and diversity perspectives is anticipated to reduce the burden of CVDs and diabetes among groups at greater social disadvantage, which contributes to reducing inequities also at the population level. The importance of a more comprehensive consideration of equity and diversity perspectives is justified through increasing population diversity in the EU and widening social inequalities, particularly among underrepresented and socially disadvantaged population groups. The JACARDI methodological framework provides the project partners, including the core pilot teams, with a shared understanding of the rationale, practical principles, and pathways for meeting the above-mentioned joint aim, including concrete tools and support for applying equity and diversity perspectives in practice.

- **Multidimensional pilot assessment:** Since 143 pilots may be highly diverse by their nature and scope, six dimensions were carefully chosen for the multidimensional assessment to help the pilot show their effect related to their general objective, including assessment, if this effect is because of the pilot activates (and not, for example, the result of usual variation). Each core pilot team will carefully study the relevance and feasibility to study all six dimensions, develop their own multidimensional assessment plan, and report on the results in a multidimensional assessment report.
- **Steps for executing the JACARDI methodological framework:** As much detailed methodological guidance as possible for each of the fifteen steps was developed, following the aligned structure. In addition to this report, a specific Booklet to support documenting the pilot journey with only information relevant to core pilot teams will be produced soon after this report's delivery.

A systematic, stepwise capacity-building approach will support the application of the implementation framework, adjusted to the needs of each WP6-11.

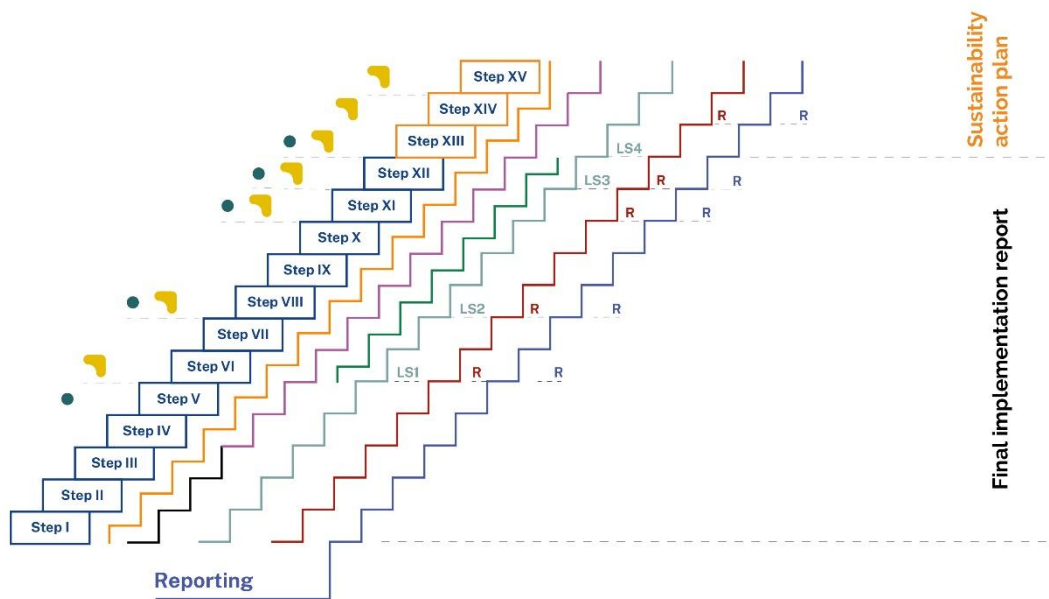


Figure 2. Visual explaining how all frameworks are interrelated

2.2 Generic principles

The evolution of the JACARDI methodological framework followed **three general principles** (*Table 2. JACARDI general principles*).

1. Build on past experience in developing implementation methodologies	The JACARDI methodological framework builds on implementation science principles (evidence-based tools and theoretical concepts) and uses proven tools from previous JA.	Previous JA: <ul style="list-style-type: none"> • JA CHRODIS³⁵ • JA CHRODIS PLUS³⁶ • JADECARE³⁷ • CARE4DIABETES³⁸
		State-of-the-art reference frameworks: <ul style="list-style-type: none"> • Model for improvement³⁹, developed by IHI • Implementation strategy⁴⁰, developed by Institute for Health Systems Research – Biosistemak, formerly Kronikgune, Basque Country, Spain

³⁵ <http://chrodis.eu/outcomes-results/>

³⁶ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/projects-details/31061266/761307/3HP>

³⁷ <https://www.jadecare.eu/>

³⁸ <https://c4djointaction.eu/>

³⁹ <https://www.ihl.org/resources/how-to-improve>

⁴⁰ <https://ijic.org/articles/10.5334/ijic.8605>

		<ul style="list-style-type: none"> • CFIR⁴¹ • SWOT⁴² and SWOT-action planning • Theory of change⁴³-action planning • JADECARE Sustainability framework⁴⁴ • SQUIRE 2.0⁴⁵ • SCIROCCO⁴⁶ for reporting <p>Additional details on the underlying methodologies are provided in Annex I.</p>
2. Define and use a single standardised methodological framework for various activities.		
3. Guarantee the framework flexibility to accommodate the diversity of the pilots.		

Table 2. JACARDI general principles

The first principle is **taking on board past experience**. The key principle of implementation science states: “Many implementation efforts fail, even with highly developed plans for execution, because contextual factors can be powerful forces working against implementation in the real world”⁴⁷. Therefore, the JACARDI methodological framework is **based on the principles of implementation science and uses proven tools from similar JA**. This work takes on board past experiences from JAs that used the implementation of pilots as an approach, such as CHRODIS, CHRODIS PLUS, and JADECARE, and from ongoing experiences, such as CARE4DIABETES, please see Chapter 1.4 ([Link](#)).

Moreover, this framework uses **evidence-based tools and theoretical concepts relevant to implementation science**, such as SWOT analysis (to assess the characteristics of the situation to support strategic decisions), CFIR constructs (to address elements of successful and sustainable implementation), SCIROCCO Maturity Model with detailed context analysis including the level of readiness, and SQUIRE 2.0 guidelines for reporting of implementation work. Please see Annex I for details.

The second principle is to define and use a single standardised methodological framework for the design and implementation of pilots, including the sustainability of results and for integrating the equity and diversity dimensions. Even though different WPs and several tasks develop specific aspects of the methodology, all elements should be joined within one methodological framework. As it could be put in lay language – the JACARDI methodological framework should “*speak to the pilots with a single voice.*”

The third principle is that, while aiming for harmonisation, the differences across the topics covered in WP6-11 and the variability across the 143 JACARDI pilots should be acknowledged and addressed. Therefore, **the standardised methodological framework must be flexible enough to accommodate most pilots**. It should specify only the generics, which can be applied across all topics and in very variable settings, and allow for further adaptation of the specifics to respond to particular needs and requirements of the implementing sites. Afterwards, they can be further developed based on the specifics of WP6-11 topics by WP6-11 leadership teams.

⁴¹ <https://cfirguide.org/>

⁴² <https://wikis.ec.europa.eu/display/ExactExternalWiki/SWOT+analysis+-+strengths%2C+weaknesses%2C+opportunities+and+threats>

⁴³ <https://unsdg.un.org/sites/default/files/UNDG-UNDAF-Companion-Pieces-7-Theory-of-Change.pdf>

⁴⁴ JADECARE Deliverable 4.3 Characteristics of JADECARE practices, leading to sustainability and integration in national policies, available at <https://www.jadecare.eu/resources/>

⁴⁵ <https://www.squire-statement.org/index.cfm?fuseaction=Page.ViewPage&PageID=471>

⁴⁶ CARE4DIABETES Deliverable 5.1 Best Practice and Situation Analysis, pending approval by the contracting authority, when approved available at <https://c4djointaction.eu/>

⁴⁷ <https://implementationscience.biomedcentral.com/articles/10.1186/s13012-022-01245-0>

2.3 Key activities addressed by the JACARDI methodological framework

The JACARDI methodological framework has a flexible structure and contains methodological support for the following activities:

- **Country-level context analysis:** mapping and analysing the context at the country and EU levels from the nationwide perspective, helping the pilots to address the needs within the country as well as facilitating policy responses at the country and EU level
- **Identification of best or other practices** that could fit the national or regional context and provide a strong evidence-based rationale for the core pilot teams to build their pilots and design the implementation of pilots, contributing to the question: “*Why did the pilot start?*”⁴⁸
- **Analysis of the situation at the pilot implementation sites and on the national/regional level from the perspective of the pilot:** activities that assess the context from the perspective of the pilot to become aware of risks and chances and to identify the best courses of action for the project definition and implementation
- **Preparation of the pilot implementation plan:** defining specifically “*What will the pilot do?*” the pilots can build these activities based on selected key elements of evidence-based interventions (best and validated practices) and adapt them to the local context with specific needs, challenges, and targets
- **Implementation, monitoring, and assessment of the pilot:** implementing the pilot according to the implementation plan, collecting qualitative and quantitative data to monitor the implementation process, and assessing the effect of the pilot ideally across six outcome dimensions of the pilot. Assessment is a crucial activity to show the effects of the pilot, helping to decide whether it should be continued and scaled up, adapted, or even cancelled. These activities answer the question: “*What did the pilot find?*”
- **Reporting:** In addition to reporting on previous activities, the report also needs to provide the interpretation of findings, such as “*What does that mean?*”
- **Integration of the equity and diversity principle**
- **Building sustainability from Day 1, including the development of the sustainability action plan** covering two years after the end of JACARDI.

2.4 Description of the process to develop this deliverable

The JACARDI methodological framework was developed within WP4 - Sustainability and WP5 - Methodological Framework and Integrative Approach, and in collaboration with WP6-11 leadership teams as part of the structure and processes of the JACARDI Implementation board.

The work of the tasks is presented in the table below (*Table 3. JACARDI WP5 and WP4 tasks' overview*).

WP	Task's objective	Milestone/Deliverable
WP5		
Task 5.1	Establish a framework to guide and facilitate the country-level context analysis, review existing European initiatives, and report findings.	The findings from tasks 5.1.1 (Country-level gap analysis) and 5.1.2 (Review and identification of Best Practices) will populate Deliverable 5.2. This deliverable

⁴⁸ Questions in this paragraph arise from SQUIRE 2.0 guidelines for reporting of implementation experience

		will consist of a report on the Context Analysis at the European and national levels, divided by thematic area, and a list of identified practices (both Best Practices and other practices) representing the rationale for the pilots implemented in JACARDI.
Task 5.3	The explanatory framework supports JACARDI WP and core pilot teams in adherence to the cross-cutting aim of integrating equity and diversity perspectives that have been agreed to be one of the core themes in JACARDI at the grant proposal stage. The task was also harmonised with other tasks in WP5.	Integrated into the JACARDI methodological framework
Task 5.4	Develop a methodological framework for pilot implementation	Responsible for Deliverable 5.1
Task 5.5	Support of capacity-building	Integrated into the JACARDI methodological framework
Task 5.6	Develop a methodological framework for the assessment of pilots and health and economic outcomes.	Integrated into the JACARDI methodological framework
Task 5.7	Develop a platform to collect relevant information about pilots	Integrated into the JACARDI methodological framework
WP 4	Task's objective	Milestone/Deliverable
Task 4.1	Support the sustainability of the JACARDI pilot implementations	Milestones “MS12 Methodology for context analysis and key stakeholders’ identification” and “MS13 Sustainability action plan methodology” are incorporated in the deliverable D5.1 and integrated into the JACARDI methodological framework

Table 3. JACARDI WP5 and WP4 tasks' overview

The Implementation board is the central coordination body for developing and applying the JACARDI methodological framework. It provides a continuous overview of the development and execution of all phases of pilot design, implementation, and reporting. The structure of the Implementation board is described in the box below (*Box 1. Structure and processes of the Implementation board*).

Members of the Implementation board are as follows:

- Leaders and co-leaders of all WPs
- Leaders and co-leaders of Tasks 5.3 (covering transversal principles of equity and diversity), 5.4 (developing the general implementation methodology), and 5.5 (running the Implementation board and developing the capacity-building approach)
- Equity, cultural, and ethnic diversity experts
- Economic evaluation expert

Some members may be included as internal observers due to their specific expertise or role in running the Implementation board.

Its main roles are:

- Discuss and potentially adapt the implementation methodology, associated generic guidance documents, and templates for each phase of design, implementation, and reporting of pilots
- Validate the practices that pilot teams proposed for use in the design of their pilots, not arising from the elements and principles of best practices at the EC's Best practice portal⁴⁹
- Organise train-the-trainer sessions for application of the JACARDI methodological framework
- Facilitate planning of the capacity-building activities within WP6-11
- Run the reflection process to identify obstacles and react with corrective activities related to applying the JACARDI methodological framework, including the generic stepwise capacity-building approach.

After its establishment on 14th November 2023, the Implementation board held regular monthly meetings in two different formats – Implementation board consensus meetings⁵⁰ and Implementation board discussion webinars. Monthly Implementation board discussion webinars were organised separately for WP6, WP7, and WP8 and for WP9, WP10, and WP11 to allow more discussion on the draft material. Implementation board consensus meetings and discussion webinars were led by the NIJZ and THL teams with the support of Biosistemak as the co-leader of Task 5.4.

Ad hoc alignment meetings were organised with WP2 – Communication and dissemination.

Box 1. Structure and processes of the Implementation board

⁴⁹ The EC's Best Practice Portal is designed to help find reliable and practical information on implemented practices recognised as best or promising in the area of public health. More information is available at: <https://webgate.ec.europa.eu/dyna/bp-portal/>

⁵⁰ Implementation board consensus meetings: 14th November 2023, 12th December 2023, 9th January 2024, 13th February, 12th March 2024, 9th April 2024, 14th May 2024, June 11 2024. Implementation board discussion webinars were held one week after consensus meetings to discuss the topics for the upcoming consensus meeting.

The Implementation board workflow (*Figure 3. Implementation board workflow*) guides the structured development and adaptation of the JACARDI methodological framework, ensuring a systematic and inclusive approach throughout the JACARDI project.

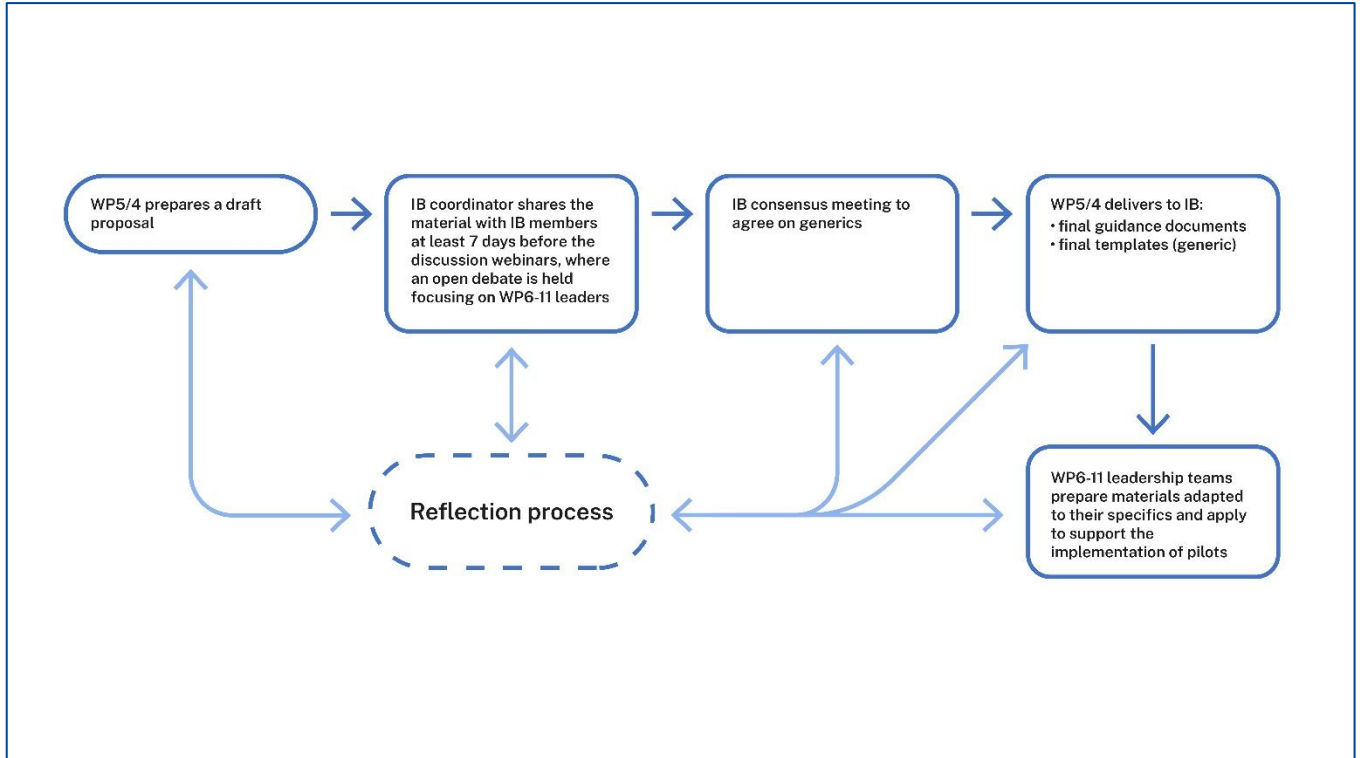


Figure 3. Implementation board workflow

The WP5 and WP4 teams prepared a draft proposal on generics, potentially applicable to all thematic areas. Materials were shared with the Implementation board members at least seven days before the Implementation board discussion webinars, where an open debate was held, focusing on the WP6-11 needs and concerns depicted by WP leadership teams. Afterwards, the Implementation board consensus meeting was held to achieve consensus on the generic core of the methodology. When the agreement was reached, WP5 and WP4 finalised and delivered the final generic guidance documents and templates to the Implementation board. The WP6-11 leadership teams adapted the generic materials to the specifics of their WPs and applied them to support and facilitate the implementation of pilots. At the end of the years 2024, 2025, and 2026, and before the summer of 2027, the Implementation board will perform a reflection process on the effectiveness of the work of the Implementation board itself and on the JACARDI methodological framework to identify obstacles, react with corrective activities and learn from mistakes.

The development of the JACARDI methodological framework started in August 2023, before the official start of the JA. The timeline is presented in the box below (*Box 2. Timeline of the development of the JACARDI methodological framework*).

The JACARDI methodological framework was developed according to the following timeline:

- August 2023** (before the official start of JACARDI): Drafting of the proposal
 Taking advantage of working together with the same partners (NIJZ, Biosistemak, THL, ISS) as in several previous JA, the first drafts of the JACARDI methodological framework were prepared already

in August 2023, before the official start of JACARDI, since the partners were fully aware of the tight schedule.

- **September-October 2023:** Sharing and discussing the draft proposals within WP5 and WP4, with WP6-11 and WP2, and later discussing them during several meetings.
- In **September 2023**, the first draft proposals of the methodology were shared within WP5. The following topics were drafted:
 - (1) Overview of the JACARDI standardised methodological framework for implementation of pilots (WP5) and sustainability activities (WP4)
 - (2) Leadership for successful implementation of sustainable pilots (learnings from JADECARE)
 - (3) Steps to study the situation analysis at pilot sites
 - (4) Steps to design pilot implementation plans
 - (5) Steps to monitor and support the process of implementation
 - (6) Steps to prepare final implementation reports
 - (7) Steps to prepare sustainability action plans
 - (8) Roles and responsibilities in the stepwise capacity-building approach
 - (9) Learnings from JADECARE standardised methodological framework for implementation of pilots
- **November 14, 2023:** Consensus on the general overview of the JACARDI methodological framework, including capacity-building
- **December 12, 2023:** Consensus on the generic methodology for Steps I-V
- **January 9, 2024:** Consensus on the generic methodology on how to include equity and diversity topics within the JACARDI methodological framework
- **March 12, 2024:** Consensus on the generic methodology of Step VI and the Capacity-building approach.
- **April 9, 2024:** Consensus on the Validation process of “other practices” used by pilots to inspire their work
- **May 14, 2024:** Consensus on the generic methodology of Steps VII-XI, including the multidimensional assessment aspect
- **June 18, 2024:** Consensus on the generic methodology of Steps XIII-XV on sustainability.

Box 2. Timeline of the development of the JACARDI methodological framework

In the backstage of this flow of discussions and meetings, enormous work was performed in teams from Tasks 5.1, 5.3, 5.4, 5.5, 5.6, 5.7, and 4.1. They had to develop task-bound frameworks, adjusted to the needs and realities of JACARDI (for example, skills and expertise in core pilot teams, tight timelines), and aligned to all other task-bound frameworks. This required flexibility, commitment, adaptation of scheduling of their work (usually faster), and the ability to co-create the common understanding of the product created in this synergy. On the other hand, all theoretical concepts within frameworks had to be translated into concrete, detailed, simple (and not too long) methodological guidance and templates that have to be applicable to all thematic areas across WP6-11. Since core pilot teams started their work mainly in the first few months of JACARDI, some of this work needed to be accomplished immediately. This collaboration was supported by at least monthly ad hoc “methodological tasks” meetings and, much more, by the commitment that exceeded the obligations defined in the JACARDI Grant Agreement (GA).

The same values and ability to work together were experienced in the consensus-seeking approach with WP6-11 leadership teams via Implementation board processes, including WPs 1 to 3, thus bringing additional horizontal perspectives of the decisions made.

Broad information sharing within the consortium was made possible by the coordinators of JACARDI by giving generous slots of time at Executive board meetings and organising dedicated meetings with WP2-WP11 to develop a shared understanding and a (more) uniform language.

The advanced draft of this deliverable was shared with teams from WP4, WP5, and with Implementation board members on June 27, 2024, for their comments and inputs. Their interest was reflected in several hundred comments, suggestions, and questions, mostly arriving by August 23, 2024, as agreed (see acknowledgements). Separate meetings were held with teams from each task involved, including a joint “methodological tasks” meeting to allow discussion across tasks. The inputs significantly improved the advanced draft; missing details were provided by the tasks responsible. The pre-final draft was kindly reviewed by Juha Koinisto from THL, Finland, who is participating in the European partnership on transforming health and care systems. In addition, a decision was made to develop a document (Booklet to support documenting the pilot journey) that will detail only the guidance and templates relevant to the pilot teams at our earliest convenience.

In this D5.1 Version 2.0, we confirm the development of the document “Booklet to guide the pilots’ journey”, which constitutes a practical and operational guideline intended to support both the Technical WP Leaders and the pilots in implementing the XV Steps of the methodology in a coherent and structured manner. Beyond serving as a reference document, the Booklet is designed to facilitate consistency in the application of the methodological framework across different implementation settings. Furthermore, it incorporates timeline, carefully adjusted to reflect and respond to the current needs of the project, thereby ensuring that the proposed approach remains both methodologically robust and operationally relevant.

3. JACARDI methodological framework

3.1 Overview

The JACARDI methodological framework integrates several elements into a single theoretical framework (See Figure 4. JACARDI methodological framework) and provides generic methodological guidance and data-collection templates for the **design, implementation, monitoring, assessment, and reporting** phases of the pilots, including the **development of sustainability action plans** with planned activities for a two-year-period after JACARDI. The transversal aims and principles of JACARDI—sustainability (i.e., establishing conditions for the long-term impact of JACARDI) and equity and diversity (covering social and commercial determinants and cultural and ethnic diversity)—are integrated into all steps for the execution of the JACARDI methodological framework.

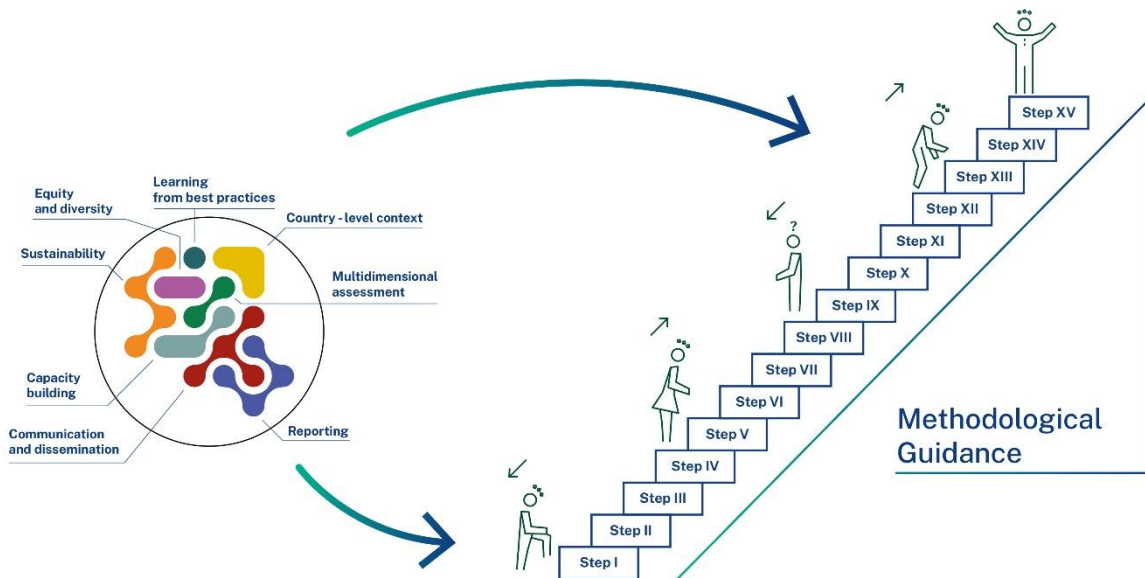


Figure 4. JACARDI methodological framework

3.2 Country-level context analysis

The methodology for country-level context analysis is a valuable tool for mapping the state of the art in CVDs and diabetes prevention and management strategies and services at both the European and topic-specific levels. The findings and results of the context analysis at both European and national levels populate Deliverable D5.2⁵¹, divided by thematic areas⁵² and diseases. Country profiles included provide a snapshot of the governance, financing, service delivery, and capacity situation in each country that responded to the survey as part of the context analysis.

Based on these findings, core pilot teams are able to determine whether their pilots are addressing the identified needs at the country level and how they are doing so. Since this information may become available only after they have already decided on their general objectives, specific objectives, and first pilot implementation plans, the core pilot teams can still use this information during the intermediate reporting. At this stage, they have the opportunity to adjust their pilots. They also benefit from the results of this mapping when developing the Final implementation report (Step XII) and, mainly, in the Sustainability action plan (Steps XIII to XV).

The developed methodology for country-level context analysis is described in detail in Annex IV. In this chapter, only basic information is available, starting with the visual presentation below (*Figure 5. Visual presentation of the methodology for country-level context analysis*).

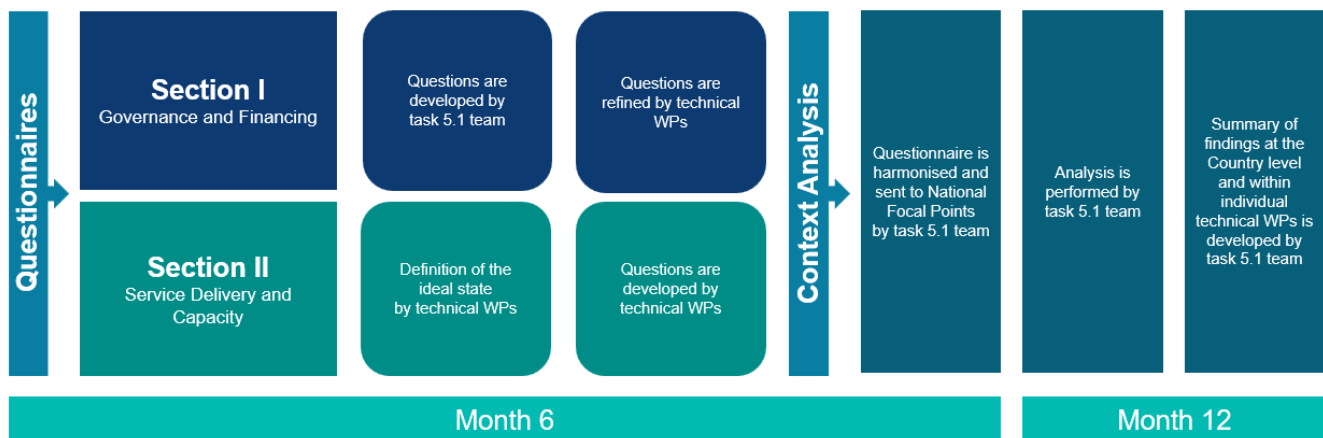


Figure 5. Visual presentation of the methodology for country-level context analysis

Data was collected using **questionnaires** specific to each thematic area and tailored for both CVDs and diabetes to map the current state at the national level (*Box 3. Data collection overview*).

The questionnaires were distributed to National Focal Points (NFP) for Health through a collaboration with the Joint Action of National Focal Points for Health (JANFP4Health) in 32 European countries; in addition to this, the questionnaires were also sent to the 21 Competent Authorities participating in JACARDI to maximize synergies between the two JAs and increase the response rate.

⁵¹ Deliverable 5.2: State of the art – Report of findings from the review and context analysis, by M18.

⁵² Thematic areas: Health literacy and awareness; Data availability, quality, accessibility and sharing; Screening high-risk populations and individuals; Integrated care pathways; Patients' self-management; Labour participation

The RedCap online software was chosen for the distribution of the questionnaires, especially for its reliability and ease of use, as well as its compliance with the standards of the General data protection regulation (GDPR) for data collection and privacy.

Along with the 12 links for the online completion of the questionnaires, each NFP received a Guide to Completion, a Glossary, and the 12 questionnaires in PDF format for preliminary consultation regarding the content (Annex IV). Online completion was strongly encouraged.

Box 3. Data collection overview

The country-level context analysis assessed two main sections for each of the six thematic areas:

- (1) Governance and financing: the state of the legal framework, policies, strategies, action plans, and financing related to CVDs and diabetes prevention and management at the national level (Legal framework, Strategic framework, Intersectional policies and practices, Equity-oriented approach, Fundings) was assessed.
- (2) Service delivery and capacity: The current implementation of services to the population was assessed.

The findings will be summarised at WP (per thematic area) and country level at the end of the analysis. A summary report will be produced for each WP and for both CVDs and diabetes. Results will be presented through a combination of figures and text boxes to return a concise yet comprehensive overview of the current status of CVDs and diabetes prevention and management at the European level. Each WP report will be complemented with country profiles providing a snapshot of the governance, financing, service delivery and capacity situation in each country that responded to the survey. More on data analysis and reporting is described in the box below (*Box 4. Data analysis and reporting*).

The data collection period started on 2 April 2024 and ended on 7 June 2024, for a total of 67 days of data collection. The collected data was shared with WP6-11 to serve as a source of information for achieving their respective Milestones based on the available information from EU countries. The data analysis is being performed by the Task 5.1 Team. The final report on the general results of the survey will be included in Deliverable 5.2 in April 2025.

Box 4. Data analysis and reporting

Country-level context analysis - Key takeaways

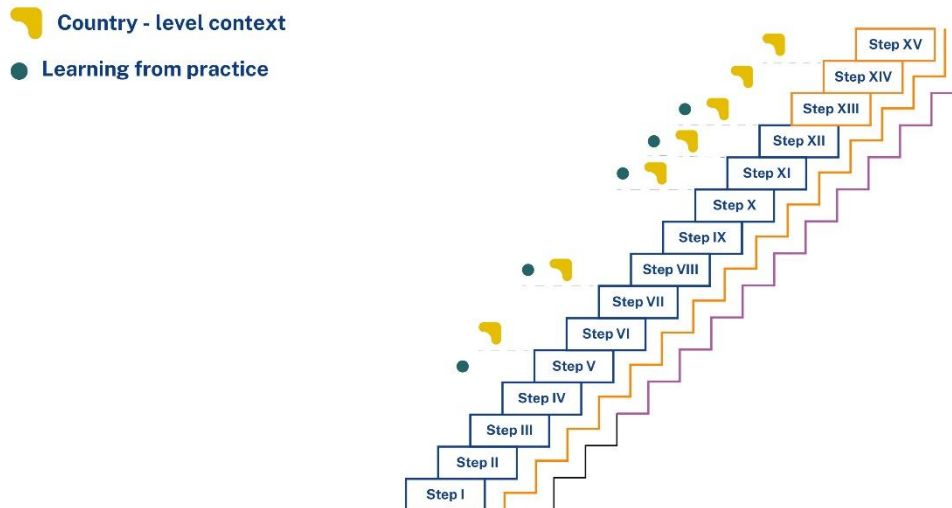


Figure 6. Country-level context analysis

In summary, some core pilot teams are still preparing their first pilot implementation plan (Step VI) when the relevant reports are available⁵³, and they can already benefit from this information and address it in their activities. All core pilot teams can consider this information at intermediary reporting 1 (Step VIII) and 2 (Step XI) when adapting the existing pilot implementation plans. It is **essential that all core pilot teams include in the final implementation report (Step XII) the relevant information based on country-level context analysis and identify the needs** that may be addressed by the pilot to additionally describe the problem and the rationale of the pilot (Introduction). The information from country-level context analysis should be collated with the situation analysis performed by the core pilot team. It should also be reflected in the Discussion by describing how the results, outcomes, and key findings may benefit the country and how this can support the sustainability of the pilot results/outcomes. In addition, using this information is **essential** in Step XIII, where the key findings of the pilot should be put in broader perspectives, and in Step XIV, when drafting and communicating the sustainability action plan to and with stakeholders. Please see the Questions and Answers box (Q&A box) below ([Box 5. Q&A](#)).

⁵³ Detailed reports on country-level context analysis is reported within respective milestones of WP6-11, in WP6-11 Teams folder Deliverables and Milestones: Milestone 22 WP6 -Mapping of available best practices/interventions on health literacy and health promotion and awareness to local needs and situation of pilot sites/countries; Milestone 27 WP7 – Mapping to identify gaps and needs for pilots' implementation; Milestone 31 WP8 – Mapping of available best practices/interventions on screening and situation of pilot site/countries; Milestone 36 Wp9- Mapping of patient care and service pathways implementation needs at all implementation sites identified; Milestone 40 WP10 – Mapping self-management support needs; Milestone WP11-Mapping of factors affecting labour participation of people with NCDs in piloting countries.

Sure you can!

May I ask something?

Q: Does it mean that the core pilot teams should reflect the results of the country-level context analysis in their analysis and final report? Even if they do not address any of the identified needs? What if the pilot's objectives are not aligned with the needs of the country/region? I think it is more evident that they would reflect on their own situation analysis as sustaining their results depends on the local needs and opportunities.

A: Yes, ideally, yes. This information should complement the situation analysis they performed in Step III (when the information from this survey was not available yet), keeping in mind who the respondents were in the country and their role in the system (for example, the Ministry of Health). However, there is only a slight chance that the pilots would provide findings not in alignment with the needs of their countries since the analysis reflects the needs in vast areas (Legal framework, Strategic framework, Intersectional policies and practices, Equity-oriented approach, Funding, and Service Delivery and Capacity). Nevertheless, this should be seen as an opportunity to put the pilot findings in broad perspective. Thus, if feasible, the core pilot team should check the alignment to the country's needs at first intermediary reporting and try to adapt the pilot activities. Any adaptations they may foresee in the second intermediary report and the implications provided in the final report are potentially helpful in communicating with stakeholders while designing a sustainability action plan. If, for example, one of the key stakeholders would be the Ministry of Health, referring to the country's needs as identified in the survey may be beneficial. For countries with regionalisation of governance, the country profiles should be carefully studied since the survey specifically asked about the situation at the regional level, too.

Box 5. Q&A

3.3 Review and identification of best practices and other appropriate practices

The findings and results of the review and identification of best practices and other appropriate practices will populate Deliverable D5.2⁵¹, which will also include a list of identified practices (both best practices from the EU Portal of Best and Promising Practices and other validated practices) that contribute to the rationale for the pilots implemented in JACARDI.

The envisaged process is pivotal in providing a solid, evidence-based rationale for the pilots. Also, it serves as an important step in team building, aimed at understanding the pilots' objectives and activities. In particular, core pilot teams have the opportunity to scan the context in other settings where practices relevant to their pilot have already been implemented and to learn from them. This is done even if they are limited by the information made available by the EU Portal of Best and Promising Practices and other publication sources. However, direct contact with practice owners increases the efficient exchange of information and lessons learnt.

The developed methodology for the review and identification of best and other appropriate practices is described in detail in *Annex IV* (templates included); in this chapter, only the basic information is available, starting with the visual of the developed methodology (*Figure 7. Visual of the Methodological framework for the identification of best practices or other appropriate practices*).

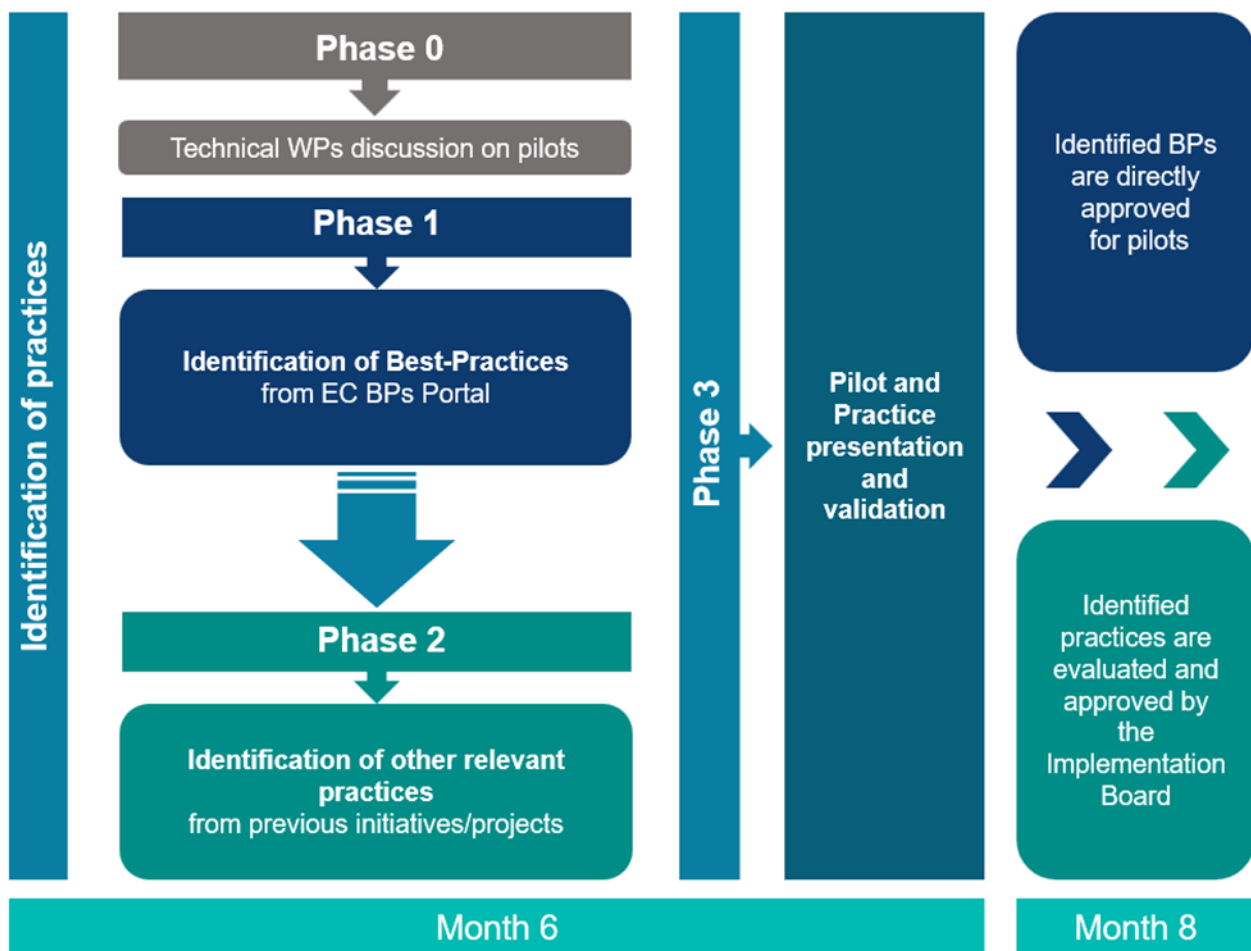


Figure 7. Visual of the Methodological framework for the identification of best practices or other appropriate practices

The identification of best practices and other practices was centred on internal discussion among WP6-11 and a review of the EU Portal of Best and Promising Practices, scientific sources, evidence from other existing projects and initiatives, and grey literature.

The process for the identification of relevant practices was conducted in **three operational phases (0,1,2)**, with an additional **Phase 3** dedicated to the presentation and validation process. The process is described in the box below (*Box 6. Description of the operational phases of the identification process*).

Phase 0 – WP6-11 discussion on pilots:

WP6-11 leadership teams and core pilot teams collaboratively reviewed the characteristics of the pilots they proposed for implementation. This assessment aimed to strengthen team building, strengthen the pilots' objectives and characteristics, and identify whether they relied on the EU Portal of Best and Promising Practices or other relevant practices from existing initiatives or projects.

Phase 1 – Identification of best practices from the EU Best Practices Portal:

Core pilot teams reviewed the EU Portal of Best and Promising Practices to determine if a best practice aligns with the proposed pilot's activities and objectives. Besides the EC's definition of best practices⁵⁴, also other criteria are considered important for the successful transferability of the practice beyond the duration of JACARDI, like a clear definition of the context, sustainability, intersectionality, and active involvement of stakeholders.

If the core pilot team identified a Best Practice that could serve as the rationale for its pilot, it proceeded by completing a dedicated template with the main information regarding the Best Practice.

If the core pilot team did not identify any best practices in the EU Portal of Best and Promising Practices, it moved to Phase 2.

Phase 2 – Identification of appropriate practices from previous initiatives/projects:

In phase 2, the core pilot team identifies appropriate practices from other resources, such as scientific evidence, literature reviews, and other European projects and initiatives. **After identifying a practice that is appropriate and aligned with the objectives and activities of the pilot, the core pilot team completes a dedicated template, including relevant information about the selected practice.**

Since these practices have not been evaluated by the meticulous process as the ones shown at the EU Portal of Best and Promising Practices after their identification, they were required to be validated by a delegation of the Implementation board through a formal presentation of the pilot project. The validation process was incorporated within the capacity-building efforts of the respective WP6-11, where all core pilot teams had the opportunity to present, share, and discuss the explanations and arguments regarding why and how the respective practices may be relevant for the pilots.

⁵⁴ EC's definition: "best practice" is defined as "a relevant policy or intervention implemented in a real life setting which has been favourably assessed in terms of adequacy (ethics and evidence) and equity as well as effectiveness and efficiency related to process and outcomes". A "promising practice" is defined as "a policy measure which has already been implemented in a real-life setting, and which may serve as inspiration for others, but which has not yet been implemented on a large scale and/or has not yet been fully evaluated".
Source: https://health.ec.europa.eu/non-communicable-diseases/best-practices_en

The validation of these practices was completed by a delegation of the Implementation board. The six criteria used by the EC, "[Criteria to select Best Practices in Health Promotion and Disease Prevention and Management in Europe](#)," were considered. **The pilot team was asked to explain how the use of the identified practice would help achieve at least one of the following six criteria:**

- i) Effectiveness and efficiency of the intervention
- ii) Equity
- iii) Transferability
- iv) Sustainability
- v) Participation
- vi) Intersectoral collaboration

Phase 3 – Pilot practice presentation and validation:

Once practices were identified by each pilot and dedicated templates completed, WP6-11 and the Implementation board delegation organised presentation sessions for each WP6-11; in preparation for these sessions, WP6-11 leadership teams provided guidance to the core pilot teams. Each core pilot team presented its objective and the identified practice (Best Practice or other practice). This process was a crucial moment for the entire JACARDI initiative, as the core pilots team had the opportunity to present their arguments and engage with other similar pilots by theme or geographical area. WP leadership teams gain deeper insights into their pilots, and the JACARDI coordination team and the WP5 team obtain an overview of the pilots to provide optimal methodological support.

Pilots that identified an "other practice" during Phase II were also required to present at least one of the six criteria (listed above) they aimed to achieve by applying the experiences from the chosen practice. The Implementation board then assessed these practices' relevance, rationale, and alignment, ultimately validating the selected practice, following an evaluation checklist (*Annex IV*).

Box 6. Description of the operational phases of the identification process

In JACARDI, the identification of practices (phases 0-2) began in December 2023 and concluded on April 30th, 2024. The presentation of the pilots and the validation of the other practices by the Implementation board (Phase 3) took place in June and July 2024.

Best and other practices identification – Key takeaways

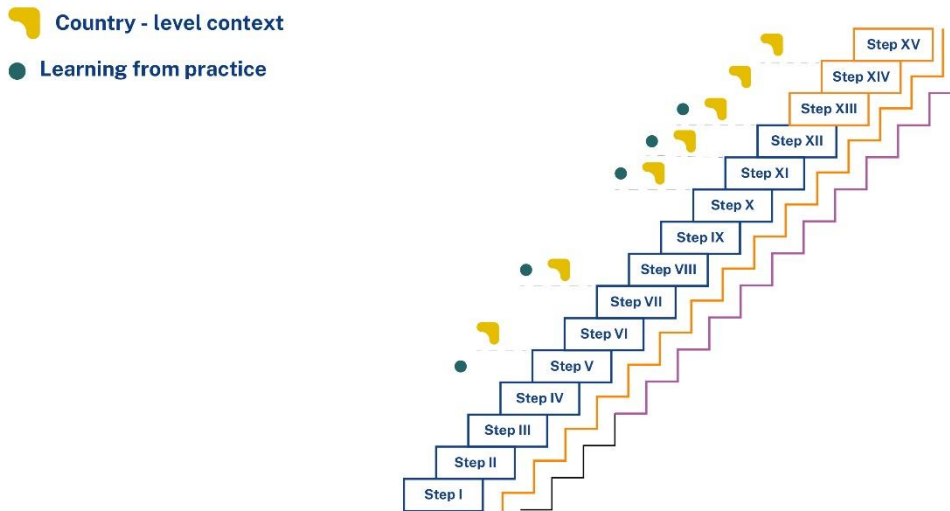
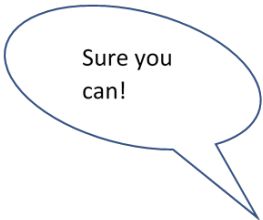



Figure 8. Best and other practices identification

In **summary**, it was **essential** that all core pilot teams identified timely (by April 2024) the potential proven practices they could learn from and be inspired by. The discussion about identified practices and which parts of the pilot may benefit from them (Effectiveness and efficiency of the intervention, Equity, Transferability, Sustainability, Participation, Intersectoral collaboration) was seen as an excellent capacity-building opportunity to discuss those perspectives in a very concrete, hands-on approach (June – July 2024). Messages taken were incorporated into developing specific objectives (Step V). Understanding those practices may be helpful when the core pilot teams design the pilot implementation plan, encounter problems and barriers (during both intermediary reporting steps), reflect on the potential implications of the key findings of the pilot in final reporting, and when focusing on key stakeholders in Step XIII to build the sustainability action plan. Please see Q&A box below ([Box 7. Q&A box](#)).



Sure you can!



May I ask something?

Q: But we only have an article or information about this practice available on the EU portal. Is that enough?

A: The time and available resources dedicated to learning from other practices are very limited within JACARDI⁵⁵ because enough time is needed to plan the implementation. Nevertheless, the information available should at least minimally cover the pilot's interests. Although not covered by JACARDI's resources, direct contact with the owners of the relevant practices may be very beneficial.

Box 7. Q&A box

⁵⁵ For example, in JADECARE, eight months and a lot of resources, including commitment from the owners of the best practices, were dedicated to perform in-depth studies on what and how made the included best practices »the best«, and how other team can learn from them.

3.4 Transversal principles

3.4.1. Sustainability

Sustainability in the context of JACARDI and other actions within the EU4Health program encompasses the expectations from EC/DG SANTE that the favourable effect of the project does not end when the financing ends. Within the description of the action⁵⁶, each project has to clearly describe the follow-up of the project after EU funding ends, how the project impact will be ensured and sustained, what will need to be done, which part of the project should be continued, and maintained; how this will be achieved; which resources will be necessary; how the results will be used; and identify possible synergies and complementarities with other (EU) funded activities that can build on the project results.

To operationalise the principle of “sustainability” in a harmonised way across the JACARDI consortium, **the working definition of sustainability** was developed and agreed upon and is as follows.

Sustainability in JACARDI is defined as the ability of JACARDI to provide structured and evidence-based support for the pilots and other JACARDI partners to support the continued utilisation of pilots’ results after the EU funding ends within their countries and/or within the key topics of JACARDI, and/or at high policy level. The post-JACARDI exploitation of the project’s results and outcomes will be supported at the following three levels:

1. Sustainability as the principle is followed along all phases of pilot design, implementation, monitoring and reporting. As the main driver of actions after the end of JACARDI, a Sustainability action plan will be developed for each JACARDI pilot. This plan defines actions that contribute to, for example:
 - the continuation of the practice within the pilot site,
 - the scaling up or transfer of the practice to other settings at a local, regional, or national level,
 - the integration of the pilot’s results into existing guidelines, strategies, or policies and
 - the success of the second and third levels.
2. A roadmap will be developed for each of the six key topics of JACARDI: 1) health literacy; 2) data availability, quality, accessibility, and sharing; 3) screening; 4) integrated care pathways; 5) self-management; and 6) labour participation. The roadmaps summarise the results of the pilots and identify factors that are important for the development of future programs, including their further implementation and/or scale-up. For potential implications, please see the box below (*Box 8. The potential of roadmaps*).

Particularly in developing self-governing capacities within complex research-action enterprises like JACARDI, the roadmaps could address the significance of fostering strong social relationships, promoting knowledge sharing, and implementing effective outcome measurement strategies to assess progress on system capacities accurately. By navigating these challenges adeptly, we can ensure the successful implementation of sustainability initiatives and pave the way for meaningful advancements in our collective endeavours.

Additionally, it is crucial for partners to assess their alignment with standards (for example, through context analysis) and to contribute to shaping policy agendas and influencing stakeholder behaviours actively. This process of system-level capacity-building might be essential not only for

⁵⁶ As part of a GA.

fostering self-governance and accountability but also for establishing synergies with various stakeholders and initiatives, thereby fostering a more holistic and coordinated approach towards achieving sustainable outcomes. In this regard, JACARDI might play a central role in framing sustainability actions within all six key topics, facilitating policy dialogues, and leading the establishment of a possible Sustainability Network within key topics.

Box 8. The potential of roadmaps

3. Collaboration between JACARDI and PreventNCD will support the high-level policy sustainability of both JA. This collaboration will materialise through the following:
 - the work of the Sustainability Coordination Body that seeks to identify and exploit synergies between the JA,
 - the Policy Decision Makers' Forum established in PreventNCD and
 - the development of the JA Sustainability Plan.

In addition, the synergies with Action Grants on prevention on NCDs are being established to integrate activities and maximise the impact of all actions. For beyond JACARDI activities, please see the box below (*Box 9. Synergies extending beyond JACARDI activities*).

Based on expectations from HADEA in going beyond the well-structured synergies with JAPreventNCD and identified Action Grants, JACARDI is establishing synergies with other European initiatives, projects and actions, and similar financial mechanisms within the framework of high-level policy sustainability, including the pivotal role of JACARDI Stakeholder Advisory Board.

The measures that will be used are linked to:

1. Policy environment: capacity-building with a focus on efficient science-to-policy interaction and policy advocacy;
2. Ownership of sustainability: the integration of the project's interventions, strategies, and approaches into existing healthcare systems and structures.
3. Culture of collaboration and consensus-seeking: the building and deployment of viable long-term partnerships with key stakeholders to leverage existing resources, expertise, and networks to support the potential impact of JACARDI beyond the project duration.

Box 9. Synergies extending beyond JACARDI activities

With **sustainability as a transversal principle** of the JACARDI methodological framework, essential elements of sustainability are included in all Steps covering the design, implementation, monitoring, assessment, and reporting to increase the ability of JACARDI pilots to have a sustainable impact in the long run (after JACARDI ends). Elements of sustainability include policy environment, ownership of sustainability, and culture of communication and consensus-seeking⁵⁷. Generally, sustainability benefits most from the iterative nature of the process.

⁵⁷ JADECARE Sustainability framework, please see Chapter 1.4 ([link](#)).

Methodological support is provided as follows:

- 1) The sustainability lens, represented by guiding questions (as “food for thought”) for the core pilot team, covers all work the core pilot team performs in Steps I-XV; with this support, sustainability is applied as an important perspective from the very beginning of the pilot⁵⁸.
- 2) Guidance for identifying key stakeholders, including the assignment of roles, in the planning phase and during the implementation of the pilot, with specific emphasis on the stakeholder board.
- 3) Guidance for assessing sustainability-supporting contextual characteristics (detailing policy environment, ownership of sustainability, and existing processes that support collaboration, consensus-seeking, and engagement of stakeholders) in the planning phase and during the implementation of the pilot
- 4) Guidance to include at least one sustainability-supporting activity in the first pilot implementation plan, monitor it, and report the result(s) and outcome(s)
- 5) Guidance on how to potentially adapt the pilot project based on intermediary reporting to maximise the effectiveness in achieving results and outcomes, as well as to increase the potential for sustainability (See *Figure 9. 4A method* and *Box 10. 4A method*).



Figure 9. 4A method

⁵⁸ Following also the learnings from JADECARE and CARE4DIABETES

At the time when intermediate results (from the implementation process or assessment plan) are assessed at intermediary reporting, they have to be compared to the expected results (progress) at that time point. Then, the activities from the implementation plan can be changed (or not):

- If the activity has already achieved the expected result, it is concluded and celebrated. If the activity achieves the expected progress but is still ongoing, it will be further **adopted** and included in the second implementation plan.
- If the activity does not achieve the expected progress, and it is known what “went wrong,” the activity can be **adapted** accordingly for the next implementation plan;
- If the activity is not bringing the expected progress or encounters massive barriers, it can be **abandoned**, i.e., not included in the subsequent implementation plan;
- If an opportunity or any other favourable change in the pilot's situation appears, a completely new activity can be **added** to the subsequent implementation plan to grasp the new potential advancement.

In some cases, intermediary assessment can signal that even specific objectives and/or general objective of the pilot need to be adapted. The changes and the justification need to be noted, justified, and reported in the Final implementation plan (see Annex VII).

The 4A method will be used as a mnemonic during continuous monitoring. It describes the practical application of interpreting the assessment of the implementation process or even multidimensional assessment if designed in this way.

Box 10. 4A method

- 6) Sustainability (and scalability/transferability) is included as one of the dimensions in the multidimensional assessment framework, so it is included in the multidimensional assessment plan as well as in multidimensional assessment reports
- 7) **Integrated reporting on sustainability process and achievements** into the final implementation report (see Annex VII, specifically Appendix B)
- 8) And as a guidance and specific training (Science to Policy communication courses and Learning lesson 4) for the last three Steps of the Methodological framework, explicitly dedicated to actively engage key stakeholders in the preparation of the sustainability action plan (Step XIII), draft sustainability action plan (Step IV), and seek approval and consensus for the **Sustainability action plan** (XV) aiming to achieve its institutional anchoring, ownership, visibility and commitment of the key stakeholders to accomplish activities, planned for the remaining months of JACARDI and for two years after JACARDI ends.

Sustainability – Key takeaways

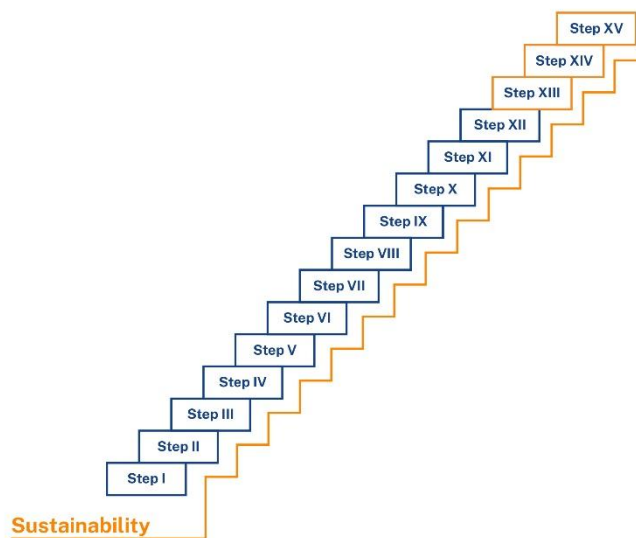
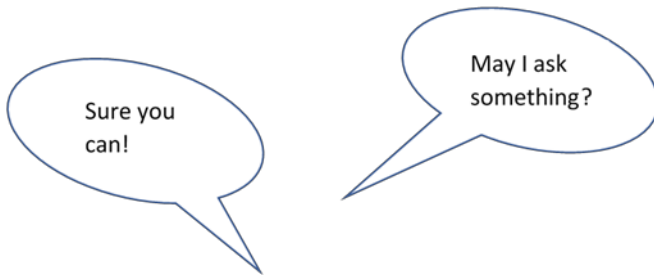


Figure 10. The integration of the sustainability principle

In **summary**, it is highly recommended that all core pilot teams apply guiding questions of the “sustainability lens” in Steps I to XV. It is **essential** that all core pilot teams assess and report to the Final implementation report on the sustainability-supporting characteristics from the pilot perspective and analyse key stakeholders in the planning phase and during implementation. Ideally, the stakeholder board is defined in Step III as part of the pilot situation analysis; it is highly advisable to specify in Step VI to co-design the implementation plan and (at least one) sustainability-supporting activity (that may as well be the proactive cooperation with stakeholder board), in Steps VIII and IX to advise on potential adaptation of the pilot, in Steps XI and XII to put the focus to sustainability developments. It is **essential** that the stakeholder board is integrated within the work of core pilot teams in Steps XIII, XIV, and XV. It is **essential** that at least the pilot organiser participates in Learning session 1 on how to develop a pilot implementation plan. It is **essential** that Pilot implementation plan No. 1 includes at least one sustainability-supporting activity and that it is monitored, assessed, and reported in the Final implementation report. It is **essential** that at least the pilot organiser participates in Learning session 2 on intermediary reporting. It is **essential** that the results of intermediary reporting are interpreted from the focus of expected progress and that activities (as well as specific objectives and/or the general objective) are reconsidered by applying the 4A method. It is **essential that the sustainability dimension is included as an obligatory one in multidimensional assessment plans** and reports. It is essential that at least the pilot organiser participates in Learning session 3 on final reporting. It is **essential** that the final implementation report covers all elements of sustainability (see Annex VII). It is **essential** that at least the pilot organiser participates in the course on science-to-policy communication and Learning session 4. It is **essential** that all core pilot teams prepare materials on essentials of pilot project results, outcomes, and key findings, adapted to the audience(s) of key stakeholders, run at least one stakeholders’ consultation meeting (Step XIII), develop draft Sustainability

action plan (Step IX), and organise at least one stakeholder consensus meeting (step XV). It is highly recommended to organise and/or participate in as many celebration events as possible to support the ownership of the Sustainability action plan among key stakeholders and increase visibility. Please see Q&A box below (*Box 11. Q&A box*).



Q: What if a pilot was not successful? Also, if a pilot is unsuccessful or seems unfeasible, should the core team develop a sustainability action plan at all?

A: The definition of success in implementation projects is not an easy one. Probably also because we have seen so many excellent little projects with marvellous results, but when it comes to the implementation in the real world, they tend to fail so frequently...

In some types of projects that are run in a controlled way in controlled environments, where the result is mainly in the hands of the team running it, the definition of success is very clear (for example, the standard operating procedure for x situation has to be written in next five days by person A and person B; if after five days this document is at the desk of the director, it was a successful project). In implementation projects, it is encouraged that the plan is adjusted when inefficient or when barriers occur (not run in a strictly controlled way). The context may have a powerful influence on the project (positive or negative), so there may be strong forces that are not in the hands of the core pilot team that runs it.

So, how do we define success? In JACARDI, we employ several approaches to maximise the potential success of all 143 pilots:

- *Application of basic project management principles: responsible person within the team that acts as single-point contact (pilot organiser), functioning core pilot team with shared values, beliefs and aims of their pilot, frequent and regular contacts among core pilot team and WP6-11 leadership, understanding the context and important players, clear general objective and specific objectives (Specific, Measurable, Achievable, Relevant, Time-Bound (SMART)), planning the activities with process measures in place, regular monitoring, intermediary reporting for potential adaptation of the plan, harmonised reporting as examples. So, one level of success in the JACARDI pilot is that all these project management measures function (for example, all plot organisers attend every monthly meeting and report on the progress, etc.).*
- *Strong push to apply the PDSA method⁵⁹ (you plan what you will do based on your best understanding, then you do that and monitor continuously what is happening, then you assess your results at some point and based on the fact if you achieved the expected results or not you*

⁵⁹ Plan-Do-Study-Act, see Chapter 1 and Annex I.

change your first plan to be “better” in the next round) as an essential approach to improve the pilot activities to achieve better results and outcomes. Another level of success in the JACARDI pilot may be that all activities with lower progress than expected are adapted to be more efficient, or abandoned and new actions included, or the encountered barriers cannot be overcome, and the pilot changes the specific objective, even general objective, etc.

- Due to the known power of the context, continuous monitoring of the context is promoted. Success in the JACARDI pilot may, therefore, be seeing and catching the opportunities for uptake of the pilot results at any point (for example, a few pilots in another JA were included in the National resilience plan, the opportunity that could not even be imagined at the beginning of this JA before the covid pandemics), and barriers, threats, bottlenecks that may impair the potential uptake of pilot results. As you pointed out, if the pilot project is not feasible at a larger scale, then it should be adapted, ideally within JACARDI, and a feasible solution should be piloted, reported, and used as a basis for the Sustainability action plan. The multidimensional assessment framework includes the feasibility assessment to facilitate this process. If the pilot cannot be adapted to overcome the barriers, clear identification of the barriers is an extremely important finding of the pilot.
- Success can be measured at the level of successful accomplishment of all activities in the plan, i.e., timely delivery of results/outputs as tangible products of activities (see Glossary for details)
- success should, of course, also be measured more traditionally by showing the effect of the pilot project; in JACARDI, we are using a multidimensional assessment framework; ideally, the pilots would need to be able to show that these effects are seen because of the pilot project, but the dilemmas are generously discussed in Annex VI. Successful pilots would, therefore, show positive effects in this assessment and would ideally be able to show that these are seen because of the pilot activities.
- In JACARDI, however, we would also like to capture the **pilot** outcomes (see Glossary) that are under the indirect influence of the pilot, for example, changes in instruments, concepts, capacity, networks, and knowledge culture. Such changes may also be a pilot's success (that's why we usually use the wording “pilot results and outcomes” in this document) and should be appropriately reported in the Final implementation report and used in developing the Sustainability action plan.
- The many layers of success also mean several layers of potential failures...and again, since the context is so powerful in implementation projects, we should be able to support all pilot projects in distinguishing what is under their control (and help them that they work with this), and what not (and remind them that they report on this). At the point of Final implementation reporting, they should, therefore, be able to report what were their results (outputs), what was the effect of the pilot (multidimensional assessment), the pilot outcomes (if any), and what are the key findings. Clear identification of key findings is also a success. For example, even if the pilot was adjusted after being assessed as not feasible for scale-up, at the end of implementation, it was still not feasible. The key findings should, therefore, clearly present what kind of changes would need to be introduced to this practice so that it would become feasible, and the Sustainability action plan should, in this case, be based mainly on the key findings.

To make the long story short – JACARDI pilots will be successful if, based on the results/outcomes and key findings from implementation, they will anchor the stakeholders to the actions in the sustainability plan, with a high level of ownership and accountability for the years after JACARDI. Even if this fails, and if the core pilot team can report on all barriers they encountered and what they tried and did not work, these may be very valuable lessons learnt on what and how to plan future implementations to avoid such problems. The only real failure thus is non-responsiveness from the core pilot team, but the proactiveness of WP6-11 leadership teams that we see tends to minimise this risk to the least possible.

Box 11. Q&A box

3.4.2 Equity and diversity

The integration of equity and diversity in JACARDI is based on the **4C principles** (Critical reflection, Co-design, Context and data, and inclusive and accessible Communications) (*Figure 11. 4C principles*). **Critical reflection** is the core underlying principle for all activities aiming at integrating equity and diversity perspectives, whereas **co-design**, **context and data**, and **inclusive and accessible communications** are concrete pathways and areas where it should be especially applied.



Figure 11. 4C principles

The 4C principle was designed as a simple framework for considering the key areas related to equity and diversity within JACARDI.

The minimum requirement for core pilot teams in JACARDI is to employ critical reflection.

Before describing the methodological tools that core pilot teams can use to integrate the equity and diversity perspectives in their work, critical reflection as the underlying principle and the three key areas of pilot implementation where it should be applied are described.

4C principles in practice

The underlying principle and key pathway to understanding the complex interactions between individual-level social determinants and exposures influencing health outcomes throughout the life course is through **developing critical reflection skills**. Critical reflection, also referred to as cultural humility, is a continuous, life-long process of critical self-reflection to examine one's own biases, prejudices, and stereotypes, as well as one's own position of power in relation to others⁶⁰. *The wheel of privilege (See Annex II) is one of the multiple ways of visualising how the power dynamics are distributed within the society.*

Cultivation and engagement with critical reflection is the key pathway for facilitating the finding of purpose and meaning in the activities aiming for the integration of equity and diversity perspectives among JACARDI partners. Change is person-centred and person-driven. For a paradigm shift to occur towards developing more equitable and diversity-inclusive actions and systems, it is imperative that those in the position of power to initiate change are willing to apply the equity and diversity lens in their activities.

In JACARDI, **critical reflection is applied**, especially in the following **three key areas of pilot implementation**: 1) co-design, 2) context and data, and 3) inclusive and accessible communications.

1) Co-design is a collaborative approach that involves actively engaging end-users/end-beneficiaries, professionals, and other relevant stakeholders in the design of projects and products, including health interventions, health promotion activities, and healthcare services⁶¹.

Co-design is relevant for the pilot implementation, from conceptualising the problem to considering the sustainability and scalability of the pilot. Meaningful engagement of stakeholders, and especially communities the pilot wants to serve, should occur at the early stages of pilot situation analysis.

The JACARDI GA mentions that pilots are advised to form a stakeholder board that can be consulted throughout pilot planning, implementation, and assessment. To more comprehensively hear the voices of the communities we wish to serve, it is advised to assemble for consultations/workshops **groups of diverse end-users/end-beneficiaries, representative of the community the pilot wants to serve**, to identify the key themes and discourses that should be considered in the pilot. This would be beneficial for collecting a better representation of diverse views to inform pilot actions and reduce potential power imbalances that are more likely to be present in “mixed” stakeholder boards involving also professionals and decision-makers.

Ideally, the general and specific objectives are defined in co-design with the communities we aim to serve.

Co-design facilitates the conduct of a comprehensive needs assessment that allows to identify barriers and facilitators (strengths) to implementing the pilot, providing nuanced insights into the context and biases in the data⁶². It is also needed for matching diverse needs based on local wisdom with available data.

⁶⁰ Tervalon, M. & Murray-Garcia, J. 1998. Cultural Humility Versus Cultural Competence: A Critical Distinction in Defining Physician Training Outcomes in Multicultural Education. *Journal of Health Care for the Poor and Underserved*. Vol 9, no 2. 117-125. doi: 10.1353/hpu.2010.0233.

⁶¹ Vargas, C., Whelan, J., Brimblecombe, J., & Allender, S. 2022. Co-creation, co-design, co-production for public health: a perspective on definition and distinctions. *Public Health Research & Practice*, 32(2).

⁶² Osborne, R. H., Cheng, C. C., Nolte, S., Elmer, S., Besancon, S., Budhathoki, S. S., Debussche, X., et al. 2022 Health literacy measurement: embracing diversity in a strengths-based approach to promote health and equity, and avoid epistemic injustice. *BMJ Global Health*. doi: <https://doi.org/10.1136/bmjgh-2022-009623>

Finally, co-design should be applied during the assessment of the pilot, when compiling the sustainability action plan, and considering the scalability of the pilot.

Box 12. Co-design in practice

2) Context and data

The social and economic context regulates the distribution of power and privilege, as well as available resources⁶³. **The context** is, therefore, of key importance from the intersectional perspectives as it entails the power dynamics in society and how these affect individual identity, social position, and health. It is important to note that the advantages and disadvantages arising from the intersectional perspectives are contextual in nature. A persons' degree of advantages or disadvantages compared to others can change with changes in the context⁶⁴.

The application of critical reflection to examine the contextual factors that create visible barriers to participation and equitable distribution of resources and opportunities for diverse social groups can facilitate the design of more equitable and diversity-inclusive actions. Conducting the impact assessment on different groups contributes to the development of universal measures and reduces the risk of unintentionally creating barriers for some population groups.

Critical reflection can start with reflecting on who all are impacted by the planned action and how these groups are impacted. It is also important to consider whether planned actions entail barriers to participation for some population groups and how these could be addressed. When considering the impact on different population groups, intersectionality should also be considered. For example, it could be considered how the planned actions impact women with disabilities, older ethnic minority women with limited digital skills, persons with functional limitations living in rural areas, and so on. Figure 12 (*Figure 12. Critical reflection in practice*) below summarises the key questions to consider when conducting an impact assessment.

Pilot impact assessment for different population groups

⁶³ Kriegel, 668–67
⁶⁴ Hill C



Define

- ✓ Who are the key groups impacted by the pilot?
- ✓ How are these groups impacted? Is the benefit equitable? Who are the winners and losers?
- ✓ What are the potential pathways and mechanisms to how the groups are impacted?
- ✓ Are there alternative ways of implementing the pilot (at least option 0: not doing anything)

30(4),

Adapt

Data is needed to conduct an impact assessment and refers to any type of information (e.g., quantitative, qualitative, observational) that we use to inform our priorities and actions.

Data plays an important role in shaping health policy and practice, and it is a general consensus that health policy should be evidence-based. Data availability influences what groups and health indicators are given visibility⁶⁵. If the data is not available, it renders the phenomenon unseen and therefore not identifiable as a priority for policy and practice - “no data, no problem.” Additionally, critical reflection can be applied to consider other possible biases in the data, including the selectivity of participants and how different methodological choices in data collection and measurement may influence results.

New data can be gathered to fill the gaps in available data and strengthen understanding of who the main groups impacted are and how these groups are impacted. Data can be collected, for example, through co-design workshops with end-users/end-beneficiaries, health professionals, non-governmental organisations (NGOs), and other relevant stakeholders, as well as interviews and surveys.

Box 13. Critical reflection and data in practice

3) Inclusive and accessible communications

Communication takes place all the time, including verbal and nonverbal communication. It can be viewed as a process of sending and receiving information and making meanings⁶⁶. Communication holds the power to reinforce or break down harmful stereotypes and include or exclude persons or communities. This is why, from an equity and diversity perspective, it is imperative to be mindful of our communication to be accessible and inclusive for diverse population groups.

Inclusive and accessible communication promotes equity and diversity and builds trust. It is reciprocal by nature and is done in collaboration with stakeholders.

For communication to be inclusive and accessible, critical reflection should be applied to ensure the information is suitable for everyone regardless of their abilities, genders, cultural and ethnic backgrounds,

⁶⁵ Kihlström, L., Satokangas, M., Skogberg, N., Viita-aho, M., Gissler, M., Nykänen, E., Keskimäki, I., & Tynkkynen, L. K. 2023. Power and politics of health system data: how data shape responses and equity during pandemics. *The European Journal of Public Health*, Vol 33, Issue Supplement 2. doi: <https://doi.org/10.1093/eurpub/ckad160.458>

⁶⁶ Turner, L. H., & West, R. 2018. *An Introduction to Communication*. Cambridge: Cambridge University Press. Available at: <https://www.book2look.com/book/9781107151048>.

or life situations. Critical reflection should be applied to consider, for example, how the communication is made and who decides what is to be communicated; what (all different) messages and meanings the communication brings across; who is reached directly or indirectly by the communication; and where and when the communication is disseminated⁶⁷.

In addition to being a key pathway in the JACARDI 4C principles for considering equity and diversity perspectives, inclusive and accessible communications are a cross-cutting theme in all JACARDI communications (WP2). The **guidelines and a checklist for inclusive and accessible communication** (See *Annex III*) were prepared and should be used by core pilot teams. These guidelines emphasise the application of critical reflection, particularly in the following circumstances: 1) communication planning, 2) use of inclusive language, 3) inclusive use of visuals, 4) digital accessibility, and 5) inclusivity in events.

Box 14. Inclusive and accessible communication in practice

Methodological tools and support

Different tools and support for the application of equity and diversity perspectives in practice are available to pilot teams:

- 1) Equity and diversity maturity matrix (Equity and diversity matrix)
- 2) Capacity-building on equity and diversity
- 3) Equity and diversity terminology glossary
- 4) Equity and diversity lens with facilitatory questions
- 5) Guidelines and a checklist for inclusive and accessible communication

1) Equity and diversity matrix

The equity and diversity maturity matrix (equity and diversity matrix) is a practical tool for core pilot teams. It provides concrete examples for integrating the equity and diversity perspectives at different levels of comprehensiveness. The steps in the matrix correspond with the XV Steps of the JACARDI methodological framework. The equity and diversity matrix draws from the 4Cs principles.

How to use the equity and diversity matrix?

The core pilot team will use the matrix to describe the pilot's consideration of equity and diversity. The different levels in the equity and diversity matrix provide concrete examples on how this can be done at different levels of comprehensiveness.

Ideally, the core pilot team will use the matrix both:

- (1) As a **guiding tool** when planning their activities. This way, the core pilot team considers equity and diversity prior to implementation cycles, improving its work.
- And, (2) as a **reporting tool** to retrospectively report consideration of equity and diversity at the following four key points of the pilot implementation:
 - Steps I-VI: when compiling a pilot implementation plan (Webropol questionnaire by October 2024, and within RedCap tool when available)
 - Steps VII-VIII: intermediary reporting 1 (Integrated within general reporting⁶⁸)
 - Steps IX-XI: intermediary reporting 2 (Integrated within general reporting⁶⁸)

⁶⁷ Calado, C. 2021. Inclusive Communication. Policy Brief. Intercultural Cities Unit, Council of Europe. Available at: <https://rm.coe.int/policy-brief-inclusive-communication-carla-calado-2021/1680a39c0b>

⁶⁸ within specific subchapters of Final implementation report template

→ Step XII-XV: final reporting (Integrated within general reporting⁶⁹ by March 2027)

The minimum requirement for core pilot teams is to use the equity and diversity matrix as a reporting tool.

The steps in the equity and diversity matrix have three levels: approaching, meeting, exceeding. Each of these three levels of comprehensiveness is provided with an explanation of what is required to meet these criteria. The core pilot teams need to describe the level that best describes their activities. This will vary depending on the resources and previous experiences in equity and diversity perspectives among the core pilot team. For some, being at the approaching level will be an important step towards the integration of equity and diversity, while some will reach the exceeding level. Additional information can be provided in the comments field. If it is difficult to identify the appropriate level, a description of activities can also be added there.

The minimum requirement for the pilots is to reach the “approaching” level in the matrix, which is the level of employing critical reflection. If, in any case, the pilots cannot reach the level mentioned above, they can select “approaching” and write an explanation for their situation.

Pilot responses will be used to identify supporting activities for integrating equity and diversity perspectives, reporting to HADEA and at General Assemblies, and in publications related to equity and diversity in JACARDI.

Box 15. How to use the equity and diversity matrix?

By considering the equity and diversity matrix alongside their decision-making, the core pilot team can gain a deeper understanding of the concepts related to equity and diversity and provide essential information for monitoring the integration of equity and diversity perspectives within JACARDI. As mentioned before, the equity and diversity matrix provides examples for each level step I to XV.

2) Capacity-building on equity and diversity

Capacity-building activities are carried out throughout the JACARDI project through masterclasses that deepen the understanding of the JACARDI partners, including core pilot teams, on the concepts related to the 4C principles for integrating equity and diversity perspectives, as well as consultations and workshops for WP leadership teams and core pilot teams that support adherence to the explanatory framework and application of the related practical tools. WPs and core pilot teams are encouraged to reach out when support is needed. The equity and diversity experts will also aim to be regularly in contact with WP leadership to identify what kind of support would be beneficial for them.

3) Equity and diversity terminology glossary

The equity and diversity terminology glossary is in *Annex II*. It has been integrated into the joint WP5 terminology glossary.

4) Equity and diversity lens with facilitatory questions

The tools to facilitate the integration of equity and diversity as a transversal principle in JACARDI were developed and tested within the first eight months of the project duration. However, core pilot teams were already established and started to work on the Steps. As equity and diversity were part of the methodology

⁶⁹ within specific subchapter of Sustainability action plan

from the very beginning, the Task 5.3 team developed facilitatory questions to include the equity and diversity perspective, similar to the sustainability lens. Since this soft approach in pointing out what is important in the respective Step was suggested to be useful by WP6-11 leadership teams in leading core pilot teams, they were developed to cover all fifteen Steps. For more details, see *Annex II*.

5) Guidelines and a checklist for inclusive and accessible communication (*Annex III*)

Please refer to Chapter 3.7 ([Link](#)).

Equity and diversity principle – Key takeaways

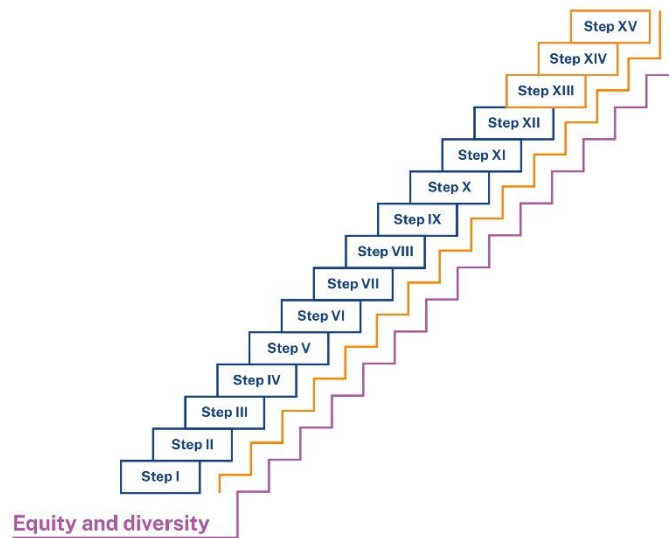


Figure 13. The integration of the equity and diversity principle

In summary, it is **essential** that all core pilot teams employ critical reflection (thus achieving “approaching level” in the equity and diversity matrix), consult equity and diversity facilitatory questions when planning their work, use the equity and diversity matrix when reporting on the integration of equity and diversity perspective the pilot covering Steps I - XV, and reflect on the importance of equity and diversity in the final implementation report and sustainability action plan. It is suggested that all core pilot team members participate in capacity-building opportunities and use the equity and diversity matrix as a guiding tool when planning their activities. Please see Q&A box below (*Box 16. Q&A box*).

Sure you can!

May I ask something?

Q: Based on the equity and diversity matrix, I believe our core pilot team does not achieve even the “approaching level.” What should I, as a pilot organiser, report in this case? Should I just leave it blank?

A: Please do not leave it blank. It is really important for us in JACARDI to collect as many authentic answers as possible since this is the first time equity and diversity are included in such a project as a transversal principle. Although we have tested the equity and diversity matrix with several pilots, your information would be very precious. So please check “approaching level” and describe the real situation in the Comments field of the matrix.

Box 16. Q&A box

3.5 Multidimensional pilot assessment

The methodological framework for the multidimensional assessment of pilots aims to guide pilot teams in assessing six key outcome dimensions (effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability - including scalability/transferability, and additional implementation and process outcomes) in determining the effects of the pilot project. The framework ensures a standardised assessment process from the start, promotes consistent criteria across pilots and facilitates the collection of high-quality data for comprehensive assessments and reporting within and across countries. It also supports the design and analysis of studies, enabling in-depth assessment of selected pilots.

The development of the multidimensional pilot assessment framework involved three key phases:

- Firstly, key dimensions were identified and defined.
- Scientifically robust methods and tools to collect data and assess each dimension were then selected and refined through discussions to meet the project's needs.
- Lastly, various study designs were presented to infer causality, including observational and experimental approaches.

The framework was iteratively refined, with the aim of offering pilot teams comprehensive guidance to help them define consistent and transparent multidimensional assessment plans.

The framework for the multidimensional assessment of pilots provides guidance on the following aspects: (1) definition of outcomes that can be assessed within the pilot, in alignment with the pilot's general and specific objectives; (2) definition of the appropriate design of the pilot and of the data collection; (3) definition of measures/indicators for the assessment and analytical methods to be used; (4) data collection and timing; (5) ethical and legal issues; (6) identification of possible barriers and enablers of data collection; and, (7) reporting.

Pilot implementation activities are supported by the multidimensional assessment framework at various steps of the implementation process, as follows:

- At Step VI, when developing the multidimensional assessment plan. At this step, Task 5.6 performs two types of activities with WP6-11: a short presentation of the framework and a more extended training session with the opportunity for pilots to start developing their assessment plans. Those sessions are organised together with the WP leadership teams.
- At Steps VII and VIII, to deliver intermediary results No. 1, if found relevant within the multidimensional assessment plan. At these steps, Task 5.6 provides continuous support to core pilot teams as they go through the implementation stage, and they may require clarifications on how to collect the required data better.
- At Steps IX, X, and XI, deliver intermediary results No. 2 if found relevant within the multidimensional assessment plan. At these steps, Task 5.6 continues to support the core pilot teams during their implementation stage, as in Steps VII and VIII.
- At Step XII, deliver the final results of the multidimensional assessment within the final implementation report. Task 5.6 provides the reporting template for multidimensional assessment that is integrated into the final implementation report.
- At Steps XIII and XIV, results from multidimensional assessment provide inputs into sustainability action plans.

Dedicated workshops and support to core pilot teams will be provided by the Task 5.6 team, starting from the design of the pilot implementation plan to apply each aspect of the multidimensional assessment framework. More specifically, these workshops will include a presentation of the framework and of the assessment plan for a sample pilot by Task 5.6, followed by the individual and group work activities dedicated to developing an assessment plan by each of the pilots and discussing the results with other pilots. Task 5.6 will be present at the discussions to answer possible questions. Sample pilot assessment plans are created before the workshops together with one volunteer pilot from each technical WP, one representative assessment plan per each WP6-11. Capacity-building activities will be conducted jointly with the Implementation board, which has an expert in economic evaluation as a member. In addition, an expert in applying multidimensional assessment framework will be available to participate in all learning sessions if invited at the discretion of WP6-11 leadership teams.

Multidimensional pilot assessment – Key takeaways

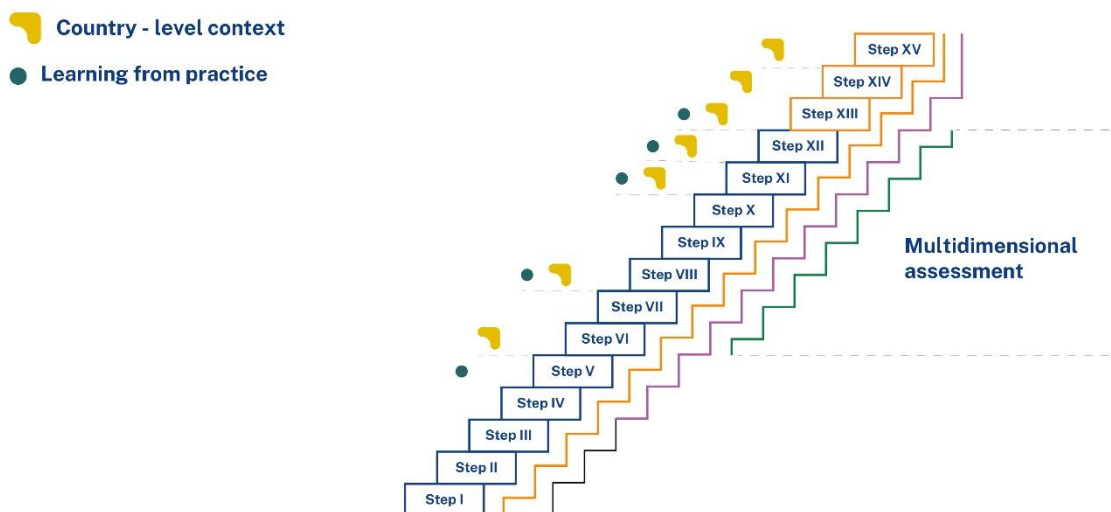
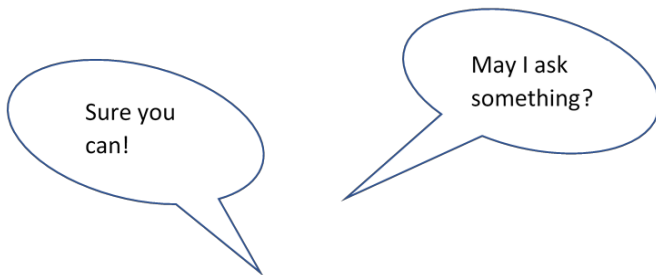


Figure 14. Multidimensional pilot assessment

In summary, it is **essential** that all core pilot teams develop a multidimensional assessment plan (Step VI) and provide the final results of the multidimensional assessment in the final implementation report (Step XII). Those core pilot teams, who identified outcomes that need to be assessed and reported at the timing of intermediary reporting, also have to provide both intermediary reports on multidimensional assessment (Steps VIII and XI). It is **essential** that all core pilot teams take into consideration all of the dimensions; for those not included in the assessment because they are not relevant and/or applicable, justification should be provided. The dimension of sustainability, including the continuation of the pilot within the same setting /scale-up/transferability, is relevant and thus essential for all JACARDI pilots since it is one of the transversal principles. It is **essential** that pilot organisers from all pilots follow all capacity-building opportunities, and

they are highly recommended to all core pilot team members. Please see Q&A box below ([Box 17. Q&A box](#)).



Q: This seems so complicated ...

A: Assessment of effects of implementation projects is really different from the evaluations that we are typically familiar with, such as randomised controlled trials, which tend to bring proof that the result of the trial is because of the drug (for example) (causal effect).

Only rarely can implementation projects by design follow the rules of randomised controlled trials. In those trials, there are inclusion and exclusion criteria, strict protocol with a tendency to limit deviations as much as possible, and detailed statistical analysis plan with calculated numbers of participants to achieve the power to really detect the difference, if it really exists, control group, among others.

Implementation projects, on the other hand, try not to limit the characteristics of the participants too narrowly (for example, all people with diabetes need education about how to live with this disease, not only the most motivated, etc.), “protocol” (pilot implementation plan) has completely different structure and core pilot teams are actually proactively asked to change it (if not achieving expected results), and mostly it is very hard to estimate, how many participants need to be included to show with usual statistical approaches the statistical significance in the different results achieved. Also, the ways to find the control groups are different. In this sense, it seems complex since we are not used to that approach. On the other hand – even if we acknowledge that we could not provide proof of causality for most of the pilots, the pilot team members will work hard for two or three years to design and run the pilot.

But what is the effect of this work? Considering all dimensions of multidimensional assessment actually opens opportunities to identify how the effect of all this work (e.g., of the pilot) may be shown and how it could be justified that these results are because of the pilot. Additionally, in Step XII, core pilot teams will be asked to provide interpretations and implications of the pilot’s results and outcomes. Isn’t it valuable to have an assessment plan in place to provide this information? In the end, we come to the sustainability and related expectations. If not before, at that time, core pilot teams will need to be very clear about the pilot’s achievements and why they may be important for future uptake. Multidimensional assessment immensely helps core pilot teams in all those perspectives.

[Box 17. Q&A box](#)

3.6 Capacity-building and supporting activities

Capacity-building is integral to the JACARDI methodological framework. A stepwise approach was chosen to cover the multiple needs of a very large and diverse JACARDI consortium. As indicated in the figure below (*Figure 15. JACARDI capacity-building approach*), first, with **train-the-trainer activities**, the number of individuals equipped with the necessary skills and knowledge to further deliver the capacity-building activities is increased. Second, a wide range of **capacity-building and supporting activities** is made available to the JACARDI consortium to enhance the capacity of pilot teams to use the proposed methodological approach. Third, a **reflection process with corrective activities** is organised annually to adapt the capacity-building approach to the results and experiences of the JACARDI consortium members and pilot teams.

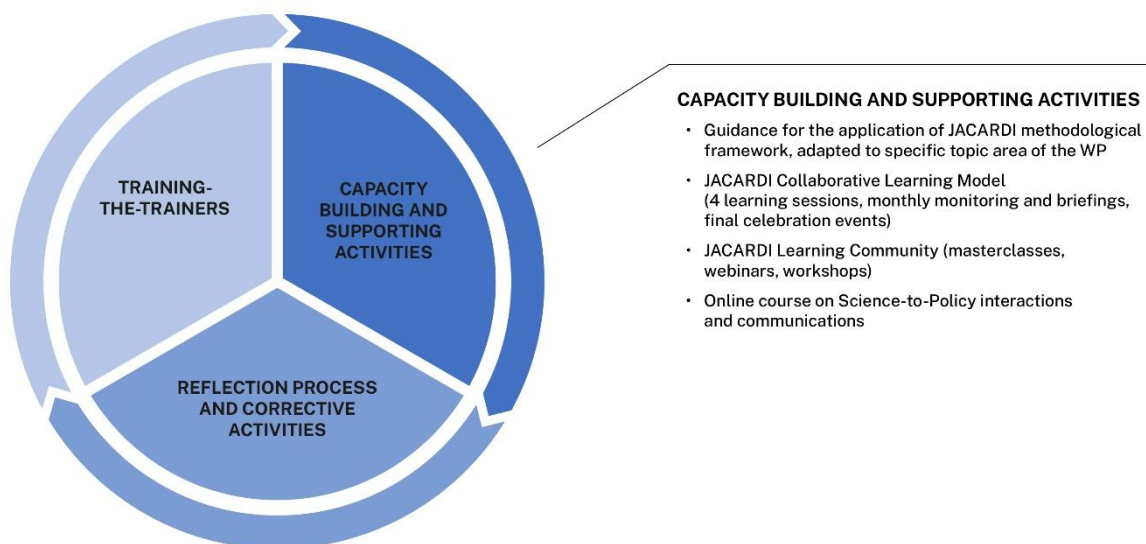


Figure 15. JACARDI capacity-building approach

For core pilot teams, it is essential that their members know how to use the proposed methodology in every implementation step efficiently. For this reason, **four sets of capacity-building activities** were developed and made available to them and other JACARDI Consortium members, including:

- Guidance for applying the JACARDI methodological framework, adapted to a specific WP and its topic (delivered within respective WP using the approach chosen by the WP leadership team)
- JACARDI collaborative learning model, delivered in a harmonised way across all topics (WP6-11), focusing on four key moments of the implementation of pilots and sustainability activities.
- JACARDI learning community activities
- Courses on "Science-to-Policy" interactions and communications

Guidance for applying the JACARDI methodological framework adapted to a specific WP and its topic

In parallel to the (evolving) common conceptual framework, covering all aspects, the generic methodological guidance (PPTs with videos, guidance documents, and templates) was developed for each step by WP4 and WP5. Still, it is up to the WP6-11 leadership teams' decision to adapt it to their WP topics and core pilot teams' needs. Once a year, the Implementation board will run a reflection process (*Figure 16. The visual presentation of the reflection process*) to define and introduce corrective measures to adapt the guidance and approach to the results and experiences of the JACARDI consortium members and pilot teams.

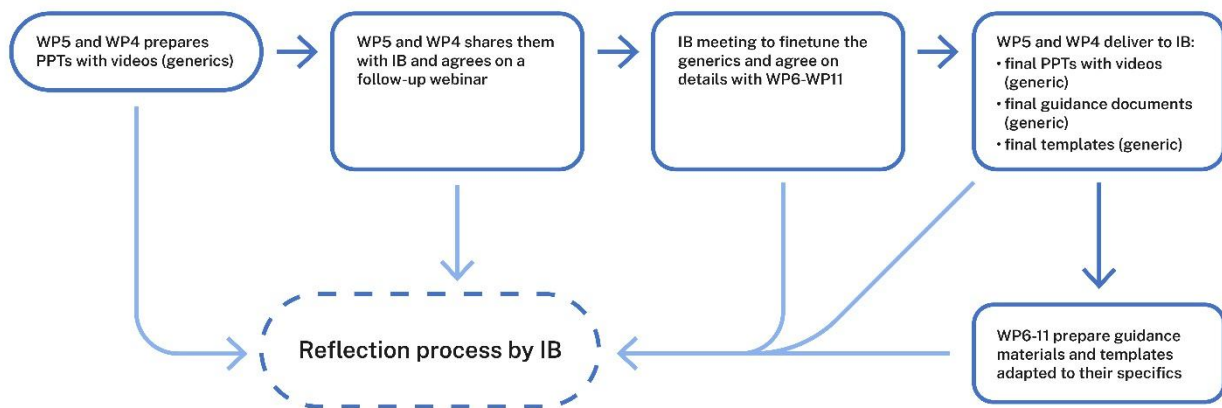


Figure 16. The visual presentation of the reflection process

JACARDI collaborative learning model

The JACARDI Collaborative learning model consists of (1) learning sessions, (2) monthly monitoring with briefings, and (3) celebration events.

1) Learning sessions

As key elements of the JACARDI collaborative model, learning sessions are the essence of the harmonised and uniform capacity-building approach. They are to be held irrespective of other supporting and capacity-building activities within WP6-11 and/or the JACARDI consortium. However, their format can be adapted to best suit core pilot teams' current needs and availability. Pilot teams become familiar with the implementation methodology by participating in learning lessons, focusing on “hot points.” Lecturing should form only a small part of the sessions to leave room for collaborative learning whereby teams work together

and learn from each other⁷⁰. The four learning sessions are delivered in each WP6-11 by WP6-11 leadership teams and should be available to all core pilot teams.⁷¹

The **four** learning sessions (*Figure 17. Learning session structure*) will cover the following **themes**:

- Development of the pilot implementation plan⁷² (at the beginning of Step VI),
- Intermediary reporting (at the beginning of Step VIII),
- Final reporting (at the beginning of Step XII),
- Preparation of the sustainability action plan (at the beginning of Step XIII).

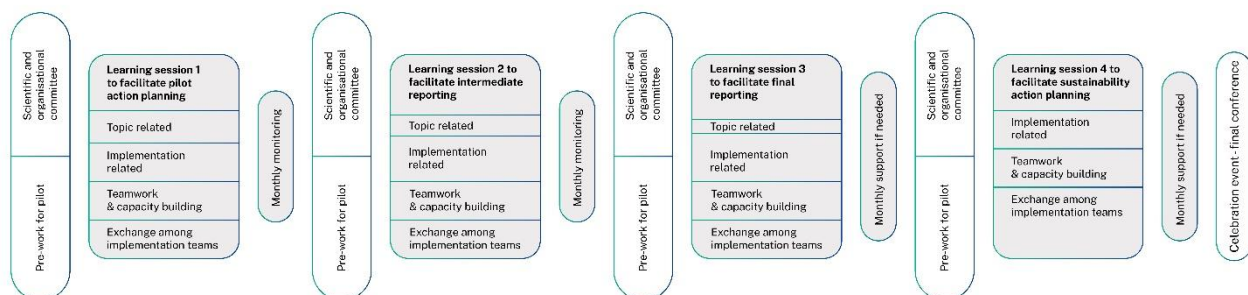


Figure 17. Learning session structure

The **Scientific and organisational committee**⁷³, assembled by WP6-11 leadership teams, is responsible for organizing the learning sessions. An expert on implementation, equity and diversity, and an expert on multidimensional assessment should be included in the committee. This committee prepares the agenda and defines the methods and activities of the learning session. The committee is recommended to envisage relevant **preparatory work** that enables collaborative learning for the pilot teams to complete before the learning session. For example, the teams may need to check that their specific objectives are defined, or they may receive short videos on relevant topics, such as methodological steps or sustainability aspects.

The learning session can adopt the following **generic structure**:

- Topic-related part: with, e.g., an interesting and useful lecture for the core pilot teams to increase or align their knowledge on a specific topic area.
- Implementation-related part relevant for the specific Step(s), for example, (1) a presentation on how the implementation plan should look like, (2) group work in breakout rooms where every core pilot team develops at least one activity to one of their specific objectives, and (3) a plenary Q&A.
- Teamwork and capacity-building throughout the session, e.g., in the form of short activities that strengthen shared values within the team.

⁷⁰ <https://www.valamis.com/hub/collaborative-learning#collaborative-learning-definition>

⁷¹ JACARDI GA, Task 5.5.3

⁷² This session introduces the pilot action planning, including related sustainability aspects, the application of the Equity and diversity matrix, and the designing of a multidimensional assessment plan. Example: WP9 Learning session 1 ([JACARDI Teams](#))

⁷³ The committee is formed by WP6-11 leadership teams. It should include topic-related experts (usually WP leadership teams), implementation experts (usually WP4 and 5 leadership teams), equity, cultural and diversity experts, and experts in assessment.

- Structured exchange among core pilot teams, e.g., via assignments completed in breakout rooms and following plenaries to share insights. Most of the time should be devoted to this part.

The time allocated to each part of the learning session should change from session to session. The amount of time allocated to the topic-related part diminishes from Learning sessions 1 to 2 and 3. It may be completely absent in Learning session 4 to allow more time for the exchanges among pilot teams.

The learning session can be a full-day online event, a set of shorter online events, a face-to-face meeting, or any combination.

2) Monthly monitoring and briefings

In steps VII and X, **monthly monitoring and briefings** will be conducted within WP6-11, led by the WP6-11 leadership team. The aim of these contacts, which are mostly in place anyway by this time, is to bring support to core pilot teams in a structured way, identifying accomplishments (all participants can learn from the successes of others), potential problems, and corrective responses (all can share their experiences on how to tackle the barriers most efficiently), and identifying the “unexpected/unplanned,” that may be the major forces that influence (in positive as well as negative way) the overall outcome of the pilot.

„Many implementation efforts fail, even with highly developed plans for execution, because contextual factors can be powerful forces working against implementation in the real world.“⁷⁴

Guiding questions for monitoring and briefings are as follows below:

Some specific questions related to the implementation should be asked:

- What is going on? What went well? What job was accomplished? Celebration!
- Is anything going wrong? What will you do? How can the WP leadership team help? Is adaptation of the plan needed (At the level of an action, at the level of a specific objective, or in some previous steps)?
- Anything unexpected (positive, negative) happened?

Box 18. Guiding questions for monthly briefings

3) Celebration events

Step XV explicitly includes organising the final conference and other local, regional, and national celebration events. This can be seen as part of the JACARDI collaborative learning model as the exchange of knowledge and experience also occurs with participants outside JACARDI. However, each internal WP6-11 meeting, each meeting with the stakeholder board, and in the broadest sense, each communication and dissemination event is an opportunity to share the results, including the accomplishments (and failures); this increases the visibility of the JACARDI pilot and shows overall credibility of JACARDI.

JACARDI Learning Community activities

Thematic masterclasses⁷⁵, webinars, and workshops are being organised for the members of the JACARDI consortium to support their work. Some of them are organised at the initiative of experts (for example, experts on equity and diversity), others on demand of WP6-11 leadership teams or core pilot teams.

⁷⁴ <https://implementationscience.biomedcentral.com/articles/10.1186/s13012-022-01245-0>

⁷⁵ For example, masterclasses on multidimensional pilot assessment (recorded for further reference) for all JACARDI partners can be organized, and WP6-11 specific workshops, preferably with a case study of pilot assessment plan for one of the pilots from the respective WP.

Additionally, the JACARDI consortium is a learning community relevant to sustainability principles. A specific task, Task 4.2, is in place to compile, analyse, share, and reinforce consortium members' insights on carriers and barriers to sustainability. Thus, the JACARDI consortium will learn from the knowledge and skills of all JACARDI partners.

Courses on efficient Science-to-Policy interactions and communications

In the “Science-to-Policy” interactions and communications courses, approximately 50 trained members of the JACARDI consortium (covering all countries with pilots) will deliver capacity-building courses to altogether approximately 300 pilot team representatives with the aim to support the development of sustainability action plans in Steps XIII-XV.

The trainers will be trained in JACARDI by the EU Joint Research Centre (JRC)-trained experts who will also supervise and support the trainers throughout the JA. The courses the trainers provide are designed **to improve** the pilot teams' **competencies in enhancing the translation of pilot findings into arguments for sustainable changes** in policies and other actions at local, regional, and national levels **by designing and delivering the sustainability action plan**. At least one course will be organised in each participating country with pilot projects. The courses are standardised by JRC, but the adjustment to JACARDI's needs is foreseen.

Capacity-building and supporting activities – Key takeaways

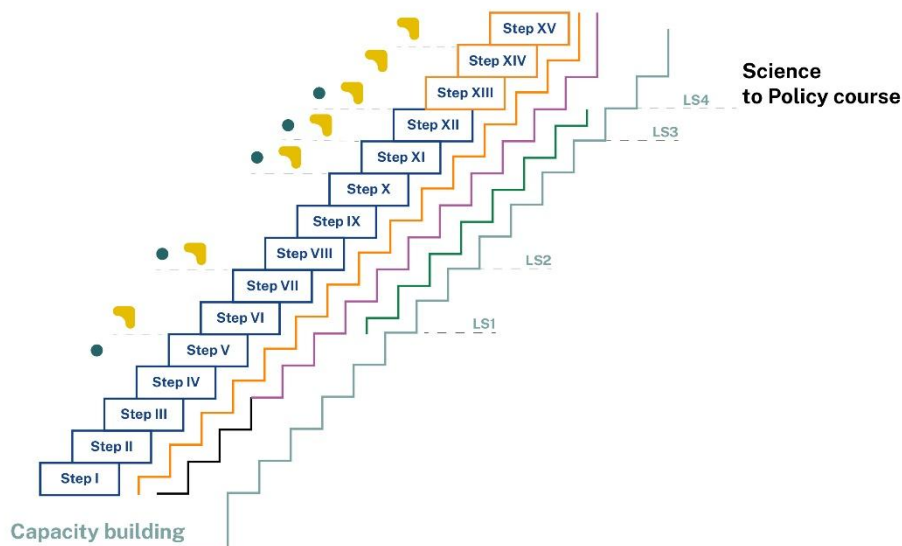


Figure 18. Capacity-building and supporting activities

In summary, it is **essential** that pilot organisers from all pilots attend all learning sessions, monthly briefings, and science-to-policy courses. It is highly recommended that all members of core pilot teams participate in those opportunities, including other learning activities and all celebration events. Please see the Q&A box below ([Box 19. Q&A box](#)).

Sure you can!

May I ask something?

Q: *We have many meetings planned that our budget does not cover. Do you have any hints?*

A: *Unfortunately, none within our team is actually a finance manager, so please take this information with a bit of caution, but hopefully, it will help you find a way. The budget in JACARDI, as usually, is preliminary. As real needs evolve, the budget can and has to be more concretised. Quite a few changes in the budget distribution within the same partner could be made by simply notifying the changes in Amendments of JACARDI (in advance) or by justifying (in the financial reports). However, there are some*

situations where explicit approval should be sought from the Coordinators or even from HADEA (subcontracting). Therefore, the suggestion would be to study the structure of your budget carefully (there is a budget related to communication and dissemination) and check with the financial officer in your institution how the budget for the meetings could be covered. Also, remember that effective meetings can be held online, and the participation rate is typically higher. Of course, they have to be run in a specific way, and as a general rule, good meetings result from good preparation from the organiser.

Box 19. Q&A box

3.7 Communication and dissemination

Communication and dissemination are important aspects of each pilot project. If strategic and effective, they contribute to the success of the pilot project and the sustainability of its results by

- Raising awareness and visibility of the pilot project
- Building and maintaining the commitment of pilot team members and other stakeholders
- Receiving feedback from different audiences
- Turning pilot results into tools for advocacy to ensure participation in shaping policies and other actions
- Increasing the potential impact of pilot results

These activities can contribute to the pilot project's success, provide feedback to adapt the project further and increase the pilot's sustainability potential.

The difference between communication and dissemination is explained in the box (*Box 20. The definition of communication and dissemination*) and the figure⁷⁶ below (*Figure 19. Communication and dissemination basics*).

Communication:

Covers the whole period of the project and includes communicating with and informing internal and external audiences about the activities of the pilot project and the promotion of its results. It is important for communication to reach the general public and the media, to inform and engage society, and to demonstrate the benefits of the work. It may be a two-way activity, sharing the results and outcomes from the pilot project to the intended audience and asking for feedback.

Dissemination:

Covers the pilot's results and outcomes only, takes place after the results and outcomes are available, and informs special audiences: groups that may use the results in their work, including peer groups, industry and professional organisations, and policymakers. It is typically a one-way activity, from the pilot project to the intended audience.

Box 20. The definition of communication and dissemination

⁷⁶ The image has been graphically modified from the original prepared by the EC. https://rea.ec.europa.eu/dissemination-and-exploitation_en

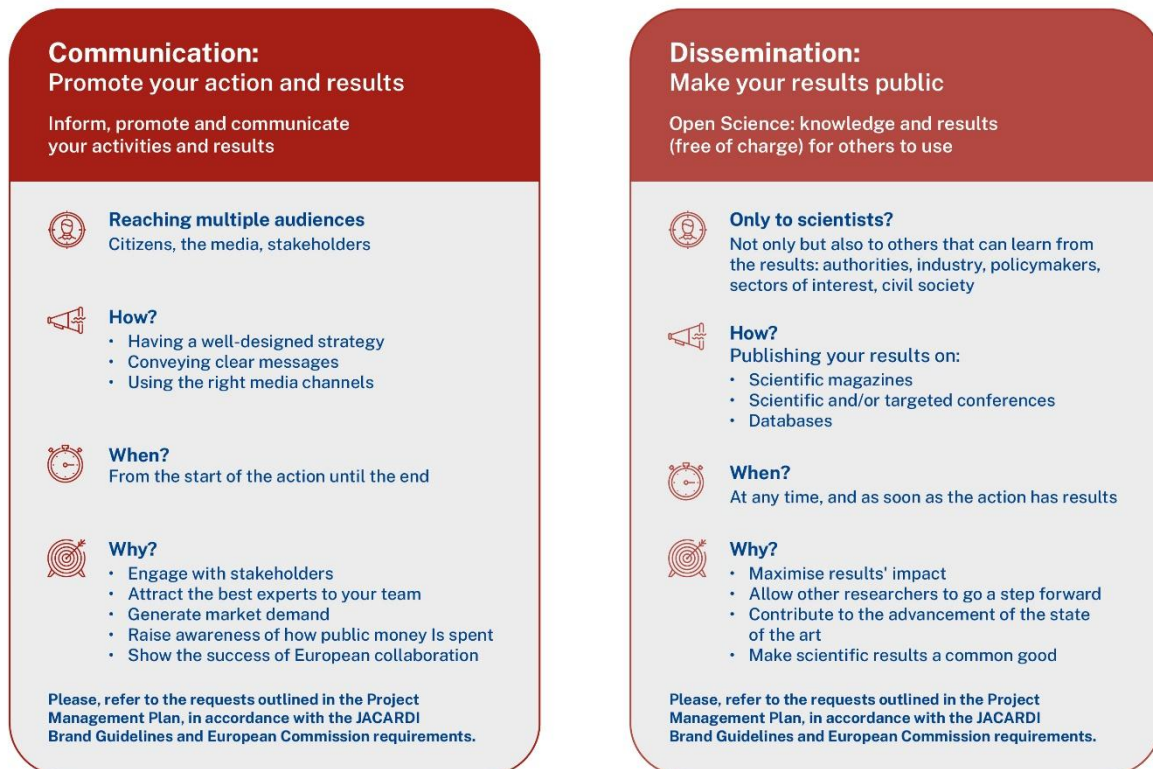


Figure 19. Communication and dissemination basics

The key is to think about communication and dissemination from the beginning to the end of the pilot project (from Step I of the JACARDI methodological framework) and plan the communication and dissemination activities in accordance with the communication and dissemination goals.

In this chapter, we aim to provide a basic orientation on

- efficient communication within the JACARDI methodological framework
- what communication and dissemination products are foreseen in the JACARDI methodological framework to support efficient communication and dissemination at the pilot project level⁷⁷
- what communication and dissemination tools and support are available to the core pilot teams in JACARDI.

Efficient communication within the JACARDI methodological framework

Every core pilot team will provide two products dedicated to communication and dissemination (*Table 4. Efficient communication within JACARDI methodological framework*):

- The **Pilot communication report** will be included as specific section in the Final implementation report. This document is the communication report for the period from Step I to Step XII; see Annex VII.

⁷⁷ Also foreseen by JACARDI GA.

- The **Overview of the planned communication and dissemination activities** will be included in the Sustainability action plan. This overview outlines strategic communication regarding the sustainability action plan within Step XV and for two years after JACARDI (life after JACARDI).

Products	Type of document on communication and dissemination	Content	Reporting/ Planning period
Final implementation report Deadline: January 2027	Pilot communication report	What communication and dissemination activities were carried out during the pilot Steps I to XII? (social media posts, campaigns, press releases etc)	Step I to Step XII
Sustainability Action Plan Deadline: March 2027	Overview of planned communication and dissemination activities	What activities will be carried out to support the sustainability action plan with efficient communication after its adoption within JACARDI and for two years after the end of the project.	Step XIV to October 2029

Table 4. Efficient communication within JACARDI methodological framework

Guidance for efficient communication within the JACARDI methodological framework

1) Pilot communication report

The Pilot communication report (as part of the Final implementation report) summarises all the communication activities undertaken from Step I to XII. For these communication and dissemination activities, WP2 will provide ongoing support, guidance, tips and tools during implementation. Details are provided in section 3 of this chapter.

On the other hand, preparing a pilot communication plan for the implementation period is not obligatory. Still, it is strongly recommended because it makes communication more effective and can be a good basis for the pilot communication report.

More information on the suggested pilot communication plan is presented in the box below (*Box 21. Pilot communication plan guidance with an example*).

PILOT COMMUNICATION PLAN – structure and example

Ideally, at the start of the pilot, the core pilot team may prepare the pilot communication plan, including:

- Communication objectives
- Target audience
- Tools and channels
- Key messages (Content)
- Timeline
- Estimated reach
- Person responsible

Pilot communication plan		
Communication activity 1		
Communication objectives	What do you want to achieve?	Example: Raising awareness about the pilot project and its objectives
Target audience	Who are your target audiences? What are their characteristics?	Example: General public
Tools and channels	What methods and channels will you use? How will you create content tailored to the target audience?	Example: Press conference and dedicated project website
Key messages	What are the key messages you want to share with the target audience?	Example: A new four-year project called JACARDI was launched in Rome on 27 November 2023. This initiative aims to assist EU member states in reducing the burden of CVDs and diabetes. Link to press release on Teams¹²
Timeline	When and how often will you deliver communication activities?	Example: The press conference will take place on 13 March 2025, at 10 am.
Estimated reach	How many journalists will attend the press conference? How many media products will be published?	Example: The press conference will be attended by 10 journalists.
Responsible person	Who is responsible for organising the press conference?	Example: XY, Institution

The pilot communication plan supports the core pilot team's communication efforts throughout the implementation cycles and facilitates the reporting of communication activities. Whether or not they have a

communication plan, core pilot teams should record all communication activities undertaken during Steps I to XI in Steps VI, VIII, XI, and XII as part of regular reporting via the REDCap tool.

Box 21. Pilot communication plan guidance with an example

In addition, for the planning and successful implementation of communication activities, the "*Communication guide for JACARDI pilots*" is being developed, which will provide pilots with further practical advice on how to communicate effectively and efficiently.

The format of the obligatory Pilot communication report was defined by WP2 and is as follows (*Box 22. Pilot communication report guidance with an example*) (See also *Annex VII*):

PILOT COMMUNICATION REPORT

Elements to be included in the Pilot communication report:

- Name of the communication activity
- Short description
- Communication channel
- Target audience
- Date
- Outcome/reach
- Subjective evaluation

Pilot communication report		
Communication activity 1		
Name of the communication activity	What type of communication activity did you carry out?	Example: Event news
Short description	What was the message or content of the communication?	Example: Event announcement: participation of a JACARDI expert at a national conference for health professionals
Target audience	Who were you trying to reach with your message?	Example: Public health professionals, relevant academic communities
Communication channel	What channel(s) did you use?	Example: Post(s) on the social media page of the pilot's partner institution, news article on the partner institution's website, newsletter, etc.
Timeline	When did you carry out these activities?	Example: From 14 April 2025 to 12 May 2026
Outcome	Measurable and non-measurable outcomes.	Summarise subjective success and measurable outcomes: <ul style="list-style-type: none"> • For social media posts: number of posts, reach, and engagement • Newsletter statistics: number of recipients, open rate, click-through-rate

			<ul style="list-style-type: none"> • For a press conference, stakeholder event, or webinar: number of attendees • For PR activities, resulting in media appearances with links • For offline campaigns: number of leaflets, posters printed, etc. • Number of visitors on the pilot's webpage if data is accessible
	Subjective evaluation	Which communication activity worked best? Which communication activity performed worst? Share one of your success stories and your least successful effort.	Example: While LinkedIn posts and live events reached their intended audience, Facebook posts and newsletters generated very low interest.

Box 22. Pilot communication report guidance with an example

2) Overview of the planned communication and dissemination activities (in the Sustainability action plan)

Since communication and dissemination are crucial for the efficient implementation of the sustainability action plan, this document will incorporate an overview of the planned communication and dissemination activities. It is designed to support the communication and dissemination of the sustainability action plan until the end of JACARDI and for two years afterwards, making these activities more strategic and effective.

This section of the Sustainability action plan identifies the following:

- Objectives of communication and dissemination
- Target audience (who is addressed by it)
- Tools and channels
- Key message(s)
- Timeline
- Estimated reach
- Responsible person(s)

When thinking about communication and dissemination opportunities, core pilot teams should think first about the celebration events during Step XV. In Step XV, core pilot teams, with the support of their key stakeholders, should begin organising local, regional, and/or national 'celebration events' (such as conferences, meetings, policy dialogues, etc.) to present and discuss their results, successes, and plans, where co-creation is a highly effective approach.

'Celebrating success' will also be a major task for JACARDI at the consortium level. In addition to other communication and dissemination opportunities, a final conference will be organised. Despite the high number of pilots, this event will serve as the main celebration, highlighting all the work accomplished with a

special focus on pilots, their results, and outcomes. It will also acknowledge the core pilot teams' ability to develop sustainability action plans, establish future ownership, and enhance the visibility of their efforts.

These events offer excellent communication and dissemination opportunities and should be incorporated into the communication and dissemination activities.

An example of communication and dissemination activity is provided in the table below (*Table 5. Example of a communication and dissemination activity*).

Communication and dissemination activity 1		
Category	Orientation questions	Example
Communication objectives	What do you want to achieve?	Engage key stakeholders to anchor ownership and increase the visibility of the pilot results.
Target audience	Who are your target audiences? What are their characteristics?	Key stakeholders of the JACARDI pilot project
Tools and channels	Which methods and channels will you use? How will you create content tailored to the target audience?	National Stakeholder Event organised by your competent authority; your task: participate and present your result.
Key messages	What are the key messages you want to share with the target audience?	<ol style="list-style-type: none"> 1. Within JACARDI, our pilot (describe key result here). 2. This is just the beginning; our goal is to (describe your aim, goal, plans, ...). 3. We are open to new partnerships (or announce a specific event/initiative aimed at attracting new stakeholders/partners).
Timeline	When and how often will you deliver communication activities?	September 2027
Estimated reach	How many stakeholders will attend the final national conference?	150
Responsible person	Who is responsible for organising the press conference?	XY, Institution

Table 5. Example of a communication and dissemination activity

WP2 prepared some tips for developing the pilot's communication and dissemination strategy (*Box 23. Sustainability action plan: Tips to consider when developing your pilot's communication and dissemination*

activities). Some of the ideas listed are lessons learnt from previous JAs, and some items are part of the JACARDI WP2 Action Plan⁷⁸ to support the sustainability efforts of the project.

Sustainability action plan: Tips to consider when developing your pilot's communication and dissemination activities

- 1) **Invest time and energy in translating your results into your national language(s).** Providing access to your results will help your local stakeholders conceptualise and understand your challenges and help you identify opportunities for success. (AI tools, such as DeepL, ChatGPT, or Gemini, are helpful).
- 2) **Ensure your findings are easily accessible online** (even after the project ends).
 - Store the content—**Decide where to store the relevant results** and appoint someone on your core pilot team to manage this content. You can choose to publish basic/key information on the jacardi.eu website (which will be operational and updated for at least two years after the project) or use your institution's website to publish updates on your progress.
 - Responsible team member—Designate one person in your core pilot team to be responsible for managing your content. Team members will come and go, but make sure you have an **email account that will be active/monitored for two years after JACARDI ends.**
- 3) **Results and Stakeholders** - What results and aspects of your pilot should be highlighted? What are the most valuable messages to communicate?
 - Please refer to the list of members of the **JACARDI Stakeholder Board** and familiarise yourself with their "hot topics". This board includes **organisations with power and expertise** in the field of CVDs and diabetes, such as WHO Europe, the European Society of Cardiology, or the European Diabetes Forum.
 - Follow their social media pages to see what is at the top of their agenda and try to identify aspects of your pilot that resonate with their initiatives. Your key findings will most likely be in line with their existing messages, but offering new perspectives on CVDs care will most likely also be embraced and amplified by them.
- 4) **Channels for publishing** - Where can you publish your results (besides the official JACARDI website)? Please refer to the **JACARDI Scientific Publication Plan** (available on Teams). This document provides a list of relevant **papers, journals, and conferences** to consider when disseminating your results and promoting your findings.
- 5) **Support** - Who in the JACARDI Consortium provides support for the development of communication materials? There are **communication leads (experts) from WP2 assigned to each WP** who you can contact directly for support (ask your WP leadership for additional support in identifying them). Alternatively, you can contact the WP2 team via e-mail at wp2.jacardi@gokvi.eu. WP2 can help you plan social media activities, draft press releases or other written documents aimed at various stakeholders, and provide basic visual/graphical support, including templates, illustrations, stock photos, etc.

Box 23. Sustainability action plan: Tips to consider when developing your pilot's communication and dissemination activities

⁷⁸ The JACARDI WP2 Action Plan will be completed and made available in JACARDI Teams.

JACARDI WP2 communication and dissemination support

1) Role of the WP2

In JACARDI, the role of WP2 is to engage stakeholders and to disseminate JACARDI results. The main objective of communication and dissemination activities is to increase the visibility and impact of JACARDI and its results at the local, national, and European levels by facilitating coherent, effective, and sustainable communication and dissemination of its objectives, activities, and results to the entire network of identified stakeholder audiences at various levels.

To that end, WP2 will prepare different tools to be used by WP6-11 leadership and pilot teams:

- Inclusive and accessible communications checklist (Annex III)
- WP5 JACARDI terminology glossary for internal and external communication (available in Teams)
- Communication Guide for JACARDI pilots - How to effectively communicate your pilot program? (will be available on Teams)
- Visual items on Teams platform: such as JACARDI Brand Guidelines (Brand book), templates, icon set

Additionally, WP6-11 will be supported by a communication and dissemination expert from the WP2 (Communication leads), who will facilitate the formation and structuring of messages and their dissemination through communication channels specific to the WP's predefined target group(s).

Communication experts will also provide a series of training and coaching sessions to WP leadership teams and pilot teams to support communication activities.

More information can be found in [JACARDI Teams](#)¹². This chapter describes only guidance on communication and dissemination important for applying the JACARDI methodological framework.

2) Communication and dissemination tool: Guidelines and a checklist for inclusive and accessible communication

Jointly with the Data Protection Team as part of WP1, WP2, and WP5 Task 5.3, compiled guidelines and a checklist for inclusive and accessible communications. These guidelines should be used when planning communications and developing written or spoken materials, websites, presentations, products, and events.

JACARDI is committed to ensuring that the voices of groups at increased risk of vulnerability and marginalisation are heard without conflicting with their legal right to services. Communications aimed at the general audience will follow principles of inclusive and accessible communication.

As outlined in the **Guidelines and Checklist for Inclusive and Accessible Communication in the JACARDI project** (*Annex III*), inclusive and accessible communication is a fundamental aspect of modern communication. JACARDI aims to communicate as inclusively and accessibly as possible while raising awareness of these perspectives. The goal is to ensure that different target groups can connect with our messages. To achieve this, communication should be:

- Reciprocal and based on active listening to audiences.
- Respectful, sensitive, and mindful of the population's diversity.
- Clear and understandable, using multiple channels.

- Multilingual when necessary.

The checklist will be used primarily by the Communication leads, assigned to WP6-11, working with core pilot teams throughout the Steps.

3) WP5 JACARDI terminology glossary for internal and external communication

The WP5 JACARDI terminology glossary for internal and external communication is another tool developed within JACARDI and can support core pilot teams when communicating and disseminating their projects. It can be found on [JACARDI Teams](#)⁷⁹¹².

Communication and dissemination – key takeaways

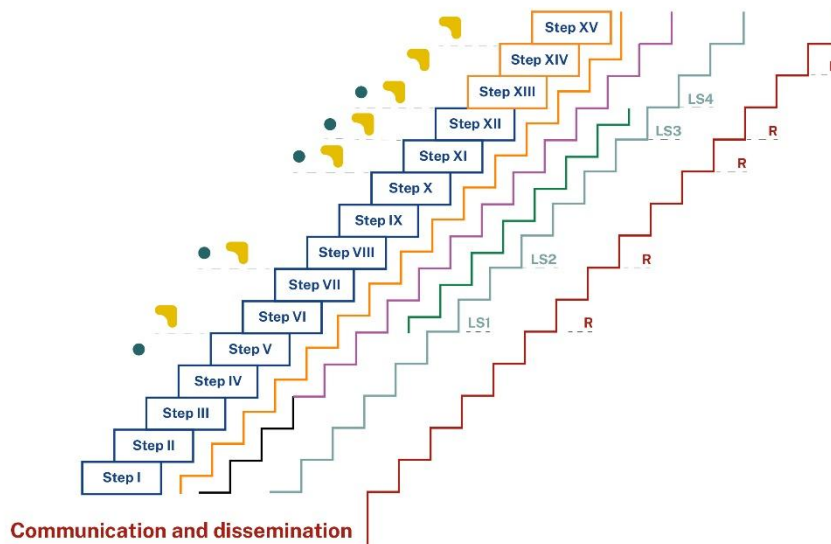
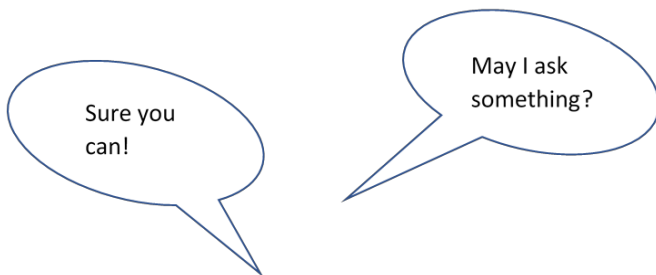


Figure 20. Communication and dissemination

In summary, it is **essential** that all core pilot teams report all their communication and dissemination activities in the Final communication report, which is part of the Final implementation report. It is also essential that communication and dissemination activities are planned within the Sustainability action plan prepared by all core pilot teams. It is highly recommended that all pilot team members engage in all opportunities that allow communication and dissemination and proactively create such opportunities. To increase the skills and capacities, it is highly recommended that most of the core pilot team members participate in capacity-building activities related to communication and dissemination. Please see the Q&A box below ([Box 24. Q&A box](#)).

⁷⁹ Accessible on to JACARDI partners.



Q: After all this work, where can we find the time for such activities ...

A: It really seems overwhelming. Indeed, there will be events specifically dedicated to JACARDI, such as yearly conferences and WP meetings, where the pilot teams usually present their work. This has to be seen as part of the project and the opportunity to practice how you describe your accomplishments. Within your country, the Ministry of Health may have the habit of inviting partners working on such projects to the meetings, and this is an excellent opportunity to be seen. Otherwise, attendance at any meeting may be a possibility to drop a slide or two on JACARDI (and how it helps our countries). If possible, however, try to get a slot each year at some national conference, such as world diabetes day or similar. Whenever preparing for such presentations, usually what you already have in your mind is enough and too much to be communicated to the audience; your main task is to pack it nicely.

Box 24. Q&A box

3.8 Reporting

Reporting on achievements and key findings of the JACARDI pilots and the process itself is at the core of implementation science⁸⁰. To centralise and standardise the reporting of pilot activities, streamline the dissemination of findings for scientific publication, and support the sustainability and scalability of successful interventions, a single-reporting system is being developed within JACARDI, using REDCap. Details are included in *Annex VII*.

Three templates are developed and adjusted to the specific needs of JACARDI:

- General information sheet below (*Box 25. General information sheet*)
- Final implementation report below (*Box 26. Final implementation report structure*)
- Sustainability action plan below (*Box 27. Sustainability action plan structure*)

The general information sheet covers basic information, mainly on the core pilot team.

The **General information sheet** includes the following sections:

- Pilot project code
- Pilot project title
- Name and surname of pilot organiser (s)
- Institution of pilot organiser
- JACARDI core pilot team

Box 25. General information sheet

The final implementation report adheres to the SQUIRE 2.0 guidelines and aligns with the format established by DG SANTE within the EU Portal of Best and Promising Practices for the practices evaluation process. This ensures that the information is presented in a format suitable for internal use within the JACARDI consortium and external dissemination to a wider audience, including policymakers and healthcare practitioners, emphasising the potential recognition of these pilots as Best Practices within the EU Portal.

The **Final implementation report** includes the following sections:

- Title and abstract
 - Title
 - Abstract
 - Keywords
- Introduction (Why did you start?)
 - Problem description, including identified country needs and reflecting also equity and diversity aspect
 - Available knowledge, including, among others also, the relevant practice(s)
 - Rationale including the general objective, reflecting also equity and diversity aspect and, among others, learnings from practices from other settings and contexts
 - Specific objectives, reflecting also equity and diversity aspect

Most relevant changes in the general and specific objectives during the pilot duration should also be included.
- Methods (What did you do?)

⁸⁰ <https://www.squire-statement.org/index.cfm?fuseaction=Page.ViewPage&PageID=471>

- Situation analysis, including the key stakeholder analysis; focus should also be given to sustainability-supporting contextual characteristics and application of equity and diversity principle
- Specifics of the team involved in the work, covering also the strengths of the team in building sustainability and application of equity and diversity principle
- Description of the pilot, including general information on pilot project implementation, the pilot activities in sufficient detail that others could reproduce it, specifically describe the activity(ies) to support sustainability and application of equity and diversity principle
- Approaches and/or measures to assess the pilot results, consisting of (1) approach for verification of progress status at the level of specific objectives and at the level of activities, (2) approach for assessment of pilot outcomes using multidimensional assessment, (3) approach for ongoing scanning of the contextual elements potentially related to sustainability, and (3) approach for the application of equity and diversity.
- Analytical methods covering (1) progress status at the level of specific objectives and the level of activities, (2) methods to analyse the pilot outcomes, (3) methods to assess the potential for sustainability, (4) methods to assess the integration of equity and diversity principle, and (5) identify the institution that undertook the evaluation
- Ethical considerations

Most relevant changes in situation analysis and stakeholders, contextual characteristics, team membership, and the pilot's description during the pilot duration should also be included.

- Results (What did you find?)

- Intermediary results, showing the information from intermediary reporting 1 (covering Steps VII and VIII with implementation activities running in Step VII) and 2 (Steps IX, X, and XI, with implementation activities running in Step X) separately:
 - (1) intermediary results related to the progress status at the level of specific objectives and at the level of activities, including the decisions on potential changes for the next cycle of implementation (reporting No. 1) or in the light of sustainability (reporting No. 2)
 - (2) if defined by the multidimensional assessment plan, intermediary results at the level of pilot outcomes by applying multidimensional assessment including the interpretation and implications; the changes in the outcomes during Step VII are represented in reporting No. 1 and during Step X in reporting No 2
 - (3) intermediary results related to sustainability, specifically outlining the intermediary results of sustainability-supporting activity(ies) and changes in contextual characteristics, separately covering Steps VII and VIII and for Steps IX, X, and XI (please note that Sustainability dimension is also included and reported within multidimensional assessment, reflecting the feasibility of the pilot continuation, and for scalability/feasibility of the pilot results and/or outcomes)
 - (4) intermediary results on the application of equity and diversity principle, separately for Steps VII and VIII (No 1) and for Steps IX, X, and XI (No 2)

The most relevant changes in the initial general objective, specific objectives and/or actions, and/or other elements should also be included.
- Final results describing
 - (1) overall evolution of initial general objective, specific objectives and/or actions, desired pilot outcomes, and/or other elements across all pilot duration
 - (2) interaction of contextual elements with the pilot, including unplanned issues; key stakeholders and their level of involvement across the pilot duration; and details on stakeholders' board, including their engagement across Steps VI to XI.

- (3) final results related to progress status at the level of specific objectives and the level of activities, including the decisions on potential continuation/changes in the light of sustainability, having in mind the whole pilot duration insight
- (4) final results at the level of pilot outcomes by applying multidimensional assessment, including the interpretation and implications
- (5) final results related to the sustainability of the pilot, including the final results of the sustainability-supporting activity(ies) with particular reference to the stakeholder board and sustainability-supporting contextual characteristics at the end of implementation (please note that the Sustainability dimension is also included and reported within the multidimensional assessment, reflecting the feasibility of the pilot continuation, and for scalability/feasibility of the pilot results and/or outcomes))
- (6) final report on the integration of equity and diversity principle

- Discussion (What does it mean?)
 - Summary, including, among others, the usefulness of pilot findings as a response to country/region needs, including, among others also, the benefits from the pilot addressing the country/region needs
 - Interpretation
 - Limitations
 - Conclusions including sustainability and, among others, the usefulness of the work, specifically addressing the respective region/country needs, and information on any synergies, compatibilities, or any conflicts between the pilot and any other similar practice implemented in the same context/region/country
- Other Information
 - Funding
- Annexes
 - Pilot communication report

The reporting is facilitated by presenting the information as much as possible in tables. In addition, some parts of the template will be accompanied by suggested texts, reflecting the commonalities in reporting (for example, to describe the purpose of JACARDI, methodologies for assessment of different perspectives of the pilot, cofounding, etc.), developed within the responsible methodological teams. The report includes learning from other practices within the pilot preparatory phase; if the learnings were applied in the following steps, they may be added to the relevant part of the final implementation report. The report includes information on interactions with key stakeholders in several places; however, the details on the stakeholder board specifically are included within the description of sustainability-supporting activity(ies) (as this may be one of them), within final results and in interpretation.

Box 26. Final implementation report structure

The sustainability action plan details specific strategies and actions designed to preserve and amplify the impact of the pilot results. The report underscores the importance of incorporating equity and diversity considerations throughout the project.

The **Sustainability action plan** includes the following sections:

- Title
- List of contributors
- Short summary
- Introduction

- Burden of cardiovascular diseases and diabetes
- JACARDI as a response of EU and EU countries
- Needs and gaps of the country/region
- Results and outcomes of the JACARDI pilot project
- Key sustainability supporting achievements of the JACARDI pilot project
- Process of development
 - Equity and diversity in action
 - Priority areas and their ranking
 - Opportunities
- Action plan
 - General objective and specific objectives
 - Actions
- Communication and dissemination

Box 27. Sustainability action plan structure

REPORTING – KEY TAKEAWAYS

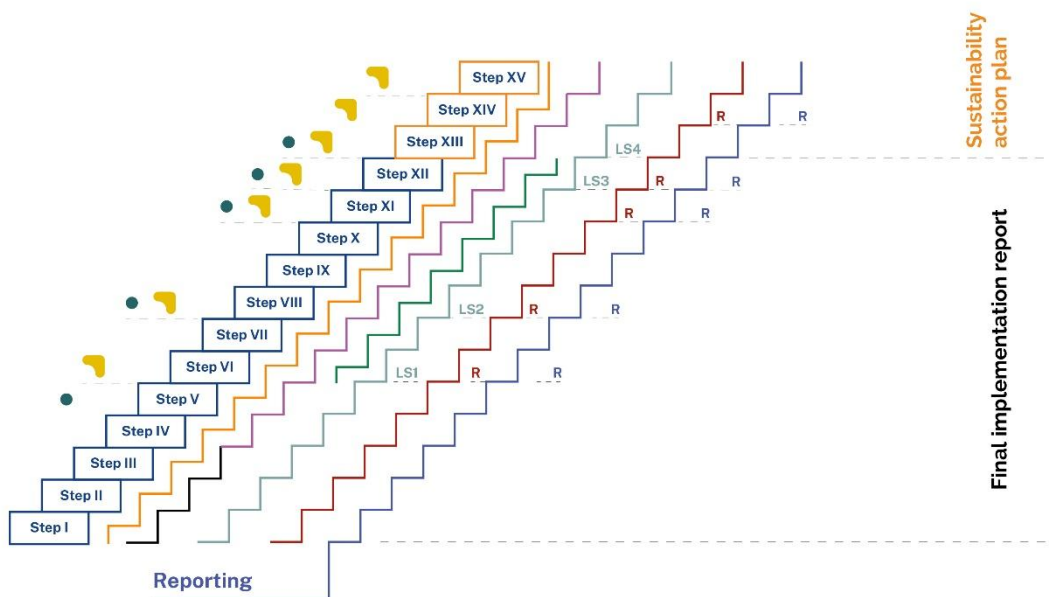


Figure 21. Reporting

In summary, this document is an **essential** tool for capturing the lessons learned from the JACARDI pilots, guiding future initiatives, and fostering the long-term impact of the project’s outcomes.

Reporting will be included in the following steps:

- General information and Final implementation report – sections covering Steps I- VI: expected by March 2025

Final implementation report template – sections covering Steps I-VI: expected by March 2025) – sections covering Steps VII to VIII: expected by October/November 2025 – sections covering Steps IX to XI: November 2026, and full report: expected by January 2027. It is **essential** that all core pilot teams provide the final version of the Sustainability action plan by March 2027.

3.9 Methodological guidance

In JACARDI, methodological guidance is structured into the following stages:

- **Action planning** (the core pilot team is established → problem and general objective defined → situation and stakeholder analysis performed → general objective refined → specific objectives defined → pilot implementation plan prepared),
- **First implementation cycle** (activities executed and monitored → results of the 1st implementation cycle analysed → changes envisaged),
- **Adaptation point** (the second pilot implementation plan prepared based on the results of the first implementation cycle),
- **Second implementation cycle** (activities executed and monitored → results of the 2nd implementation cycle analysed → changes envisaged from the perspective of sustainability action planning),
- **Interpretation of results** (the results, outcomes, and key findings are reported, including interpretations and implications),
- **Sustainability action planning** (the essential messages are adapted to the target audience of key stakeholders and discussed at consultation meeting(s), the sustainability action plan is drafted and then agreed upon at consensus meeting with key stakeholders, the sustainability action plan is supported by communication and dissemination activities).

The JACARDI methodological framework provides generic guidance for these stages and consists of **15 steps (Steps I to XV)** (*Figure 24. JACARDI methodological framework: Steps*):

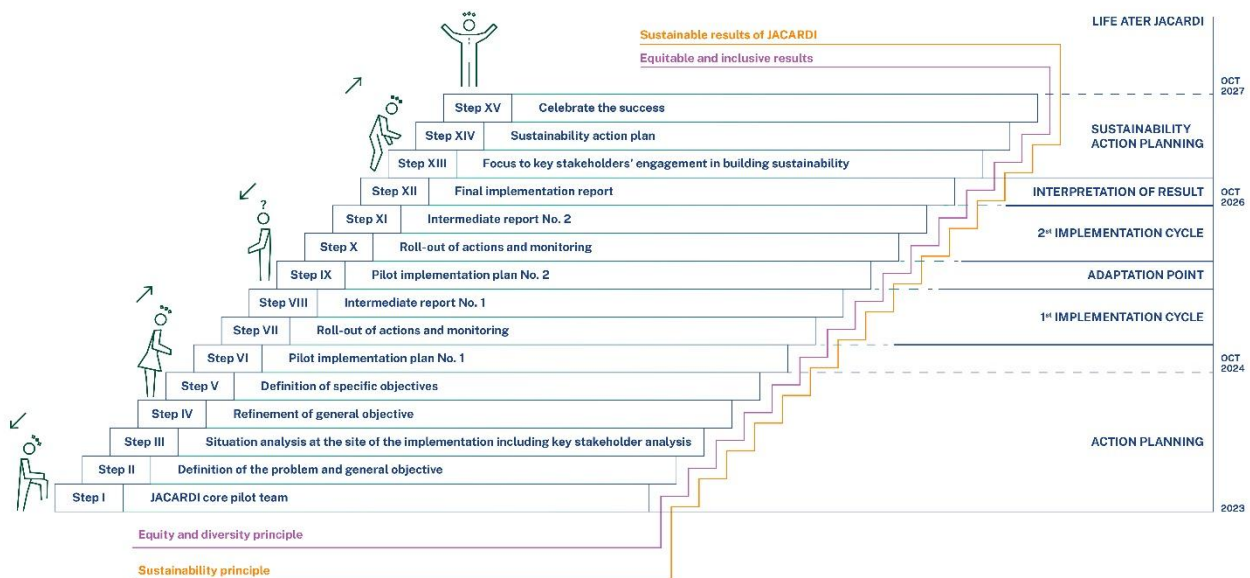


Figure 24. JACARDI methodological framework: Steps

The steps imply certain consecutiveness⁸¹. However, by the nature of successful implementation, **the process is iterative**—the result of a certain step may suggest rethinking the work done in the previous one(s)⁸². The refinement of previous steps may also happen across a longer time horizon.

Because of the iterative process, flexibility and reporting on changes made to the pilot are highly desired. Such information is very important not only for the pilot in question but also for other pilots.

A systematic, stepwise capacity-building approach will support the application of the Steps, adjusted to the needs of each WP6-11. Four learning sessions will be organised to increase the competencies of the core pilot teams in applying the JACARDI methodology. Moreover, core pilot teams will receive continuous support through monitoring and monthly briefings, masterclasses, science-to-policy interactions and communication courses, and ad hoc training.

The four learning sessions will cover the following teams:

1. Development of the pilot implementation plan (at the beginning of Step VI),
2. Intermediary reporting (at the beginning of Step VIII),
3. Final reporting (at the beginning of Step XII),
4. Preparation of the sustainability action plan (at the beginning of Step XIII).

The **timeline** differs between WPs. The following main timeframes are common to all WPs, however, and should be considered by core pilot teams:

- **Steps I to V** should be accomplished by the end of the first year of JACARDI (**October 2024**)
- **Steps VI to XI** should be accomplished by the end of the third year of JACARDI (**October/November 2026**)
- **Steps XII (January 2027 full final implementation report) to XV** should be accomplished in the sense of delivering the sustainability action plan by the middle of year four of JACARDI (**March 2027**) to allow time to develop the final deliverables of most of the WPs; however, communication and dissemination activities, including celebration events, continue to the end of the fourth year.

⁸¹ For example, the core pilot team as the “think tank” of the pilot, first needs to be constituted, only then its members can start defining the problem and the general objective.

⁸² For instance, while digging into the problem, members of the core pilot team can identify areas that cannot be covered by them. To move forward, they will have to invite new members with adequate knowledge, skills and experience to join their team.

3.9.1 Step I: JACARDI Core pilot team⁸³

In the first step, **the core pilot team has to be established**. Afterwards, additional changes to membership can be made.

The objectives of this step are:

- Define the core pilot team and the roles and responsibilities of its members
- Start favourable team dynamics

Tacit objectives of this step may also be to understand team members' strengths; start developing common attitudes, values and beliefs; share passion; build up a sense of cohesion within the team; and promote openness in communication.

The core pilot team is **the “think-tank” of the pilot**, guiding the work of other team members. Its **tasks** are foreseen **by the JACARDI GA** and include:

- Defining the problem, general objective, and specific objectives of the pilot
- Reviewing the context and identifying and involving stakeholders from the beginning
- Designing the pilot implementation plan
- Designing the assessment of the expected outcomes
- Monitoring the implementation process
- Reporting of intermediate and final results
- Developing the interpretations and implications of the results (to adapt the implementation plan, to develop a sustainability action plan)
- Adapting the pilot implementation plan
- Developing the final implementation report and the sustainability action plan
- Participating in capacity-building activities
- Contributing to the JACARDI collaborative learning and generating new knowledge within the JACARDI consortium.

Experiences from previous JAs⁸⁴ have shown the extreme importance of team structure, shared beliefs, and dynamics in designing and implementing sustainable pilots and practices.

As regards **the team structure**, every core pilot team should have an **organiser** (obligatory role), **several experts** with knowledge and skills from different relevant fields, and, optionally, **decision-makers in the role of advisers**. When defining the core pilot team, special attention should be paid to the organiser.

The core pilot team should be small, carefully composed, and multi-/trans-disciplinary. Additional information is presented in the table below (*Table 6. Structure of the JACARDI core pilot team with the roles and responsibilities of its members*).

⁸³ At the time when full scale JACARDI methodological framework was developed, majority of the pilots already accomplished Steps I-V, so their description is as was defined in Milestone 12 with slight adaptations; they do not systematically include all the elements as described in Chapters 3.2 to 3.9, since they were not fully developed. For the use in other projects and JA, these steps too will be redefined in the next documents.

⁸⁴ For example, CARE4DIABETES Deliverable 5.1 Best practice and situation analysis, internal document.

Team role	Responsibilities	Characteristics
<p>Organiser</p> <p>The organiser is an obligatory member.</p> <p>This person should understand JACARDI in depth.</p>	<ul style="list-style-type: none"> Communicating with the leadership of WP Facilitating JACARDI reporting (drafts reports, reaches consensus within the core team, provides final versions) In charge of meetings (prepares invitations and agendas, chairs them, and provides timely reporting) 	<p>JACARDI core pilot teams' members should possess the following characteristics:</p> <ul style="list-style-type: none"> High level of readiness for changing roles and responsibilities of the core pilot team Open to change in general Positive attitude towards reflective processes, monitoring, and evaluation within the team Inclined to participate in the process of improvement of the pilot Able to participate in „meta-learning “ Flexible Patient (to see the results) Resilient Passionate Understand the context/situation within the country/region/setting of the JACARDI pilot Can co-create the pilot (adopt-adapt-abandon-add activities based on the results).
<p>Experts</p> <p>The number of experts depends on the needs of the pilot.</p>	<p>They provide knowledge and skills from different fields:</p> <ul style="list-style-type: none"> Medicine Social science Implementation science Communication (See Chapter 3.7 (link)) Project management (with experience in the actual implementation of projects) Others (depending on the topic of the pilot) <p>They have the necessary personality and character traits to motivate and empower others and to equip and support a multi-/transdisciplinary team.</p>	
<p>Decision-makers</p> <p>They act as advisers.</p>	<p>Decision-makers can:</p> <ul style="list-style-type: none"> Eliminate potential bottlenecks during the implementation Provide strategic vision Bring insight into the implementation process from the institutional level (municipality, ministry, ...) Facilitate sustainability activities and scalability <p>It would be wise that decision-makers selected to be part of the core pilot team have a high level of engagement. Otherwise, it would be more desirable</p>	

Team role	Responsibilities	Characteristics
	to involve them in the pilot implementation as key stakeholders (for example, by advising on solving a problem or providing useful policy information, etc.).	

Table 6. Structure of the JACARDI core pilot team with the roles and responsibilities of its members

The template below (*Template 1. STEP I: JACARDI core pilot team members*)⁸⁵ (Annex VI) can be used when defining the core pilot team.

JACARDI, WPX, Pilot xx			
Step I. JACARDI core pilot team members			
Role	Name Surname/initials (apply GDPR)	Institution	Area(s) of expertise
Organiser			
Expert			
Add lines			
Decision maker			
Add lines			

Template 1. STEP I: JACARDI core pilot team members

The core pilot team should consider the **equity and diversity principle, as well as the sustainability principle** (Chapter 3.4 ([link](#))). The following questions can be used.

Sustainability lens

Guiding questions

Why is the pilot important for the individual member of the team?
 What kind of knowledge and expertise does each team member bring to the team?
 What would individual members and the team like to accomplish within the work of JACARDI?
 Is the team aware of the policy environment, such as strategies, broader actions, and initiatives relevant to the pilot's topic?
 Can the team identify the potential holder of sustainability who is willing and able to support the further deployment of pilot results after the end?

Box 28. STEP I Sustainability lens

Equity and diversity lens⁸⁶

Guiding questions

Is the team homogenous, or is there diversity, for example, in disciplines, educational background and stage of career, age and gender, cultural background, and ethnicity?
 Is, for example, a person with lived experience included?

⁸⁵ All the proposed templates are optional, and can be changed, adapted, or even, new ones can be prepared by the WP6-11 leadership teams. Some of them from Steps I to VI are visually adjusted to better fit the Final implementation report.

⁸⁶ The questions in Italics and the Equity and diversity matrix were not included in JACARDI Milestone 12.

Are the members curious? Do they have a positive attitude for change? Are they committed to proactively considering diverse perspectives?

Are they aware of the concepts and processes relevant to equity and diversity, such as critical reflection, co-design, inclusive communication, and the search for the “missing view”?

Is the core pilot diverse and representative of the communities it aims to serve?

Does the core pilot team actively apply the 4C principles of equity and diversity (Critical reflection, Co-design, Context and data, inclusive and accessible Communications)?

Box 29. STEP I Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix⁸⁷ below to integrate the equity and diversity principle in its work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step I. JACARDI core pilot team, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
1.1 Compose a diverse core pilot team	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	b) The core pilot team consists of professionals from different disciplines and social groups (e.g., age, gender, ethnicity) and is moderately representative of the community the pilot aims to serve (i.e. 50% of key characteristics of the served community are represented within the team).	c) The core pilot team consists of professionals from diverse disciplines, social groups, and is representative of the community the pilot aims to serve (i.e. 75% or more of the key characteristics identified are represented within the team).	
1.2 Strengthen capacity in equity and diversity within the core pilot team	a) The core pilot team members understand and can explain the 4Cs principle and the relevance of equity and diversity in JACARDI to other partners and this is demonstrated through integrating equity and	b) The core pilot team members understand how to include equity and diversity perspectives in their pilot implementation but need support (e.g. consultations, workshops) of equity and diversity subject	c) The core pilot team members feel empowered to apply sufficiently concrete equity and diversity aspects in their implementation plans in an autonomous manner, and actively seek opportunities to	

⁸⁷ Only the part relevant for the current step is included, the whole matrix can be found in *Annex IV*. Of note, Equity and diversity matrix was finalised when most of the pilots were at Step V/VI, so for these Steps it was not possible to apply it in the planning phase. However, inclusion of equity and diversity principle was facilitated by the guiding questions.

	diversity perspectives in the pilot implementation plan.	matter experts on how to apply them in practice.	strengthen their capacity in equity and diversity beyond JACARDI structures, for example through external seminars, trainings and independent readings.	
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Box 30. STEP I Equity and diversity matrix

REPORTING TIPS

A single-reporting system via REDCap is available from Step VI, where the reporting tips for Step I are also included.

Taking notes in every step can make the preparation of the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams.

Box 31. STEP I Reporting tips

3.9.2 Step II: Definition of the problem and general objective⁸⁸

Once the core pilot team is established, the planning of the pilot project continues with the second step, in which the core pilot team **defines the problem and the general objective of the pilot** to be implemented within JACARDI. Namely, the JACARDI GA only briefly describes the topics and aims of the pilots.

The objectives of this step are:

- Reach an agreement within the core pilot team on what the problem is
- Define the general objective (purpose) of the pilot (within JACARDI)

Tacit objectives of this step may also be to develop common attitudes, values, and beliefs; share passion; build a sense of cohesion within the team and foster openness in communication.

The core pilot team can use different approaches when defining the problem and the general objective. One is described in the box below (*Box 32. Potential approach to defining the problem and general objective of the pilot*).

The **potential approach** that was used in JA CARE4DIABETES is composed of two steps.

Firstly, the core pilot team members answer the following questions:

- What would you personally like to accomplish within the work of JACARDI?
- When JACARDI ends, what would you like to see as the result?
- What would you like to see happen after JACARDI ends?
- The organiser collects their responses.

Secondly, the organiser collates the responses and organises a consensus meeting of the core pilot team to discuss and reach an agreement on the problem and the general objective of the pilot.

Box 32. Potential approach to defining the problem and general objective of the pilot

When defining the general objective, the core pilot team should consider the JACARDI working definition of the general objective and the difference between the general and specific objectives (*Box 33. JACARDI working definition of the general and specific objective*).

The **general objective** (other words can also be found, such as purpose) is **the overall goal/ultimate goal** towards which all the activities within a JACARDI pilot project are directed. Everything you do has a final meaning, where you want to go, which is the sum of the steps taken to achieve it. This is the objective, and on your ability to achieve it or not, your success or failure will generally depend. The general objective is **very comprehensive and only broadly involves a task**. On the contrary, specific objectives are bound to a specific task.

Box 33. JACARDI working definition of the general and specific objective

Guidelines for defining the general objective are:

- It should reflect the main goal of the pilot, its ultimate mission. It can only be achieved once the specific objectives are reached.

⁸⁸ At the time when full scale JACARDI methodological framework was developed, majority of the pilots already accomplished Steps I-V, so their description is as was defined in Milestone 12 with slight adaptations; they do not systematically include all the elements as described in Chapters 3.2 to 3.9, since they were not fully developed. For the use in other projects and JA, these steps too will be redefined in the next documents.

- It is usually concrete and summarised in a single sentence, although it can be as extensive as desired.
- It should always be written with an infinitive verb (to define, to distinguish, to register, to identify ...) and in a way that leads to the set of specific objectives (that are defined in the next step).
- It has to be clear and concise.
- It has to be achievable (you must know the available resources and other possible limitations).
- It has to focus on the achievements (not on processes or activities).
- It should be written in SMART format - Specific, Measurable, Achievable, Relevant, and Time-defined (set time limits).

The general objective should be ambitious, feasible, and sustainable. As part of an iterative process, the decisions are not final; consequently, **the general objective can be changed**. However, at the end of the second step, the core pilot team should have a common view of the problem and the general objective.

The template below (*Template 2. STEP II: General objective*) (*Annex VI*) can be used when defining the general objective.

JACARDI, WPX, Pilot xx
Step II. General objective
The general objective is: Xxx

Template 2. STEP II: General objective

The core pilot team should consider **the equity and diversity principle, as well as the sustainability principle** (Chapter 3.4 ([link](#))). The following questions can be used.

Sustainability lens

<p>Guiding questions</p> <p>When JACARDI ends, what would individual members and the team like to see as the result? What would individual members and then the team like to see that would happen after JACARDI ends? What are individual members and the team trying to accomplish with the pilot? How would the team know that the results of the pilot represent a change towards an improvement?</p>

Box 34. STEP II Sustainability lens

Equity and diversity lens⁸⁹

<p>Guiding questions</p> <p>Although this step is performed among the team members, did their expertise and experiences bring out equity and diversity perspectives based on their knowledge, research, literature, and known practices? If a</p>
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⁸⁹ The questions in Italics and the Equity and Diversity Matrix were not included in Milestone 12.

member with lived experience is included, how were these views incorporated within the definition of the problem and the general objective? Did the team identify what/whose perspectives are missing and tend to engage the relevant stakeholders within the next step?

Were the problem and the general objective defined based on critical reflection and co-design with the end-users/end-beneficiaries and other main stakeholders?

Box 35. STEP II Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix⁹⁰ below to integrate the equity and diversity principle in its work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step II. Definition of the problem and the general objective, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
2.1 Apply equity and diversity principles in the definition of the problem and the general objective	a) Definition of the problem and general objective were defined based on critical reflection of available quantitative and qualitative data on population demographic, socioeconomic, and ethnic and cultural diversity.	b) In addition to using available quantitative and qualitative data, the definition of the problem and the general objective involved consultations (e.g. workshops, interviews) with health professionals and end-users.	c) In addition to using available quantitative and qualitative data, the definition of the problem and the general objective involved meaningful engagement of health professionals and end-users through co-design .	

Box 36. STEP II Equity and diversity matrix

REPORTING TIPS⁹¹

A single-reporting system via REDCap is available from Step VI, where the reporting tips for Step II are included.

Taking notes in every step can make the preparation of the Final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11 and developed by WP6-11 leadership teams.

Box 37. STEP II Reporting tips

⁹⁰ Only the part relevant for the current step is included, the whole matrix can be found in *Annex IV*. Of note, Equity and diversity matrix was finalised when most of the pilots were at Step V/VI, so for these Steps it was not possible to apply it in the planning phase. However, inclusion of equity and diversity principle was facilitated by the guiding questions.

⁹¹ This is additional guidance on reporting was not discussed and agreed upon in the structure and processes of the Implementation board., and it was not included in the Milestone 12.

3.9.3 Step III: Situation analysis at the site of the implementation including key stakeholder analysis⁹²

After reaching a general agreement within the core pilot team on the problem and the general objective of the pilot, the third step can start. It consists of two elements – **situation and key stakeholder analysis**. Both the situation and stakeholders have an important impact on the implementation of the pilot and the sustainability of its results. This has been well determined and is one of the core principles of implementation science. The importance of this step was also confirmed in a previous JA⁹³.

The objectives of this step are:

- to define positive (enablers) and negative (potential barriers) characteristics of the pilot situation at the national/regional level and at the level of the implementation site. These characteristics will be defined in two timeframes: current and future.
- to identify key stakeholders and define their level of involvement.

Tacit objectives of this step may also be to develop common attitudes, values, and beliefs; share passion; build up a sense of cohesion within the team and encourage openness in communication; strengthen the readiness for change and the resilience of the team; run a reflective process and build a shared vision.

Different approaches can be used in situation analysis. In most cases, the detailed approach for the **situation analysis** will be defined by WP6-11 leadership teams as specific topic-relevant questions that need to be included and addressed. The methods for data collection may also vary across the WPs. For example, the co-design step will be extensive in topics in which designing the pilot requires a high level of co-design. It may be repeated iteratively when testing the designed activities.

An approach for the situation analysis that core pilot teams can use is suggested based on experiences from JADECARE⁹⁴ and CARE4DIABETES⁹⁵. Step III represents the first phase of the so-called “two-phase situation analysis.” In this phase (within Step III), the aim is (1) to collect relevant information from different levels and stakeholders, analyse them from the perspective of the core pilot team, and (2) classify them according to the influence that the core pilot team has on a specific characteristic (positive, negative). Afterwards, in the second phase (in Step IV of the JACARDI methodological framework), based on this classification, these characteristics are defined as strengths, weaknesses, opportunities, or threats for the implementation of the pilot, considering whether they are under the influence of the core pilot team or not.

The suggested approach to be used in Step III for the situation and key stakeholder analysis is as follows:

(1) The core pilot team identifies all appropriate individuals at the country level (national and regional) (in addition to its team members). The organiser then calls a meeting with them to discuss and agree on the most relevant (positive and negative) characteristics of the pilot situation at the national or regional level for

⁹² At the time when full scale JACARDI methodological framework was developed, majority of the pilots already accomplished Steps I-V, so their description is as was defined in Milestone 12 with slight adaptations; they do not systematically include all the elements as described in Chapters 3.2 to 3.9, since they were not fully developed. For the use in other projects and JA, these steps too will be redefined in the next documents.

⁹³ This step is the first part of so-called two-step Pilots from JADECARE. At the end of this JA, the implementers reflected on their implementation experience, and described that not being well-oriented within their specific situations and not involving the main stakeholders from the earliest phases of design of their pilots had had major influence on encountering barriers during the implementation phase and on the sustainability of their result. This was actually their biggest regret.

⁹⁴ <https://www.jadecare.eu/>

⁹⁵ CARE4DIABETES Deliverable 5.1 Best Practice and Situation Analysis, pending approval by the contracting authority, when approved available at <https://c4djointaction.eu/>

two timeframes - current and future. To ensure the transversal inclusion of the sustainability principle, as well as the equity and diversity principle, these areas need to be covered in the situation analysis.

The core pilot team can use the *template* below (*Template 3. STEP III: Situation analysis (at national/regional level)*) (Annex VI).

JACARDI, WPX, Pilot xx			
Step III. Situation analysis			
At national/regional level			
Current situation		Future	
Positive	Negative	Positive	Negative
1	1	1	1
Add lines			

Template 3. STEP III: Situation analysis (at national/regional level)

(2) The core pilot team identifies all appropriate individuals within the pilot setting (in addition to the members of the core pilot team). The organiser then calls a meeting with them to discuss and agree on the most relevant positive and negative characteristics of the pilot situation in the implementation setting. To ensure the transversal inclusion of the sustainability principle and the equity and diversity principle, these areas need to be covered in the situation analysis (Please see the guiding questions at the end of this chapter).

Some characteristics may be positive and negative at the same time (for example, depending on the focus); if so, an explanation should be added.

The core pilot team can use the *template* below (*Template 4. STEP III: Situation analysis (at the level of the pilot setting)*) (Annex VI).

JACARDI, WPX, Pilot xx			
Step III. Situation analysis			
At the level of pilot setting			
Current situation		Future	
Positive	Negative	Positive	Negative
1	1	1	1
Add lines			

Template 4. STEP III: Situation analysis (at the level of the pilot setting)

(3) Informed by the situation analysis, the core pilot team identifies key stakeholders and defines their level of involvement. To assure the transversal inclusion of the sustainability principle as well as the equity and diversity principle, these areas need to be covered in the situation analysis.

When performing the key stakeholder analysis, the core pilot team can use the template below (*Template 5. STEP III: Key stakeholders and their level of involvement*) (*Annex VI*).

JACARDI, WPX, Pilot xx			
Step III. Key stakeholders			
Key stakeholders and their level of involvement			
Institution/person (Initials)	Contact known yes/no ⁹⁶	Level of involvement ⁹⁷	Comments
Add lines			

Template 5. STEP III: Key stakeholders and their level of involvement

More information on the key stakeholder's involvement can be found below (*Box 38. Key stakeholders' involvement*).

The key stakeholder's involvement

Key stakeholders are individuals, institutions, or organisations that in any way **may show interest** in the activity, program, intervention, or policy relevant to the JACARDI pilot's field or **are affected by** the work within JACARDI or **are important advocates** for the continuation and potential scalability of JACARDI's results when JA ends.

They can come from different fields and have distinct expertise and experience (healthcare, education, research, communication and ICT technology, NGOs, patients' associations, and civil society) to be as enriching and comprehensive as possible.

They may differ in their interest and power. Specifically, those with high interest and power should be closely involved as early as possible. They will also constitute a **stakeholder board** that will be actively involved in the pilot's work and extensively involved during the design of the sustainability action plan.

Ideally, the stakeholder board may be organised already in this step to participate in the situation analysis. The next opportunity is within Step VI when the stakeholder board would be consulted on the most appropriate sustainability-supporting activity(ies)⁹⁸ that need to be included in the first pilot implementation plan. However, organising a stakeholder board with plans for interactions may also be a sustainability-supporting activity since the stakeholder board needs to be consulted at the intermediary reporting of the

⁹⁶ Contact details should be known to the organiser, here report just yes (known) or no (not known yet).

⁹⁷ Levels of involvement: full participation, consultation, informed.

⁹⁸ Also per Grant Agreement

pilot's progress to adjust the pilot if needed. However, the stakeholder board plays a pivotal role in Steps XIII and XV, when consultation and consensus meetings with the stakeholder board have to be organised.

Levels of involvement:

The participation of the key stakeholders may be:

- Full participation: the stakeholder may even be directly included in the core pilot team
- Consultation: the stakeholder is actively consulted during the process
- Informed: the stakeholder is fully informed on decisions and decision-making process, or only briefly informed as usual contacts or during usual JACARDI communication and dissemination activities at national, regional and local levels.

⁹⁹The type and diversity of stakeholders crucial for the completion and sustainability of a given pilot may vary substantially depending on the context and content of the pilot. Not all pilots need to involve all imaginable stakeholder groups. The key stakeholders may come from the core pilot team's own organisation, from outside their organisation, or both.

In some cases, such as in operational-level pilots related to the technical development of registers, all key stakeholders may be found within the core pilot team's organisation, and the stakeholder board may be composed exclusively of in-house experts. In such cases, contacting external stakeholders, such as representatives of ministries or regional authorities, may only be confusing to the external stakeholders, particularly if the content of the pilot is beyond their understanding, if the pilot does not require their approval, or if the pilot does not influence the way the external stakeholders use the end product of the pilot (e.g., a register or a statistical report produced based on the register).

In other cases, in turn, reaching out to external stakeholders may be necessary. For example, if the building of a national register lacks a mandate from relevant authorities, if the core pilot team does not own the pilot practice/tool or the platform on which the practice/tool is built, or if the core pilot team is not committed to maintaining the practice/tool but requires an external body that adopts the ownership of the product after JACARDI.

Case example No. 1:

THL's WP7 pilot that works on an operational level with focus on the construction of the data architecture of existing National Clinical Quality Registers that are developed and owned by THL with a strong mandate from the Ministry of Social Affairs and Health. The key stakeholders of this pilot comprise the following in-house personnel:

- technical staff
- substance-matter experts
- technical experts
- developers of the registers
- developers of the applied data architecture model/method

Case example No. 2:

A pilot conducted by THL and the Finnish Diabetes Association (FDA) focuses on the implementation of a peer-led, culturally sensitive lifestyle intervention for Somalis in Finland. The key stakeholders include:

⁹⁹ This part was not included in Milestone 12.

- National immigrant associations - *full participation*
- Local/grass-root immigrant associations - *full*
- The FDA (i.e., a national patient organisation) - *full*
- THL - *full*
- The wellbeing services counties of Finland (i.e., regional authorities responsible for organising healthcare and social welfare services for their residents) - *briefly informed*
- The University of Eastern Finland (the coordinator of the research consortium that originally developed the lifestyle intervention model to be piloted) - *consulted/informed*

Box 38. Key stakeholders' involvement

Other evidence-based approaches, such as the CFIR¹⁰⁰ or SCIROCCO²² (Annex I), can also be used for the situation analysis if feasible for the pilots.

The core pilot team should also consider the **equity and diversity principle, and the sustainability principle** (Chapter 3.4 ([link](#))). The following questions can be used.

Sustainability lens

Guiding questions

The situation analysis process should address the following:

Policy environment: Identify health strategies and initiatives at local/regional/national health policy that the pilot could be linked to. Search for an opportunity on how the pilot could become a part of larger schemes of health system transformation, and search for the options, how pilot outcomes could be used as one of the resources. Search for a way to establish solid top-down and bottom-up linkages to other key stakeholders in the system that can assure the systemic funding and continuity of the pilot's outcomes.

Ownership of sustainability: Search for a way for the pilot to establish links (formal and informal) to different levels of governance structures that are accountable for the topic the pilot works on. Establish links (formal and informal) to other stakeholders with power (including networking and coordinating power) and/or interest in this field; the linkages may need to be adapted over time.

Culture of collaboration and consensus-seeking: Align to and operate in concordance with the cultural characteristics of the setting. Strengthen the culture of collaboration and building consensus when planning and implementing activities. Create numerous bottom-up and top-down interactions among the stakeholders, including communities. Consider relevant characteristics of the population addressed and foster patient/user-led engagement in developing and implementing the solutions.

Box 39. STEP III Sustainability lens

¹⁰⁰ <https://cfirguide.org/>

Equity and diversity lens¹⁰¹

Guiding questions

The situation analysis process should address the following:

Application of critical reflection skills related to equity and diversity.

Examination of biases, stereotypes, prejudices, and power dynamics. Consult the target population and other relevant and diverse stakeholders, and – even better – work with them (co-design) to analyse the situation. Critical reflection on the potential bias due to the data availability - “no data – no problem?”.

Was the pilot-level stakeholder analysis conducted in co-design with diverse groups affected by the pilot? Was a diverse stakeholder board established? Were diverse groups of end-users, representative of the community the pilot wants to serve, assembled for relevant consultations/workshops to identify the key themes and discourses that should be considered in the pilot?

Were the 4C principles considered during the situation analysis (e.g., in communication and meaningful engagement of stakeholders through co-design, identification of the impact of the pilot on diverse groups)?

Box 40. STEP III Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹⁰² below to integrate the equity and diversity principle in its work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step III. Situation analysis at the site of the implementation including key stakeholder analysis, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
3.1 Conduct a pilot-level stakeholder analysis	a) Critical reflection was applied to identify diverse stakeholders during the pilot-level stakeholder analysis conducted internally by the core pilot team.	b) Consultations were conducted with diverse individuals, groups, or entities considered to be potentially directly or indirectly affected by the pilot to comprehensively identify all relevant stakeholders.	c) The pilot level analysis was carried out in co-design with diverse individuals, groups, or entities considered directly or indirectly affected by the pilot.	

¹⁰¹ The questions in Italics and the Equity and Diversity Matrix were not included in Milestone 12.

¹⁰² Only the part relevant for the current step is included, the whole matrix can be found in *Annex IV*. Of note, Equity and diversity matrix was finalised when most of the pilots were at Step V/VI, so for these Steps it was not possible to apply it in the planning phase. However, inclusion of equity and diversity principle was facilitated by the guiding questions.

3.2 Meaningfully engage diverse stakeholders	<p>a) The pilot-level stakeholder board was established together with stakeholders and is diverse in its composition (e.g. experts and professionals, policymakers representing different disciplines and social groups, and persons with lived experiences).</p>	<p>b) In addition to the pilot-level stakeholder board, groups of diverse end-users/end-beneficiaries representative of the community the pilot wants to serve were assembled for relevant consultations/workshops to identify the key themes and discourses that should be taken into account in the pilot.</p>	<p>c) In addition to the pilot-level stakeholder board and groups of diverse end-users/end-beneficiaries, the pilot flexibly assembled other groups on specific topics (e.g. constituting of specific professional groups or groups that have relevant insights in some current theme related to pilot implementation) to gain more comprehensive insights that benefit the pilot.</p>	
3.3 Identify the impact on diverse end- users/ end- beneficiaries	<p>a) Impact on diverse end-users/ end-beneficiaries was identified through critical reflection on existing data and good practices.</p>	<p>b) Impact on diverse end-users/ end-beneficiaries was identified through critical review of existing data and good practices and consultations with diverse end-users and other relevant stakeholders.</p>	<p>c) Impact on diverse end-users/ end-beneficiaries was identified through critical review of existing and new data and good practices and meaningful engagement through co-design with diverse end-users and other relevant stakeholders.</p>	

Box 41. STEP III Equity and diversity matrix

REPORTING TIPS¹⁰³

A single-reporting system via REDCap is available from Step VI, where reporting tips for Step III are also included.

Taking notes in every step can make the preparation of the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams.

Box 42. STEP III Reporting tips

¹⁰³ This is additional guidance on reporting was not discussed and agreed upon in the structure and processes of the Implementation board., and it was not included in the JACARDI Milestone 12.

3.9.4 Step IV: Refinement of general objective¹⁰⁴

Understanding the situation in which the pilot will be implemented and knowing the key stakeholders, the core pilot team can start **refining the general objective** in Step IV.

The objectives of this step are:

- Define the strengths, weaknesses, opportunities, and threats of the pilot
- Re-evaluate the general objective of the pilot

Tacit objectives are to develop common attitudes, values and beliefs; share passion; build a sense of cohesion within the team and promote openness in communication; strengthen the readiness for change and resilience of the team; run a reflective process; and build a common vision.

Step IV represents the second phase of the so-called “two-phase situation analysis,” based on experience from JADECARE¹⁰⁵. After collecting all relevant information from different levels and stakeholders (in Step III), the core pilot team has to **assess and classify them into four categories (strengths, weaknesses, opportunities, and threats of the pilot)** according to the impact that its members can have on a specific characteristic.

In short, characteristics that are within the power of the core pilot team are strengths (positive) or weaknesses (negative). Those not within the power of the core pilot team or in the future are opportunities (positive) or threats (negative). More details on SWOT¹⁰⁶ analysis can be found in *Annex I*. If feasible for pilots, other evidence-based approaches can also be used (like CFIR¹⁰⁷, please see *Annex I*).

When defining the pilot’s strengths, weaknesses, opportunities, and threats, the *templates* below can be used (*Template 6. STEP IV: Identification of strengths and weaknesses*, *Template 7. STEP IV: Identification of opportunities and threats*) (*Annex VI*).

JACARDI, WPX, Pilot xx	
Step IV. Identification of strengths and weaknesses	
Characteristics identified within Step III that are within the power of the JACARDI core pilot team and/or the fully involved stakeholders	
Positive = strengths	Negative = weakness
1	1

¹⁰⁴ At the time when full scale JACARDI methodological framework was developed, majority of the pilots already accomplished Steps I-V, so their description is as was defined in Milestone 12 with slight adaptations; they do not systematically include all the elements as described in Chapters 3.2 to 3.9, since they were not fully developed. For the use in other projects and JA, these steps too will be redefined in the next documents.

¹⁰⁵ <https://www.jadecare.eu/>

¹⁰⁶ <https://wikis.ec.europa.eu/display/ExactExternalWiki/SWOT+analysis+-+strengths%2C+weaknesses%2C+opportunities+and+threats>

¹⁰⁷ <https://cfirguide.org/>

Add lines	
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Template 6. STEP IV: Identification of strengths and weaknesses

JACARDI, WPX, Pilot xx	
Step IV. Identification of opportunities and threats	
Characteristics identified within Step III that are not within the power of the JACARDI core pilot team and/or the fully involved stakeholders or are in the future	
Positive = opportunities	Negative = threats
1	1
Add lines	

Template 7. STEP IV: Identification of opportunities and threats

Informed by complex situation analysis and building upon the involvement of key stakeholders, the perspective of the core pilot team on “what the problem is and what the general objective could be” may change.

In the second part of Step IV, based on the assessment and embracing strengths, seizing opportunities, minimising weaknesses, and reducing the impact of threats, the general objective of the pilot should be re-evaluated and refined. It should stay ambitious, feasible, and sustainable. This step also offers the base for strategic decisions for designing strategic objectives and actions during the next steps.

When re-financing the general objective, the *template* below (*Template 8. STEP IV: Refined general objective*) (*Annex VI*) can be used.

JACARDI, WPX, Pilot xx
Step IV. Refined general objective
Based on this assessment, by embracing strengths, seizing opportunities, minimising weaknesses, and reducing the impact of the threats, the general objective is: xxx

Template 8. STEP IV: Refined general objective

The core pilot team should consider the **equity and diversity principle**, and the **sustainability principle** (Chapter 3.4 ([link](#))). The following questions can be used.

Sustainability lens

Guiding questions

If relevant strategies and initiatives were identified – how did this fact inform your general objective? How did the potential existence of links (formal and informal) to different levels of governance structures influence your general objective? And what are the possible links (formal and informal) to other stakeholders with power? Did this exercise of reaching out for opinions and information from the core implementation team help you align to and operate in concordance with cultural characteristics and strengthen the culture of collaboration and consensus-building for future work, including patient/user-led engagement in the development and implementation of the solutions?

Box 43. STEP IV Sustainability lens

Equity and diversity lens¹⁰⁸

Guiding questions

Did some stakeholders have open equity and diversity perspectives that were not known to the core team before? Were representatives of key identified impacted populations actively engaged in situation assessment? How were these views incorporated within the refinement of the general objective? If a member with (lived, first hand) experience of the result within the pilot's topic is included in the team, how were these views incorporated within the refinement of the general objective? Can you now identify additional perspectives that are missing?

Was the general objective refined based on critical reflection within the core pilot team and in co-design with end-users and other diverse stakeholders to meet the community's needs optimally the pilot aims at serving?

Box 44. STEP IV Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹⁰⁹ below to integrate the equity and diversity principle in its work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step IV. Refinement of the general objective, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
4.1 Engage diverse stakeholders in refinement of the	a) The general objective was refined with the pilot team, applying critical reflection in	b) The general objective was refined based on consultations with	c) The general objective was refined in co-design with diverse	

¹⁰⁸ The questions in Italics and the Equity and Diversity Matrix were not included in Milestone 12.

¹⁰⁹ Only the part relevant for the current step is included, the whole matrix can be found in *Annex IV*. Of note, Equity and diversity matrix was finalised when most of the pilots were at Step V/VI, so for these Steps it was not possible to apply it in the planning phase. However, inclusion of equity and diversity principle was facilitated by the guiding questions.

general objective	consideration of equity and diversity among the end-users/ end-beneficiaries.	diverse stakeholders and end-users/ end-beneficiaries.	stakeholders and end-users/ end-beneficiaries.	
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Box 45. STEP IV Equity and diversity matrix

REPORTING TIPS¹¹⁰

A single-reporting system via REDCap is available from Step VI, where the reporting tips for Step IV are included.

Taking notes in every step can make preparing the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams.

Box 46. STEP IV Reporting tips

¹¹⁰ This is additional guidance on reporting, was not discussed and agreed upon in the structure and processes of the Implementation board., and it was not included in the Milestone 12.

3.9.5 Step V: Definition of specific objectives¹¹¹

After refining the general objective, the core pilot team **defines specific objectives in the fifth step.**

The objectives of this step are:

- Identify best practices and/or other appropriate practices, or single elements of them, to be used in the pilot design
- Define specific objectives of the pilot (up to 3)

This step leads from the refined general objective to specific objectives. The core pilot team should consider those elements that must **be included in the pilot to achieve the envisaged improvement.**

The working definition of **specific objectives** is provided in the box below (*Box 47. JACARDI working definition of the specific objective*).

Specific objectives are:

- short- to medium-term goals that must be realised to achieve the general objective;
- usually several and diverse, while the general is usually one;
- derived from the general objective;
- short or medium-term since they imply partial stages for the fulfilment of the general objective;
- often imply gradual, measurable progress, and they can be successive (one is needed first to reach another);
- can be achieved by activities that will be defined in the next step while defining the pilot implementation plan

Box 47. JACARDI working definition of the specific objective

The approach that can be used in this step may be, for example, the Theory of Change¹¹² (*Box 48. Theory of change*), SWOT¹¹³-based action planning,¹¹⁴ or any other feasible approach.

Theory of Change is a theory-driven framework and method to improve the evaluation of complex health interventions, which is expected to bring long-term outcomes. A Theory of Change aims to explain how a project or intervention is understood to work. It helps to identify specific evaluation questions, relevant variables that should be included in the data collection, intermediate outcomes that can be used as markers of success in situations where the impacts of interest will not occur during the time frame of the evaluation, aspects of implementation that should be examined and potentially relevant contextual factors that should be addressed in the data collection and in the analysis¹¹⁵.

Box 48. Theory of change

¹¹¹ At the time when full scale JACARDI methodological framework was developed, majority of the pilots already accomplished Steps I-V, so their description is as was defined in Milestone 12 with slight adaptations; they do not systematically include all the elements as described in Chapters 3.2 to 3.9, since they were not fully developed. For the use in other projects and JA, these steps too will be redefined in the next documents.

¹¹² <https://unsdg.un.org/sites/default/files/UNDG-UNDAF-Companion-Pieces-7-Theory-of-Change.pdf>

¹¹³ <https://wikis.ec.europa.eu/display/ExactExternalWiki/SWOT+analysis+-+strengths%2C+weaknesses%2C+opportunities+and+threats>

¹¹⁴ Not included in the document as WP6-11 leadership teams suggested that this step should contain only the generics.

¹¹⁵ CARE4DIABETES Deliverable 3.1 MONITORING AND EVALUATION PLAN, pending approval by contracting authority, when approved available at <https://c4djointaction.eu/>

An additional approach that **has to** be used by the core pilot team is identifying **best practices (from the EU Best Practice portal¹¹⁶) and/or other practices, and their validation¹¹⁷**. More information can be found in the box below (*Box 49. Identification of best and other practices and their validation*).

Identification of best and other practices and their validation

The core pilot team scans for the experience in other settings where practices relevant to its pilot have already been implemented (such as the EU Best Practice Portal, published literature, and elsewhere) and learns from them. This can be done even if the core pilot team is limited by the information made available by the EU Best Practice Portal and other publication sources. However, contacting the owners of the practice would bring better results.

The reason for identifying successful practices and interventions, or single elements of them, that have already been implemented elsewhere lies on the idea that only relevant and appropriate practices should be implemented at pilot sites and that each pilot should have a strong evidence-based rationale at its basis. This way, it increases the probability that the pilots to be implemented are effective and efficient, transferable, sustainable, and encompass participation and intersectoral collaboration as well as the equity approach, following the core and qualifier criteria from DG SANTE evaluation of Best Practices.

Identifying key elements of best practices and other relevant and appropriate practices and their potential adaptation and later implementation within pilot sites should be done with a focus on the sustainability of the pilot's results. This process is pivotal in providing a rationale for the pilots and serves as an important step in team building aimed at understanding the pilots' objectives and activities.

For more information on the identification of best practices and other practices, please refer to Chapter 3.3 ([link](#)).

Box 49. Identification of best and other practices and their validation

The *template* below (*Template 9. STEP V: Definition of specific objectives*) (*Annex VI*) can be used when defining specific objectives.

JACARDI, WPX, Pilot xx
Step V. Definition of specific objectives
Based on the general objective (Step IV), the specific objectives are:
1.
2.

¹¹⁶ <https://webgate.ec.europa.eu/dyna/bp-portal/>

¹¹⁷ Only the validation of other practices is necessary.

3.

Template 9. STEP V: Definition of specific objectives

The core pilot team should consider the **equity and diversity principle, and the sustainability principle** (Chapter 3.4 ([link](#))). The following questions can be used.

Sustainability lens

Guiding questions

How do the specific objectives correspond to the policy environment and broader actions and initiatives relevant to the pilot's topic?

How do they address the inclusion of the potential holder of sustainability who is willing and able to support further deployment of pilot results after the end of JACARDI?

How do they support the collaboration and achieving consensus with the identified key stakeholders?

Box 50. STEP V Sustainability lens

Equity and diversity lens¹¹⁸

Guiding questions

How do the specific objectives address concepts and processes relevant to equity and diversity, such as critical reflection, co-design, inclusive communication, and the search and inclusion of the "missing view"?

Were the 4C principles applied in the definition of specific objectives (incl. co-design with diverse stakeholders)?

Were the 4C principles considered when selecting best practices or other evidence-based practices?

Box 51. STEP V Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹¹⁹ below to integrate the equity and diversity principle in its work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step V. Definition of specific objectives, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments

¹¹⁸ The questions in Italics and the Equity and Diversity Matrix were not included in Milestone 12.

¹¹⁹ Only the part relevant for the current step is included, the whole matrix can be found in *Annex IV*. Of note, Equity and diversity matrix was finalised when most of the pilots were at Step V/VI, so for these Steps it was not possible to apply it in the planning phase. However, inclusion of equity and diversity principle was facilitated by the guiding questions.

5.1 Apply the equity and diversity perspectives in the definition of specific objectives	a) Specific objectives were defined within the pilot team based on critical reflection on equity and diversity among the end-users/end-beneficiaries.	b) Specific objectives were defined based on consultations with diverse end-users/end-beneficiaries and other stakeholders.	c) Specific objectives were defined in co-design with diverse end-users/end-beneficiaries and other stakeholders.	
5.2 Consider equity and diversity when selecting EU best practices/other evidence-based practices	a) Critical reflection considering equity and diversity perspectives was applied when selecting previous good practices (either from the EU Best Practices Portal or other evidence-based practices).	b) EU Best practices/other evidence-based practices were selected based on critical reflection and consultations with diverse stakeholders.	c) EU best practices/other evidence-based practices were selected based on critical reflection and co-design with diverse stakeholders.	

Box 52. STEP V Equity and diversity matrix

REPORTING TIPS

A single-reporting system via REDCap is available from Step VI, where the reporting tips for Step V are included.

Taking notes in every step can make the preparation of the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams.

Box 53. STEP V Reporting tips

3.9.6 Step VI: Pilot implementation plan No. 1

Once the core pilot team is established, the problem is identified, the general objective is defined, the pilot situation is analysed, the key stakeholders are identified, and the specific objectives are defined, the core pilot team can, in step VI, outline the activities necessary to achieve the pilot’s general and specific objectives (pilot implementation plan) and define how the pilot’s effects will be assessed (multidimensional assessment plan). The preparation of both plans proceeds in parallel.

The **objectives** of this step are:

- to prepare the first pilot implementation plan
- to prepare a multidimensional assessment plan
- to report on Steps I-VI

The **operational objectives** of this step are:

- Proactively interact with respective WP6-11 leadership teams
- Attend capacity-building activities
- Consult country profiles with identified needs (if already available)
- Check the suggestions for implementation activities in the best/validated practice
- Integrate the sustainability principle and define at least one sustainability-supporting activity (in the pilot implementation plan)
- Integrate the equity and diversity principle
- Engage in the communication and dissemination activities
- Review the Final implementation report template, paying special attention to the sections corresponding to steps I to VI, and take notes to prepare relevant information in the defined format
- Fill in the report when the REDCap tool is in place.

The **expected outputs** of this step are:

- Pilot implementation plan No. 1 prepared
- Multidimensional assessment plan prepared
- Steps I-VI reported (Deadline: March 2025 or within two months of availability of the REDCap tool).

STRUCTURE OF THE PILOT IMPLEMENTATION PLAN

The **pilot implementation plan** should include the already defined **general and specific objectives** and preferably **up to 5 activities for each specific objective**. For each activity, the core pilot team should nominate a **responsible person** and define the **deadline** and the **indicator for accomplishment**, showing that the activity is fulfilled.

The template below (*Template 10. STEP VI: Pilot implementation plan No.1*) (Annex VI) can be used when preparing the pilot implementation plan.

JACARDI, WPX, Pilot xx	
Step VI. Pilot Implementation Plan No.1	
GENERAL OBJECTIVE	Please write your general objective (Step IV)

Specific Objective 1 Please write one of your specific objectives (Step V)				
<i>Activities</i>	<i>What?</i>	<i>Who?</i> ¹²⁰	<i>When?</i>	<i>Indicator for the accomplishment of the activity</i>
	<i>Brief description of what has to be done to achieve the specific objective?</i>	<i>Who does what, and who is responsible for implementation?</i>	<i>Deadline for the completion</i>	<i>How will you know that the activity was realised as planned?</i>
Activity 1.1				
Add lines if needed.				
Specific Objective 2 Please write one of your specific objectives (Step V)				
<i>Activities</i>	<i>What?</i>	<i>Who?</i>	<i>When?</i>	<i>Indicator</i>
Activity 2.1				
Add lines if needed.				
Specific Objective 3 Please write one of your specific objectives (Step V)				
<i>Activities</i>	<i>What?</i>	<i>Who?</i>	<i>When?</i>	<i>Indicator</i>
Activity 3.1				
Add lines if needed.				

Template 10. STEP VI: Pilot implementation plan No.1

The **defined activities** for each specific objective should lead to its achievement. At their consideration, the core pilot team may use SWOT¹²¹-inspired action planning to assess the feasibility and importance of each activity. When elaborating the chronological order of specific objectives, the core pilot team may use the Theory of Change¹²² to define what should happen first and what should follow.

For each activity, the core pilot team must define:

- a **responsible person** to monitor the implementation and ensure the activity is accomplished successfully.
- a realistic **deadline** that the team strives to meet, mainly if the completion of the activity is a prerequisite for the start of the next activity. Attention should be paid to any signs of delays, and as needed, the pilot implementation plan should be adjusted accordingly.
- an **indicator** (i.e., a means of verification) **for the accomplishment of the activity** to show that the activity is fulfilled. In most cases, these indicators represent process indicators. If an indicator seems impossible to develop, the activity may have to be rephrased or redefined. The indicator doesn't need to be numerical. *For example, the WP9 leadership team asked the core pilot teams to define an activity's output(s), assuming that if the output is achieved, then the activity is accomplished. Another example of a non-numeric indicator is: "a training material that meets the expectations set previously."*

¹²⁰ The organiser should know this but reporting names is not required.

¹²¹ <https://wikis.ec.europa.eu/display/ExactExternalWiki/SWOT+analysis+-+strengths%2C+weaknesses%2C+opportunities+and+threats>

¹²² <https://unsdg.un.org/sites/default/files/UNDG-UNDAF-Companion-Pieces-7-Theory-of-Change.pdf>

Additionally, the first pilot implementation plan needs to include **at least one sustainability-supporting activity**. Generic guidance with examples is provided in the Sustainability lens box below. More on sustainability in general can be found in Chapter 3.4 ([link](#)).

Sustainability lens

When developing **sustainability-supporting activities**, the core pilot teams should consider what small steps can be taken to integrate pilot results and outcomes within their local, regional, and/or national settings. In short, how to make the results and outcomes useful.

Activities can be aimed at:

- **Interacting with the policy environment** by identifying and/or engaging relevant initiatives, strategies, and structures that are active in the field of diabetes/CVDs management and could be supportive of the implementation.
- **Identifying/engaging potential holders of sustainability beyond JACARDI**. These could include individual organisations or departments, formal or informal networks of organisations, steering groups of national NCD programs, etc.
- **Fostering a culture of collaboration and consensus-seeking** by involving all the stakeholders impacted by the pilot in a meaningful way in pilot development, implementation, and assessment.

The table below presents **some examples of activities** that can support the sustainability of the pilot.

Activities	What	Who	When (Deadline)	Indicator for the accomplishment of the activity
Activity x.1	Establishment of a stakeholder board with periodic meetings organised to monitor and support the implementation process	The core pilot team and representatives of key internal and/or external stakeholder groups, such as technical or substance matter experts, developers/owners of applied methods/tools, end-users, third sector organisations, regional authorities, or relevant ministries	By month, year	Stakeholder board established (YES/NO); Meeting minutes

Activity x.2	Identification of relevant national strategies, programs, policy frameworks, and/or initiatives with the potential for sustainable implementation of pilot results and outcomes	The core pilot team and, e.g., experts, representatives of national health authorities, and/or project/program leaders	By month, year	List of strategies, programs, initiatives
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Continuous engagement of stakeholders throughout the implementation process increases the changes that the pilot results will sustain after the project ends. Active engagement enhances the stakeholders' sense of ownership and perceived pilot value.

During Step III, the core pilot teams identified key stakeholders and defined their level of involvement. Ideally, that step also included **establishing a stakeholder board**, and the board was fully engaged in defining the general and specific objectives (Steps IV-V). If not, the stakeholder board can be established in Step VI, and the board can be involved in the subsequent implementation steps. The board should involve at least the stakeholders whose level of involvement was defined as "full participation" or "consultation."

The stakeholder board can be engaged, e.g., with **structured communication**. This communication should aim to identify sustainability-supporting activities when preparing the pilot implementation plans No. 1 (Step VI) and No. 2 (Step IX). Productive interaction with the stakeholders will be especially important in Steps XIII-XV, in which the core pilot teams develop their sustainability action plans and build ownership for the time after JACARDI.

The following checklist helps the core pilot team plan and monitor the engagement of their stakeholder board in each phase of the process within JACARDI.

Steps	Stakeholder Board Engagement in:	Yes	No	Description of the means of engagement (How?)
Step VI	Action planning			
Step VII	Roll-out of activities and monitoring			
Step VIII	Assessment of outcomes			

Step IX	Pilot adaptation as part of the Pilot implementation plan No. 2			
Step X	Roll-out of activities and monitoring			
Step XI	Pilot adaptations as part of the Intermediate report No. 2			
Step XIII	Dissemination of preliminary/final results			
Step XIV	Sustainability action plan development (essential)			

Box 54. STEP VI Sustainability lens with examples of sustainability-supporting activities and stakeholder board engagement checklist

The core pilot team should consider the **equity and diversity principle** (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Equity and diversity lens

Guiding questions

Was the pilot implementation plan co-designed with the stakeholder board?
 Were the 4C principles of equity and diversity integrated throughout the pilot implementation plan?

Box 55. STEP VI Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹²³ below to integrate the equity and diversity principle in its work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step VI. Pilot Implementation Plan No.1, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments

¹²³ Only the part relevant for the current step is included, the whole matrix can be found in *Annex IV*. Of note, Equity and diversity matrix was finalised when most of the pilots were at Step V/VI, so for these Steps it was not possible to apply it in the planning phase. However, inclusion of equity and diversity principle was facilitated by the guiding questions.

6.1 Engage diverse stakeholders in the development of the pilot implementation plan	a) Key stakeholders/stakeholder board was informed on relevant parts of the pilot implementation plan.	b) Key stakeholders/stakeholder board was consulted when developing the pilot implementation plan.	c) Key stakeholders/stakeholder board was meaningfully engaged through co-design when developing the pilot implementation plan.	
6.2 Integrate equity and diversity perspectives in the pilot implementation plan	a) Equity and diversity perspectives were integrated in the general objective of the pilot implementation plan.	b) The pilot implementation plan had at least one specific objective related to equity and diversity.	c) The pilot implementation plan had an activity on equity and diversity under each specific objective.	
6.3 Integrate equity and diversity perspectives in the pilot communication	a) The pilot implementation plan explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 (Annex III) and the WP5 JACARDI terminology glossary for internal and external communication (Annex II) in the pilot implementation plan.	b) The pilot implementation plan had a specific objective related to inclusive and accessible communications for pilot internal and external communication.	c) The pilot implementation plan integrated an activity on inclusive and accessible communications for external and internal communication under each specific objective.	

Box 56. STEP VI Equity and diversity matrix

The core pilot team should also engage in **communication and dissemination** activities (Chapter 3.7 ([link](#))) and include them in the pilot implementation plan if feasible.

In this step, the core pilot team should also scan the results of the **country-level context analysis** and consult the country profiles with identified needs, if already available. Based on this information, the core pilot team can adapt its activities in the pilot implementation plan to address the identified needs at the country level.

CAPACITY-BUILDING ACTIVITIES

The core pilot team learns more about the development of the pilot implementation plan during the **first learning session**, which should ideally take place at the beginning of this step. This session introduces the **pilot action planning**, including related sustainability aspects, the application of the equity and

diversity matrix, and designing a multidimensional assessment plan. This session should include the presentation of the framework, some sample assessment plans, and a Q&A segment.

Example: WP9 Learning session 1 ([JACARDI Teams](#)).

More information can be found in Chapter 3.6 ([link](#)).

Box 57. STEP VI Capacity-building box

STRUCTURE OF THE MULTIDIMENSIONAL ASSESSMENT PLAN

The core pilot team should define a **multidimensional assessment plan** that helps assess the effect(s) of the pilot across several dimensions. Assessing pilot outcomes may help to decide whether to adopt, adapt, abandon, or add specific activities in steps VIII, XI, XII, and XIV. Please see Chapter 3.5 ([link](#)).

The structure of the multidimensional assessment plan is provided in the template below (*Template 11. STEP VI Multidimensional assessment plan*) (*Annex VI*).

JACARDI, WPX, Pilot xx					
Step VI. Multidimensional assessment plan					
Primary and secondary outcomes of the pilot					
	Description of the outcome	Definition of the measure/indicator	Data collection approach	Timing for data collection	Timing for reporting
Primary outcome 1					
Add lines					
Secondary outcome 1					
Add lines					
Dimensions for the assessment of the pilot					
Effectiveness					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Health outcome/patient-reported outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Patient experience					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Patient-reported experience measure 1					
Add lines					
If not relevant or applicable, provide justification:					
Economic efficiency					

	Description of the outcome	Definition of the measure/indicator and the analytical method and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Economic efficiency-related outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Equity and diversity					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Equity and diversity-related outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Sustainability, including scalability and/or transferability					
	Approach chosen	Approach to collect information	Approach to reach conclusions (for example, SWOT analysis)		
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends					
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends					
This dimension is relevant for all pilots in JACARDI.					
Implementation and process outcomes					
	Approach chosen	Approach chosen to collect information	Approach to reach conclusions (for example, facilitators and barriers identified)		
Implementation or process outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Ethical and legal issues are identified, addressed and reported in the chapter on Ethical considerations in the Final implementation report.					

Template 11. STEP VI Multidimensional assessment plan

The core pilot team should consider all the dimensions; justification should be provided for those not included in the assessment because they are not relevant and/or applicable. The dimension on sustainability, including scalability/transferability, is relevant and thus **essential** for all JACARDI pilots since it is one of the transversal principles.

CAPACITY-BUILDING ACTIVITIES

The core pilot team learns more about developing the multidimensional assessment plan during a dedicated workshop within Learning session 1 and other supporting activities organised by the Task 5.6 team and WP6-11 leadership teams. These sessions introduce the multidimensional pilot assessment framework and give the core pilot teams the opportunity to start developing their assessment plans.

More information can be found in the Chapter 3.6 ([link](#)).

Box 58. STEP VI Capacity-building box on the multidimensional assessment plan

REPORTING TIPS

A single-reporting system via the REDCap tool should be available in this step. Therefore, all information collected until this point within steps I to VI should be reported in the General information sheet and Final implementation report. Their structure and detailed instructions are available in *Annex VII*.

The language used in articles from peer-reviewed journals in medicine (in the broadest sense) should be used.

In summary, the reporting should cover:

- Pilot project identification details
- (working) Title of the pilot
- Introduction, covering problem description, available knowledge, rationale including general objective and specific objectives
- Methods, covering situation analysis including key stakeholder analysis, specifics of the team involved in the work, description of the pilot, approaches and/or measures to assess the pilot project results, analytical methods and ethical considerations, and
- All communication and dissemination activities are reported within the pilot communication report in the Annex of the final implementation report.

If relevant changes appear during the next steps, the existing information should be updated and changes justified.

Reporting covers the sustainability principle. If the REDCap tool is not in place yet, the core pilot team will report on equity and diversity integration at the end of the sixth step using the Webropol questionnaire.

Timely reporting facilitates the work of core pilot teams, WP6-11 leadership teams, and others within JACARDI. The deadline for this reporting is March 2025 (or within two months of the availability of the REDCap tool).

Taking notes in every step can make the preparation of the Final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams. They should help core pilot teams compile the relevant parts of the Final implementation report.

Box 59. STEP VI Reporting tips

3.9.7 Step VII: Roll-out of actions and monitoring

When the first pilot implementation plan, including at least one sustainability-supporting activity, is prepared, and the multidimensional assessment plan and its execution mechanisms are in place, the first implementation cycle with the roll-out of activities can start. In the seventh step, the core pilot team **performs the activities**, and the WP6-11 leadership team **monitors** the implementation process. The latter is needed not only for reporting but also for capacity-building and supporting activities, namely **monthly briefings**.

The **objective** of this step is:

- to deliver the activities and monitor the implementation process

The **operational objectives** of this step are:

- Proactively interact with respective WP6-11 leadership teams
- Attend capacity-building activities (monthly briefings)
- Collect all the data necessary for multidimensional assessment
- Integrate the sustainability principle and scan for new relevant policies, initiatives, and strategies; identify and engage new potential holders of sustainability beyond JACARDI; and identify new means for a meaningful way of interaction with stakeholders
- Integrate the equity and diversity principle
- Engage in communication and dissemination activities
- Review the Final implementation report template, paying special attention to the sections corresponding to step VII, and take notes to prepare relevant information in the defined format

The **expected outputs** of this step are:

- Activities delivered
- Monthly briefings executed

Translating the implementation plan into action is challenging, as unforeseen contextual factors may hamper the pilot's delivery. Thus, the core pilot team must have efficient mechanisms to detect and respond to early signs of delays, unforeseen weaknesses in the team, and unavoidable threats outside the team.

WP6-11 leadership team monitors the roll-out of activities and performs **monthly briefings** with the core pilot team to exchange information on the implementation process. These briefings, **as elements of the JACARDI capacity-building approach**, offer the opportunity:

- to notice and appreciate the work done and celebrate the goals achieved.
- to detect problems early enough to prevent delays in the implementation of the pilot or its failure.
- to discuss if anything unexpected happened as it could represent a significant opportunity for the implementation of the pilot and its sustainability if detected early enough; on the other hand, if unnoticed, it could represent a significant threat.

The template below (*Template 12. STEP VII: Roll-out of actions and monitoring*) (Annex VI) provides guiding questions that the WP leadership team and the core pilot team should use for the monitoring and briefings.

JACARDI, WPX, Pilot xx	
Step VII: Roll-out of actions and monitoring	
What is going on? What went well? What job was accomplished?	
Is anything going wrong? What will you do? How can the WP leadership team help? Is adaptation of the plan needed (At the level of an action, at the level of a specific objective, or in some previous steps)?	
Anything unexpected (positive, negative) happened?	

Template 12. STEP VII: Roll-out of actions and monitoring

Monthly briefings can be a set of shorter online meetings, face-to-face meetings, oral briefings, or any combination of these. The main aim of these contacts is interactions, so just collecting the pilots' status in written format may not provide the support needed. If needed, more briefings or longer meetings can be organised, for example, to explain and discuss deviations or present good implementation experiences.

The core pilot team should consider the **equity and diversity principle, and the sustainability principle** (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Sustainability lens

Guiding questions

Is the pilot as currently set up perceived as sustainable among the core pilot team members?

Is the pilot perceived as sustainable among stakeholders?

Which supportive or adverse influences or circumstances affecting sustainability are arising during implementation?

Are there any unplanned activities, opportunities, and/or events that may be important for sustainability?

Box 60. STEP VII Sustainability lens

In this step, the core pilot team should scan for new relevant policies, initiatives, and strategies, identify and engage new potential holders of sustainability beyond JACARDI, and identify new means of meaningful interaction with stakeholders.

Equity and diversity lens

Guiding questions

Were the 4C principles applied in monitoring of objectives and roll-out of actions?

Did the core pilot team continue strengthening their capacity in equity and diversity, and was representation considered?

Box 61. STEP VII Equity and diversity

In addition, the core pilot team can use the equity and diversity matrix¹²⁴ below to integrate the equity and diversity principle in their work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step VII. Roll-out of activities and monitoring, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
7.1 Identify how equity and diversity principles will be monitored	a) Plans for monitoring the principles of equity and diversity during the roll-out of actions were identified based on critical reflection within the pilot team.	b) Plans for monitoring equity and diversity principles during roll-out were identified in consultations with diverse end-users/end-beneficiaries and other stakeholders.	c) Plans for monitoring equity and diversity principles during roll-out were identified in co-design with diverse end-users/end-beneficiaries and other stakeholders and based on the pilot implementation plan.	
7.2 Apply equity and diversity perspectives during roll-out of actions	a) Critical reflection was applied within the core pilot team during the roll-out of actions (e.g. how are different groups affected; are some groups unintentionally left behind; are relevant and diverse stakeholders meaningfully involved; are pilot communications	b) Consultations with diverse end-users/end-beneficiaries and other stakeholders took place to support the roll-out of the project.	c) The roll-out was conducted in co-design with diverse end-users/end-beneficiaries and other stakeholders during the project's roll-out.	

¹²⁴ Only the part relevant for the current step is included, the whole matrix can be found in *Annex IV*.

	inclusive and accessible for the target populations).			
7.3 Continue strengthening capacity in equity and diversity within the pilot team	a) The core pilot team members understand and can explain the 4Cs principle and the relevance of equity and diversity in JACARDI to other partners and this is demonstrated through integrating equity and diversity perspectives in the pilot implementation plan.	b) The core pilot team members understand how to include equity and diversity perspectives in their pilot implementation but need support (e.g. consultations, workshops) of equity and diversity subject matter experts on how to apply them in practice.	c) The core pilot team members feel empowered to apply sufficiently concrete equity and diversity aspects in their implementation plans in an autonomous manner, and actively seek opportunities to strengthen their capacity in equity and diversity beyond JACARDI structures, for example through external seminars, trainings and independent readings.	
7.4 Consider core pilot team composition	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	c) The core pilot team consists of professionals from diverse disciplines, social groups, and is representative of the community the pilot aims to serve (i.e. all of the key characteristics identified are represented within the team).	

Box 62. STEP VII Equity and diversity matrix

The core pilot team should also engage in **communication and dissemination** activities if feasible. Please see Chapter 3.7 ([link](#)).

REPORTING TIPS

All information collected within Step VII should be reported in the final implementation report in Step VIII, where reporting tips are also included.

Taking notes in every step can make the preparation of the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11,

and developed by WP6-11 leadership teams. They should help core pilot teams compile the relevant parts of the final implementation report.

Box 63. STEP VII Reporting tips

3.9.8 Step VIII: Intermediate report No. 1

In this step, the core pilot team prepares the first intermediate report, covering the progress status of the pilot at the level of specific objectives and for accomplishments of activities, at the level of pilot outcomes (if defined in the assessment plan), and includes intermediary results related to sustainability as well as integration of equity and diversity principle. The report also addresses any unexpected findings during this implementation cycle. The core pilot team can use this report in the subsequent step to adjust its pilot implementation plan before commencing the second implementation cycle. This report refers to Step VII.

The objectives of this step are:

- to prepare the first intermediate report
- to prepare the multidimensional assessment report (only if planned in the multidimensional assessment plan)
- to report on Steps VII and VIII

The **operative objectives** of this step:

- Proactively interact with respective WP6-11 leadership teams
- Attend capacity-building activities
- Consider the findings from the country context analysis
- Check the suggestions for implementation activities in the best/validated practice
- Integrate the sustainability principle
- Integrate the equity and diversity principle
- Engage in communication and dissemination activities
- Review the final implementation report template, paying special attention to the sections corresponding to steps VII and VIII and take notes to prepare the relevant information in the defined format
- Fill in the report using the REDCap tool.

The **expected outputs** in this step are:

- Intermediate report No.1 prepared
- Multidimensional assessment report (only if planned in the multidimensional assessment plan) prepared
- Steps VII and VIII reported (Deadline: October/November 2025)

STRUCTURE OF THE INTERMEDIATE REPORT NO. 1

The intermediate report portrays the progress of pilot implementation at the end of the first implementation cycle. It consists of the progress status of the activities and specific objectives, multidimensional assessment with respect to pilot outcomes, intermediary results related to the sustainability of the pilot and the application of the equity and diversity principle. In addition, the report should include any unexpected findings during the first implementation cycle (within the column “Decisions on potential changes”, and their potential impact on pilot implementation plan No. 2. The report outlines the potential changes that could be introduced in the second implementation plan (in Step VIII).

The core pilot team can use the template below (*Template 13. STEP VIII: Intermediate report No. 1*) in relation to the progress status and should feed into Table 10 of the final implementation report.

JACARDI, WPX, Pilot xx			
Step VIII. Intermediate report No.1 - progress status			
GENERAL OBJECTIVE			
Specific Objective 1			Progress status (0%-25%-50%-75%-100%)
Activities	Description of progress based on the chosen indicator for the accomplishment of the activity	Summary of deviations	Decision on potential changes (adopt-adapt-abandon-add)
Activity 1.1			
Add lines, if needed.			
Specific Objective 2			
Specific Objective 2			Progress status (0%-25%-50%-75%-100%)
Activities	Description of progress ...	Summary of deviations	Decision on potential changes (adopt-adapt-abandon-add)
Activity 2.1			
Add lines, if needed.			
Specific Objective 3			
Specific Objective 3			Progress status (0%-25%-50%-75%-100%)
Activities	Description of progress ...	Summary of deviations	Decision on potential changes (adopt-adapt-abandon-add)
Activity 3.1			
Add lines, if needed.			

Template 13. STEP VIII: Intermediate report No. 1

The core pilot team should assess the implementation progress for each specific objective by choosing one of the following levels of accomplishment:

- **0% - NOTHING DONE:** No progress towards the objective or initial steps taken.
- **25% - BEGINNING:** Initial progress made, and preliminary steps completed.
- **50% - MIDWAY:** The objective is halfway achieved with several key activities accomplished.
- **75% - ADVANCED:** The objective is mostly accomplished with most activities completed.
- **100% - COMPLETED:** The objective is fully achieved, and all activities are completed.

Based on the results of the first implementation phase, the core pilot team should use the 4A principle (**adopt, adapt, abandon, add**) to determine required changes to the activities, specific objectives, or the general objective of the pilot. For example:

- If the activity has already achieved the expected result, it is concluded and celebrated. If the activity achieves the expected progress but is still ongoing, it will be further **adopted** and included in the second implementation plan.
- If the activity fails to yield the expected results and the reason for the failure is known, the activity can be **adapted** accordingly in the next implementation plan.
- If the activity fails to yield the expected results or encounters massive barriers, it can be **abandoned** from the next implementation plan.
- If opportunities for advancement arise or any other favourable changes appear in the pilot situation, new activities can be **added** to the following implementation plan.

When deciding on potential changes, the core pilot team should also consider **the findings of the country-level context analysis** (See Chapter 3.2 ([link](#))) and determine the extent to which and how their pilot addresses the identified needs at the country level and, if feasible, adjust their pilot to address these needs better.

In addition, the core pilot team should check the suggestions for implementation activities in **the best/validated practice**. Understanding these practices may be helpful when encountering problems and barriers.

To reflect on the needed adjustments from the sustainability perspective, the core pilot team can use the following questions (Chapter 3.4 ([link](#))).

Sustainability lens

Guiding questions:

Were the sustainability-supporting activities implemented as intended?

What were the relevant achievements? Which results might be significant for the policymakers?

Which needs within the (health) system does the pilot address?

Are there any discrepancies between the pilot's trajectory and the stakeholders' needs that the pilot impacts?

What would need to change in your setting or system for the adoption and spread of your pilot results and outcomes?

Is there a need for adjustments in your pilot to make it sustainable?

Considering your current achievements, opportunities, and supportive and negative factors, what could be the following activities to enhance further the sustainability of your pilot and/or to solve potential sustainability-related challenges?

Box 64. STEP VIII Sustainability lens

Sustainability-supporting activities included in the first pilot implementation plan should be assessed like other activities. In addition, there might be important aspects of sustainability that are impactful but were not directly included in the implementation plan. These aspects should also be included in the first intermediate report. Please see box below ([Box 65. STEP VIII: Sustainability-supporting questions](#)).

Results of activity(-ies) planned to increase the potential for sustainability
Potential sustainability-supporting changes of contextual characteristics (existing health strategies/policy frameworks), potential holders of sustainability, and processes that support collaboration, consensus-seeking, and engagement of stakeholders:
Unplanned activities (including past events and arising opportunities) with potential impact on sustainability:
Supportive and/or negative factors (organisational, systemic, community, resources, individual):
Proposed future actions/solutions:

Box 65. STEP VIII: Sustainability-supporting questions

The core pilot team should consider the **equity and diversity principle** (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Equity and diversity lens

Guiding questions

Were diverse stakeholders engaged in the assessment of intermediate results?

Were the 4C principles of equity and diversity integrated in the intermediate reporting?

Box 66. STEP VIII Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹²⁵ below to integrate equity and diversity principle in their work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step VIII. Intermediate Report No. 1, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
8.1 Engage diverse stakeholders in the assessment of intermediate results	a) Critical reflection was applied within the core pilot team to consider whether there is a need for changes at the action level or specific	b) Consultations were conducted with diverse end-users/end-beneficiaries and other stakeholders to consider whether	c) Diverse end-users/end-beneficiaries and other stakeholders were meaningfully engaged through co-design to consider	

¹²⁵ Only the part relevant for the current step is included, the whole matrix can be found in Annex IV.

	objectives levels that would further strengthen equity and diversity perspectives in the pilot, and these were described and assessed in the intermediate report. Relevant stakeholders were informed of key aspects of the intermediate report.	there is a need for changes at general objectives or specific objectives level that would further strengthen equity and diversity perspectives in the pilot, and these are described and assessed in the intermediate report.	whether there is a need for changes at the action level or specific objectives level that would further strengthen equity and diversity perspectives in the pilot, and these were described and assessed in the intermediate report.	
8.2 Integrate equity and diversity perspectives in intermediate reporting	a) Equity and diversity perspectives were reported under the general objective .	b) A specific objective related to equity and diversity (other than inclusive and accessible communications) was reported	c) An activity related to equity and diversity (other than inclusive and accessible communications) was reported in relation to each specific objective.	
8.3 Integrate equity and diversity perspectives in intermediate reporting on pilot communication	a) The report explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 (Annex III) and the WP5 JACARDI terminology glossary for internal and external communication (Annex II).	b) A specific objective related to inclusive and accessible communications for pilot internal and external communication was reported.	c) An activity on inclusive and accessible communications for external and internal communication was reported in relation to each specific objective.	

Box 67. STEP VIII Equity and diversity matrix

CAPACITY-BUILDING ACTIVITIES

The members of the core pilot team learn more about the preparation of the first intermediate report during **Learning session 2**, which should ideally take place at the beginning of Step VIII. More information is provided in Chapter 3.6 ([link](#)).

Box 68. STEP VIII Capacity-building activities

MULTIDIMENSIONAL ASSESSMENT REPORT NO. 1

The intermediate multidimensional assessment report is produced only if planned by a multidimensional assessment plan. The structure is presented in the template below (*Template 14. STEP VIII. Multidimensional assessment report No. 1*) (Annex VI) and should feed into Table 12 of the Final implementation report (Annex VII).

Multidimensional assessment report No. 1 (Annex VI) and should feed into Table 12 of the Final implementation report (Annex VII).

JACARDI, WPX, Pilot xx		
Step VIII. Multidimensional assessment report No. 1		
Primary and secondary outcomes of the pilot		
	Intermediary results	Interpretation and implications
Primary outcome 1		
Add lines		
Secondary outcome 1		
Add lines		
Dimensions for the assessment of the pilot		
Effectiveness		
	Intermediary results	Interpretation and implications
Health outcome/patient-reported outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Patient experience		
	Intermediary results	Interpretation and implications
Patient-reported experience measure 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Economic efficiency		
	Intermediary results	Interpretation and implications
Economic efficiency-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Equity and diversity		
	Intermediary results	Interpretation and implications
Equity and diversity-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Sustainability, including scalability and/or transferability		
	Intermediary results	Interpretation and implications
Feasibility of the continuation of the pilot (or its outcome) within		

the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis, and interpretation:		
Implementation and process outcomes		
	Intermediary results	Interpretation and implications
Implementation or process outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		

Template 14. STEP VIII. Multidimensional assessment report No. 1

CAPACITY-BUILDING ACTIVITIES

At this step, Task 5.6 provides continuous support to core pilot teams as they go through the implementation stage, and clarifications may be required on how to collect the necessary data better.

Box 69. STEP VIII Capacity-building activities on multidimensional assessment

The core pilot team should also engage in **communication and dissemination** activities (Chapter 3.7 ([link](#))) if feasible.

REPORTING TIPS

A single-reporting system via the REDCap tool should be used in this step. All information collected within steps VII and VIII should be reported in the final implementation report. Structure and detailed instructions are available in *Annex VII*.

The language used in articles from peer-reviewed journals in medicine (in the broadest sense) should be used.

In summary, the reporting should cover:

- Results – section on intermediary results
- All communication and dissemination activities reported within the pilot communication report in the Annex of the Final implementation report.

If relevant changes appeared with respect to the information already reported, the existing information should be updated and the changes justified.

Reporting covers the sustainability principle, as well as the integration of the equity and diversity principle.

Timely reporting facilitates the work of core pilot teams, WP6-11 leadership teams, and others within JACARDI. The deadline for this reporting is October/November 2025.

Taking notes in every step can make the preparation of the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams. They should help core pilot teams in compiling the relevant parts of the final implementation report.

Box 70. STEP VIII Reporting tips

3.9.9 Step IX: Pilot implementation plan No. 2

After testing the pilot in a real-life situation, in Step IX, the core pilot team prepares the second pilot implementation plan based on the findings of the first implementation cycle and decisions taken in the first intermediate report.

The **objective** of this step is:

- to prepare the second pilot implementation plan

The **operative objectives** of this step are:

- Proactively interact with respective WP6-11 leadership teams
- Consult country profiles with identified needs
- Check the suggestions for implementation activities in the best/validated practice
- Integrate the sustainability principle; reflect on and adapt, if needed, the sustainability-supporting activities
- Integrate the equity and diversity principle
- Engage in communication and dissemination activities
- Review the final implementation report template, paying special attention to the sections corresponding to Step IX and take notes to prepare the relevant information in the defined format

The **expected output** of this step is:

- Pilot implementation plan No. 2 prepared

STRUCTURE OF THE PILOT IMPLEMENTATION PLAN

The structure of the second implementation plan remains the same as the first one (Please see Step VI). In this step, the core pilot team can use the template below (*Template 15. STEP IX: Pilot implementation plan No. 2*) (Annex VI).

JACARDI, WPX, Pilot xx				
Step IX. Pilot implementation plan No. 2				
GENERAL OBJECTIVE				
Specific Objective 1				
Activities	What?	Who? ¹²⁶	When?	Indicator for the accomplishment of the activity
	<i>Brief description of what has to be done to achieve the specific objective</i>	<i>Who does what, and who is responsible for implementation?</i>	<i>Deadline for the completion</i>	<i>How will you know that the activity was realised as planned?</i>
Activity 1.1				
Add lines, if needed.				

¹²⁶ The organiser should know this but reporting names is not required.

Specific Objective 2				
<i>Activities</i>	<i>What?</i>	<i>Who?</i>	<i>When?</i>	<i>Indicator for the accomplishment of the activity</i>
Activity 2.1				
Add lines, if needed.				
Specific Objective 3				
<i>Activities</i>	<i>What?</i>	<i>Who?</i>	<i>When?</i>	<i>Indicator for the accomplishment of the activity</i>
Activity 3.1				
Add lines, if needed.				

Template 15. STEP IX: Pilot implementation plan No. 2

In this step, sustainability-supporting activities should also be adjusted based on the decisions made during intermediate reporting. If needed, additional activities can be introduced in the second implementation plan. The following guiding questions can help to integrate sustainability into this process.

Sustainability lens

Guiding questions:

Based on intermediary results, specifically those relevant to sustainability, what adaptations can be made in the second implementation plan to further build the sustainability potential of pilot results and outcomes?

How can the role of the stakeholder board be reinforced during this planning phase? Which additional stakeholders can be included to support implementation?

Box 71. STEP IX Sustainability lens

The core pilot team should consider the **equity and diversity principle** (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Equity and diversity lens

Guiding questions

Were diverse stakeholders engaged in the development of the pilot implementation plan?

Were the 4C principles of equity and diversity integrated throughout the pilot implementation plan?

Box 72. STEP IX Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹²⁷ below to integrate the equity and diversity principle in their work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step IX. Pilot implementation plan No. 2, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
9.1 Engage diverse stakeholders in the development of the pilot implementation plan	a) Implementation plan No. 2 compiled by the pilot team and key stakeholders/the stakeholder board was informed on relevant revisions of the pilot implementation plan	b) Key stakeholders/ the stakeholder board was consulted when developing the pilot implementation plan No. 2.	c) Key stakeholders/the stakeholder board was meaningfully engaged through co-design when developing the pilot implementation plan No. 2.	
9.2 Integrate equity and diversity perspectives in the pilot implementation plan	a) Equity and diversity perspectives were integrated in the general objective of the pilot implementation plan No. 2.	b) The pilot implementation plan had at least one specific objective related to equity and diversity of the pilot implementation plan No. 2.	c) The pilot implementation plan had an activity on equity and diversity under each specific objective of the pilot implementation plan No. 2.	
9.3 Integrate equity and diversity perspectives in the pilot communication	a) The pilot implementation plan explicitly mentioned the inclusive and accessible communications checklist produced by WP2 (Annex III) and the WP5 JACARDI terminology glossary for internal and external communication (Annex II) in the pilot implementation plan.	b) The pilot implementation plan had a specific objective related to inclusive and accessible communications for pilot internal and external communication.	c) The pilot implementation plan integrated an activity on inclusive and accessible communications for external and internal communication under each specific objective.	

Box 73. STEP IX Equity and diversity matrix

¹²⁷ Only the part relevant for the current step is included, the whole matrix can be found in Annex IV.

The core pilot team should also engage in **communication and dissemination** activities (Chapter 3.7 ([link](#))) and include them in the pilot implementation plan if feasible.

REPORTING TIPS

All information collected within Step IX should be reported in the final implementation report in Step XI, where reporting tips are also included.

Taking notes in every step can make the preparation of the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams. They should help core pilot teams in compiling the relevant parts of the final implementation report.

Box 74. STEP IX Reporting tips

3.9.10 Step X: Roll-out of actions and monitoring

When the pilot implementation plan No. 2 is prepared, the second implementation cycle with roll-out of activities can start. In the tenth step, the **core pilot team performs the activities**, and the WP leadership team **monitors** the implementation process. The latter is needed not only for reporting but also for capacity-building and supporting activities, namely, **monthly briefings**.

The **objective** of this step is:

- to deliver the activities and monitor the implementation process

The **operative objectives** of this step are:

- Proactively interact with respective WP6-11 leadership teams
- Attend capacity-building activities (monthly briefings)
- Collect all the data necessary for multidimensional assessment
- Integrate the sustainability principle and scan for new relevant policies, initiatives, and strategies; engage new potential holders of sustainability beyond JACARDI and identify new means for a meaningful way for interaction with stakeholders
- Integrate the equity and diversity perspective
- Engage in communication and dissemination activities
- Review the Final implementation report template, paying special attention to the sections corresponding to Step X and take notes to prepare relevant information in the defined format

The **expected outputs** of this step are:

- Activities delivered
- Monthly briefings executed

Translating the implementation plan into action is a challenging phase, as unforeseen contextual factors may hamper the delivery of the pilot. The core pilot team must thus have efficient mechanisms to detect and respond to early signs of delays, unforeseen weaknesses in the team, and unavoidable threats outside the team.

WP6-11 leadership team monitors the roll-out of activities and performs **monthly briefings** with the core pilot team to exchange information on the implementation process. These briefings, **as elements of the JACARDI capacity-building approach**, offer the opportunity:

- to notice and appreciate the work done and celebrate the goals achieved.
- to detect problems early enough to prevent delays in the implementation of the pilot or its failure.
- to discuss if anything unexpected happened as it could represent a significant opportunity for the implementation of the pilot and its sustainability if detected early enough; on the other hand, if unnoticed, it could represent a significant threat.

The template below (*Template 16. STEP X: Roll-out of actions and monitoring*) (Annex VI) provides guiding questions that the WP leadership and core pilot teams should use in the monitoring and briefings.

JACARDI, WPX, Pilot xx

Step X: Roll-out of actions and monitoring

What is going on? What went well? What job was accomplished?	
Is anything going wrong? What will you do? How can the WP leadership team help? Is adaptation of the plan needed (At the level of an action, at the level of a specific objective, or in some previous steps)?	
Anything unexpected (positive, negative) happened?	

Template 16. STEP X: Roll-out of actions and monitoring

Monthly briefings can be a set of shorter online meetings, face-to-face meetings, oral briefings, or any combination of these. The main aim of these contacts is interactions, so just collecting the status of the pilots in written format may be insufficient to provide the support needed. If needed, more briefings or longer meetings can be organised, for example, to explain and discuss deviations or present good implementation experiences.

The core pilot team should consider the sustainability principle (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Sustainability lens

Guiding questions

- Is the pilot as currently set up perceived as sustainable among the core pilot team members?
- Is the pilot perceived as sustainable among stakeholders?
- Which supportive or adverse influences or circumstances affecting sustainability are arising during implementation?
- Are there any unplanned activities, opportunities and/or events that may be important for sustainability?

Box 75. STEP X Sustainability lens

In this step, the core pilot team should scan for new relevant policies, initiatives, and strategies; identify and engage new potential holders of sustainability beyond JACARDI; and identify new means for meaningful interaction with stakeholders.

The core pilot team should also consider the **equity and diversity principle** (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Equity and diversity lens

Guiding questions

Were the 4C principles applied in monitoring of objectives and roll-out of actions?

Did the core pilot team continue strengthening capacity in equity and diversity, and was representation considered?

Box 76. STEP X Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹²⁸ below to integrate the equity and diversity principle in their work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step X. Roll-out of activities and monitoring, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
10.1 Monitor (and, if needed, revise) equity and diversity principles	a) Equity and diversity perspectives monitored were identified based on critical reflection within the pilot team.	b) Equity and diversity perspectives monitored were identified in consultations with diverse end-users/end-beneficiaries and other stakeholders.	c) Equity and diversity perspectives monitored were identified in co-design with diverse end-users/end-beneficiaries and other stakeholders.	
10.2 Apply equity and diversity perspectives during roll-out of actions	a) Critical reflection was applied within the core pilot team during the roll-out of actions (e.g. how are different groups affected; are some groups unintentionally left behind; are relevant and diverse stakeholders meaningfully involved; are pilot communications inclusive and	b) Consultations with diverse end-users/end-beneficiaries and other stakeholders took place to support the project's roll-out.	c) The roll-out was done in co-design with diverse end-users/end-beneficiaries and other stakeholders during the project's roll-out.	

¹²⁸ Only the part relevant for the current step is included, the whole matrix can be found in Annex IV.

	accessible for the target populations).			
10.3 Continue strengthening capacity in equity and diversity within the pilot team	A) The core pilot team members understand and can explain the 4Cs principle and the relevance of equity and diversity in JACARDI to other partners and this is demonstrated through integrating equity and diversity perspectives in the pilot implementation plan.	b) The core pilot team members understand how to include equity and diversity perspectives in their pilot implementation but need support (e.g. consultations, workshops) of equity and diversity subject matter experts on how to apply them in practice.	c) The core pilot team members feel empowered to apply sufficiently concrete equity and diversity aspects in their implementation plans in an autonomous manner, and actively seek opportunities to strengthen their capacity in equity and diversity beyond JACARDI structures, for example through external seminars, trainings and independent readings.	
10.4 Consider core pilot team composition	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	c) The core pilot team consists of professionals from diverse disciplines, social groups, and is representative of the community the pilot aims to serve (i.e. all of the key characteristics identified are represented within the team).	

Box 77. STEP X Equity and diversity matrix

The core pilot team should also engage in **communication and dissemination** activities (Chapter 3.7 ([link](#))) if feasible.

REPORTING TIPS

All information collected within Step X should be reported in the final implementation report in Step XI, where reporting tips are also included.

Taking notes in every step can make the preparation of the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11,

and developed by WP6-11 leadership teams. They should help core pilot teams in compiling the relevant parts of the final implementation report.

Box 78. STEP X Reporting tips

3.9.11 Step XI: Intermediate report No. 2

In this step, the core pilot team prepares the second intermediate report with a view to the sustainability of the pilot results and/or outcomes, covering the progress status of the pilot at the level of specific objectives and with respect to accomplishments of activities, at the level of pilot outcomes (if defined in assessment plan), and includes intermediary results related to sustainability as well as integration of equity and diversity principle. The report also addresses any unexpected findings during this implementation cycle. The core pilot team can use this report in the subsequent steps in the process of sustainability action planning. This report refers to Steps IX and X.

The **objectives** of this step are:

- to prepare the second intermediate report
- to prepare the multidimensional assessment report (only if planned in the multidimensional assessment plan)
- to report on Steps IX to XI

The **operative objectives** of this step are:

- Proactively interact with respective WP6-11 leadership teams
- Consider the findings of the country-level context analysis
- Check the suggestions for implementation activities in the best/validated practice
- Integrate the sustainability principle
- Integrate the equity and diversity perspective
- Engage in communication and dissemination activities
- Review the final implementation report template, paying special attention to the sections corresponding to steps IX to XI, and take notes to prepare relevant information in the defined format.
- Fill in the report in the REDCap tool

The **expected outputs** in this step are:

- Intermediate report No. 2
- Multidimensional assessment report (only if planned in the multidimensional assessment plan)
- Steps IX-XI reported (Deadline: November 2026)

STRUCTURE OF THE INTERMEDIATE REPORT NO. 2

The **structure of the second intermediate report** generally remains the same as that of the first; however, the decisions, interpretations, and implications should be made in light of sustainability and scalability/transferability. It consists of the progress status of the activities and specific objectives, multidimensional assessment with respect to pilot outcomes, intermediary results related to the sustainability of the pilot, and the application of the equity and diversity principle. In addition, the report should include any unexpected findings during the second implementation cycle (within the column “Decisions on potential changes”) and their potential impact on sustainability, including scalability/ transferability of pilot results and/or outcomes. The report outlines the potential changes to be considered when delivering the final implementation report and sustainability action plan (in Steps XIII and XIV).

The core pilot team can use the template below ([Template 17. STEP XI: Intermediate report No. 2](#)) in relation to the progress status and should feed into Table 11 of the Final implementation report (Annex VII).

JACARDI, WPX, Pilot xx			
Step XI. Intermediate report No.2 - progress status			
GENERAL OBJECTIVE			
Specific Objective 1			Progress status (0%-25%-50%-75%-100%)
Activities	<i>Description of progress, based on the chosen indicator for the accomplishment of the activity</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add) in light of the continuation of the pilot and/or scalability/transferability</i>
Activity 1.1			
Add lines, if needed.			
Specific Objective 2			
Activities	<i>Description of progress...</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add) in the light of the continuation of the pilot and/or scalability/transferability</i>
Activity 2.1			
Add lines, if needed.			
Specific Objective 3			
Activities	<i>Description of progress...</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add) in light of the continuation of the pilot and/or scalability/transferability</i>
Activity 3.1			
Add lines, if needed.			

Template 17. STEP XI: Intermediate report No. 2

The core pilot team should assess the implementation progress for each specific objective by choosing one of the following levels of accomplishment:

- **0% - NOTHING DONE:** No progress towards the objective or initial steps taken
- **25% - BEGINNING:** Initial progress made and preliminary steps completed

- **50% - MIDWAY:** The objective is halfway achieved, with several key activities accomplished
- **75% - ADVANCED:** The objective is mostly accomplished with most activities completed
- **100% - COMPLETED:** The objective is fully achieved and all activities completed

Based on the results of the second implementation phase, the core pilot team should use the 4A principle (**adopt, adapt, abandon, add**) to determine the required changes to the activities, specific objectives, or the general objective of the pilot with a view to the sustainability of the pilot results and/or outcomes (life after JACARDI). For example:

- If the activity has already achieved the expected result, it is concluded and celebrated. If the activity achieves the expected progress but is still ongoing, it will be further **adopted** and included in the second implementation plan.
- If the activity fails to yield the expected results and the reason for the failure is known, the activity can be **adapted** accordingly in the next implementation plan.
- If the activity fails to yield the expected results or encounters massive barriers, it can be **abandoned** from the next implementation plan.
- If opportunities for advancement arise or any other favourable changes appear in the pilot situation, new activities can be **added** to the next implementation plan.

When deciding on potential changes, the core pilot teams should **also consider** the **findings of the country-level context analysis** (Chapter 3.2 ([link](#))). The core pilot teams should determine **the extent to which and how their pilots address the identified needs at the country level** and, if feasible, adjust their pilots to address them better.

In addition, the core pilot team should check the suggestions for the adaptations in the best/validated practice. Understanding these practices may be helpful when encountering problems and barriers.

Sustainability lens

The core pilot teams can use the guiding questions in the box below to reflect on needed adjustments from the sustainability perspective.

Guiding questions

Were the sustainability-supporting activities implemented as intended?
 What were the relevant achievements? Which results might be significant for the policy-makers?
 Which gaps within the healthcare system does the pilot address or even 'close'?
 Are there any discrepancies between the pilot's trajectory and the stakeholders' needs that the pilot impacts?
 If not, what within your setting or system would need to change for the adoption and potential spread of your pilot results and outcomes?
 Is there a need for adjustments to your pilot to make it sustainable?
 Consider your current achievements, opportunities, and supportive and negative factors. What could be your following planned activities to enhance further the sustainability of your pilot and/or potentially solve sustainability-related challenges?

Box 79. STEP XI Sustainability lens

Sustainability-supporting activities included in the second implementation plan should be assessed like other activities. In addition, there might be important aspects of sustainability that are impactful but were not directly included in the implementation plan. These aspects should be included in the second intermediate report (*Box 80. STEP XI Sustainability-supporting questions*).

Results of activity(-ies) planned to increase the potential for sustainability
Potential sustainability-supporting changes of contextual characteristics (existing health strategies/policy frameworks), potential holders of sustainability, and processes that support collaboration, consensus-seeking, and engagement of stakeholders:
Unplanned activities (including past events and arising opportunities) with potential impact on sustainability:
Supportive and/or negative factors (organisational, systemic, community, resources, individual):
Proposed future actions/solutions:

Box 80. STEP XI Sustainability-supporting questions

The core pilot team should consider the **equity and diversity principle** (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Equity and diversity lens

Guiding questions

Were diverse stakeholders engaged in the assessment of intermediate results?

Were the 4C principles of equity and diversity integrated in the intermediate reporting?

Box 81. STEP XI Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹²⁹ below to integrate the equity and diversity principle in their work and actions. (→ *Box 15. How to use the equity and diversity matrix?* **Box 15. How to use the equity and diversity matrix?**)

JACARDI, WPX, Pilot xx

¹²⁹ Only the part relevant for the current step is included, the whole matrix can be found in Annex IV.

Step XI. Intermediate Report No. 2, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
11.1 Engage diverse stakeholders in the assessment of intermediate results	a) Critical reflection was applied within the core pilot team to consider whether there is a need for changes at the action level or specific objectives levels that would further strengthen equity and diversity perspectives in the pilot, and these were described and assessed in the intermediate report. Relevant stakeholders were informed of key aspects of the intermediate report.	b) Consultations were conducted with diverse end-users/end-beneficiaries and other stakeholders to consider whether there is a need for changes at general objectives or specific objectives level that would further strengthen equity and diversity perspectives in the pilot, and these are described and assessed in the intermediate report.	c) Diverse end-users/end-beneficiaries and other stakeholders were meaningfully engaged through co-design to consider whether there is a need for changes at action level or specific objectives level that would further strengthen equity and diversity perspectives in the pilot, and these were described and assessed in the intermediate report.	
11.2 Integrate equity and diversity perspectives in intermediate reporting	a) Equity and diversity perspectives were reported under the general objective .	b) A specific objective related to equity and diversity (other than inclusive and accessible communications) was reported.	c) An activity related to equity and diversity (other than inclusive and accessible communications) was reported in relation to each specific objective.	
11.3 Integrate equity and diversity perspectives in intermediate reporting on pilot communication	a) The report explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 (Annex III) and the WP5 JACARDI terminology glossary for internal and external	b) A specific objective related to inclusive and accessible communications for pilot internal and external communication was reported.	c) An activity on inclusive and accessible communications for external and internal communication was reported in relation to each specific objective.	

	communication (Annex II).			
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Box 82. STEP XI Equity and diversity matrix

MULTIDIMENSIONAL ASSESSMENT REPORT NO. 2

The intermediate multidimensional assessment report is produced only if planned by a multidimensional assessment plan. The structure is presented in the template below (*Template 18. STEP XI Multidimensional assessment report No. 2*) (Annex VI) and feeds into Table 13 of the Final implementation report.

JACARDI, WPX, Pilot xx		
Step XI. Multidimensional assessment report No. 2		
Primary and secondary outcomes of the pilot		
	Intermediary results	Interpretation and implications
Primary outcome 1		
Add lines		
Secondary outcome 1		
Add lines		
Dimensions for the assessment of the pilot		
Effectiveness		
	Intermediary results	Interpretation and implications
Health outcome/patient-reported outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Patient experience		
	Intermediary results	Interpretation and implications
Patient-reported experience measure 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Economic efficiency		
	Intermediary results	Interpretation and implications
Economic efficiency-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Equity and diversity		
	Intermediary results	Interpretation and implications
Equity and diversity-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Sustainability, including scalability and/or transferability		
	Intermediary results	Interpretation and implications

Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis, and interpretation:		
Implementation and process outcomes		
	Intermediary results	Interpretation and implications
Implementation or process outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		

Template 18. STEP XI Multidimensional assessment report No. 2

CAPACITY-BUILDING

At this step, Task 5.6 provides continuous support to core pilot teams as they go through the implementation stage, and clarifications may be required on how to collect the required data better.

Box 83. STEP XI Capacity-building box

The core pilot team should also engage in **communication and dissemination** activities (Chapter 3.7 ([link](#))) if feasible.

REPORTING TIPS

A single-reporting system via the RedCap tool should be used in this step. All information collected within steps IX to XI should be reported in the final implementation report. Structure and detailed instructions are available in Annex VII.

The language used in articles from peer-reviewed journals in medicine (in the broadest sense) should be used.

In summary, the reporting should cover:

- Results – section on intermediary results
- All communication and dissemination activities are reported within the pilot communication report in the Annex of the final implementation report.

If relevant changes appeared with respect to the information already reported, the existing information should be updated and the changes justified.

Reporting covers the sustainability principle and the integration of the equity and diversity principle.

Timely reporting facilitates the work of core pilot teams, WP6-11 leadership teams, and others within JACARDI. The deadline for this reporting is November 2026.

Taking notes in every step can make the preparation of the final implementation report much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams. They should help core pilot teams in compiling the relevant parts of the final implementation report.

Box 84. STEP XI Reporting tips

3.9.12 Step XII: Final implementation report

Ideally, the core pilot team has already reported all the necessary information and data for steps I-VI (March 2025), VII-VIII (October/November 2025), and IX-XI (November 2026). In this step, the core pilot team has to update the information, add the missing data, interpret the results, and finalise the final implementation report. The latter serves as one of the principal instruments for documenting the implementation of each pilot within JACARDI and supports the sustainability of pilot results and outcomes.

The objective of this step is:

- to finalise the final implementation report

The **operative objectives** of this step are:

- Proactively interact with respective WP6-11 leadership teams
- Attend capacity-building activities (learning session 3 on final reporting)
- Deliver final multidimensional assessment results (within the final implementation report)
- Consider the findings from the country context analysis
- Reflect potentially on the learnings from best/validated practices
- Integrate the sustainability principle
- Integrate the equity and diversity perspective
- Engage in communication and dissemination activities
- Review the final implementation report template (all sections) and take notes to prepare relevant information in the defined format.
- Fill in the report using the REDCap tool.

The expected outputs of this step are:

- Final implementation report prepared (Deadline: January 2027)

The reporting in Step XII covers the following items:

- Reporting and updating all the necessary information and data for steps I-XI
- Final results (overall results, covering both implementation cycles, across Step VI to Step XI; see details in final implementation report templates)

Specific objective 1 description	Progress status assessment:		
Activity 1 description	Description of the progress based on the chosen indicator/means for the accomplishment of the activity	Summary of deviations	Decision on potential changes (adopt-adapt-abandon-add) in the light of pilot continuation and/or scalability/transferability
Add lines			

Template 19. Step XII. Final report – overall progress status

- Discussion (covering “What does that mean?”, i.e., interpretation, limitations, and conclusions including sustainability; see details in final implementation report template)

Primary and secondary outcomes of the pilot					
	Final results		Interpretation and implications		
Primary outcome 1					
Add lines					
Secondary outcome 1					
Add lines					
Dimensions for the assessment of the pilot					
Effectiveness					
	Final results		Interpretation and implications		
Health outcome/patient-reported outcome 1					
Add lines					
Barriers and enablers of data collection, analysis and interpretation:					
Patient experience					
	Final results		Interpretation and implications		
Patient-reported experience measure 1					
Add lines					
Barriers and enablers of data collection, analysis and interpretation:					
Economic efficiency					
	Final results		Interpretation and implications		
Economic efficiency-related outcome 1					
Add lines					
Barriers and enablers of data collection, analysis and interpretation:					
Equity and diversity					
	Final results		Interpretation and implications		
Equity and diversity related outcome 1					
Add lines					
Barriers and enablers of data collection, analysis and interpretation:					
Sustainability, including scalability and/or transferability					
	Final results (for example SWOT analysis)		Interpretation and implications		
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends					
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends					
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis and interpretation:					
Implementation and process outcomes					
	Final results (for example facilitators and barriers)		Interpretation and implications		
Implementation or process outcome 1					
Add lines					
Barriers and enablers of data collection, analysis and interpretation:					

Template 20. STEP XII: Multidimensional overall assessment

- Reporting and updating the reported information on all communication and dissemination activities (Pilot communication report summarises all the communication and dissemination activities undertaken from Step I to XII.)

For more information on the structure and detailed instructions on how to fill in the required information, please refer to Chapter 3.8 ([link](#)), especially Annex VII.

The same single-reporting system via the REDCap tool should be used for reporting. Once all pertinent data has been fed into the digital platform, the Final implementation report can be automatically generated and downloaded.

As previously stated, reporting covers the sustainability principle and the integration of equity and diversity principle. All core pilot teams use the equity and diversity matrix to report on the integration of the latter.

In addition, all information collected within Steps I to XI (including General information) should be checked, potentially updated, and justified, and the appropriate tenses should be used¹³⁰.

The deadline to finalise the final implementation report is January 2027. At this point in JACARDI, timely reporting is even more important since structured reporting of information facilitates the work of the core pilot team in sustainability planning (Steps XIII to XV). Final implementation reports are essential for WP6-11 leadership teams and several other tasks¹³¹ and WPs to produce the JACARDI final deliverables.

Also, in this step, the core pilot team should consider the **equity and diversity principle, as well as the sustainability principle** (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Sustainability lens

Guiding questions

Think about the final results from the sustainability perspective.

Were the sustainability-oriented actions implemented as intended?

What were the relevant achievements? Which results might be significant for the policymakers?

Which healthcare or other relevant systems gaps does the pilot address or close?

Are there any discrepancies between the pilot's trajectory and the stakeholders' needs that the pilot impacted?

What would need to change in your organisation or system for the adoption and spread of the pilot results?

Is there a need for adjustments to the pilot to make it sustainable?

Box 85. STEP XII Sustainability lens

¹³⁰ Abstract – past tense, Introduction – present tense, Methods – past tense, Results – past tense, Discussion – present tense and past tense

¹³¹ Please see Chapter 1 and 2 of this Deliverable

Integration of sustainability principle in JACARDI pilots is included in the Final implementation report, covering

- (a) key stakeholders and their level of involvement
- (b) relevant contextual characteristics
- (c) strengths of the core pilot team in achieving sustainability
- (d) specific sustainability-supporting activities, including the stakeholder board
- (e) sustainability as one of the dimensions within multidimensional assessment
- (f) and interpretation, implications and key findings relevant to sustainability.

For details, please see Appendix B of *Annex VII*.

Stakeholder	Level of involvement	Comments

Template 21. STEP XII: Template to report key stakeholders and their involvement during the implementation

Description of activity (What)	Final results	Interpretation and implications
Add lines		

Template 22. STEP XII: Template to report the final results of sustainability-supporting activities

General areas of contextual characteristics that potentially support sustainability	Sustainability-supporting contextual characteristics of the pilot
Existing health strategies/policy frameworks with strong connections to the pilot	
Potential holders/owners of sustainability	
Existing processes that support collaboration, consensus-seeking and engagement of stakeholders	

Template 23. STEP XII: Template to report on the sustainability-supporting contextual characteristics at the end of implementation

Equity and diversity lens

Guiding questions

Were the equity and diversity perspectives considered and clearly reported in the objectives?

Were the equity and diversity perspectives assessed in the results?

Is the report written using an inclusive and accessible language and editing?

Were the end-users engaged in interpreting and assessing the results?

Were the 4C principles applied in the dissemination of results?

Box 86. STEP XII Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹³² below to integrate the equity and diversity principle in their work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step XII. Final Implementation Report, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
12.1 Return results to the community and engage diverse stakeholders in the assessment of results	a) The assessment of results was conducted based on critical reflection within the core pilot team, and relevant stakeholders, including end-users and end-beneficiaries, were informed of the results.	b) Consultations were conducted with diverse end-users/end-beneficiaries when interpreting and assessing the results.	c) Results were interpreted and assessed in co-design with diverse end-users/end-beneficiaries.	
12.2 Integrate equity and diversity perspectives in reporting	a) Equity and diversity perspectives were reported under the general objective .	b) A specific objective related to equity and diversity (other than inclusive and accessible communications) was reported.	c) An activity related to equity and diversity (other than inclusive and accessible communications) was reported in relation to each specific objective.	
12.3 Integrate equity and diversity perspectives in reporting on pilot communication	a) The report explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 (Annex III) and the WP5 JACARDI terminology glossary for internal and external communication (Annex II).	b) A specific objective related to inclusive and accessible communications for pilot internal and external communication was reported.	c) An activity on inclusive and accessible communications for external and internal communication was reported in relation to each specific objective.	

Box 87. STEP XII Equity and diversity matrix

¹³² Only the part relevant for the current step is included, the whole matrix can be found in Annex IV.

CAPACITY-BUILDING ACTIVITIES

The core pilot team will learn more about finalising the final implementation report during **Learning session 3**, which should ideally take place at the beginning of Step XII. Since the reporting of the results has been generally covered in Learning session 2, the third learning session concentrates more on key findings, interpretation of results, and their implications – aiming at supporting the core pilot team to answer the question “What does that mean?”. For more information, please refer to Chapter 3.6 ([link](#)).

Box 88. STEP XII Capacity-building box

The core pilot team should also engage in **communication and dissemination** activities (See Chapter 3.7 ([link](#))) if feasible.

REPORTING TIPS

Timely reporting facilitates the work of core pilot teams, WP6-11 leadership teams, and others within JACARDI.

Box 89. STEP XII Reporting tips

3.9.13 Step XIII: Focus on key stakeholders' engagement in building sustainability

When the implementation within JACARDI ends and the final implementation report is almost prepared, the sustainability action planning begins. Step XIII focuses on **key stakeholders' engagement in developing the sustainability action plan** (Step XIV). This plan outlines the approach and activities needed to attain the sustainability of the pilot's results and outcomes.

The **objectives** of this step are:

- to organise at least one stakeholder board consultation meeting to identify priority areas and opportunities for future continuation, scale-up, and/or transfer of the key results, outcomes, and key findings of the pilot project to be included in the sustainability action plan

The **operative objectives** of this step are:

- Proactively interact with respective WP6-11 leadership teams
- Attend capacity-building activities ("Science-to-Policy" communication and interaction course, Learning session 4 on sustainability action planning)
- Consult country profiles with identified needs
- Check for the potential ideas in the best/validated practice
- Integrate the equity and diversity principle
- Engage in communication and dissemination activities
- Review the Sustainability action plan template and take notes to prepare relevant information in the defined format

The **expected result** of this step is:

- At least one stakeholder board consultation meeting organised

STAKEHOLDER BOARD CONSULTATION MEETING

To prepare for developing the sustainability action plan (Step XIV), the core pilot team will organise at least one stakeholder board consultation meeting with stakeholders that could contribute to the sustainability of the pilot's results, outcomes, and key findings.

Revisiting key stakeholders and their level of involvement

Ideally, the core pilot team has already established its stakeholder board during the situation and stakeholder analysis (Step III) or the development of the first pilot implementation plan (Step VI) and has engaged the board in the pilot's planning, implementation and assessment phases. However, while planning the stakeholder board consultation meeting, the core pilot team should revisit and (as needed) update their prior stakeholder analyses. The guiding questions below may facilitate this task:

- Which stakeholders could support the pilot to become a part of larger schemes of health system transformation?
- Which stakeholders or governance structures of the health system could assure systemic funding for and the continuity of the pilot's outcomes?
- Which stakeholders have the potential to become long-term owners of the pilot's outcomes?
- Which stakeholders (e.g., professional, patient, or community organisations) are impacted by the pilot's outcomes?

When revisiting the key stakeholder analysis, the core pilot team can use the template below ([Template 24. STEP XIII: Revisiting key stakeholders and their level of involvement](#)) (Annex VI).

JACARDI, WPX, Pilot xx			
Step XIII. Focus on key stakeholders' engagement in building sustainability			
Revisiting key stakeholders and their level of involvement			
Key stakeholders identified in Step III and their level of involvement	Key stakeholders identified during the implementation and their level of involvement	Key stakeholders identified in the present Step XIII and their level of involvement	
Final implementation report, Table 1	Final implementation report, Table 16	Institution/ person (Initials)	Level of involvement

Template 24. STEP XIII: Revisiting key stakeholders and their level of involvement

When reflecting on key stakeholders' engagement, the core pilot team should also consider the end-users/end-beneficiaries. A suggestion in this regard can be found in the box below (*Box 90. The importance of including diverse groups of end-users/end-beneficiaries*).

To achieve impactful, credible, and sustainable results, it is imperative to **ensure that the results of the pilot maximally meet the needs of the populations the pilots aim to serve (i.e. the end-users or end-beneficiaries)**. The optimal way to achieve this is by engaging diverse groups of end-users/end-beneficiaries from planning to implementation until dissemination of results. After all, the end-users/end-beneficiaries are the best to know what they need.

While end-users/end-beneficiaries are naturally also one of the stakeholder groups in the pilot, it is unlikely that a stakeholder board alone can provide a sufficiently broad range of lived experiences that are imperative for optimally understanding the end-users/end-beneficiaries.

Power imbalances likely to be present in stakeholder boards among different stakeholders may also prevent the end-users/end-beneficiaries from speaking up. Assembling several groups of diverse end-users/end-beneficiaries allows us to identify the key themes and discourses that should be considered in pilot actions.

Considering the 4Cs equity and diversity principles in end-users/end-beneficiaries' engagement contributes to end results that are more likely to be inclusive and accessible for a more significant proportion of the population, which is key for sustainability and social impact.

Box 90. The importance of including diverse groups of end-users/end-beneficiaries

Agenda of the stakeholder board consultation meeting(s)

The objectives of the stakeholder board consultation meeting are:

- to share key results, outcomes, and key findings of the pilot project
- to share key sustainability-related achievements of the pilot project
- to consult on country/region needs, potentially related to pilot project findings
- to consult on potentially supporting context characteristics
- to consult on other key stakeholders and communication opportunities
- to identify priority areas for future continuation /scale-up/transfer and rank them based on potential impact
- to identify opportunities for future continuation /scale-up/transfer and rank them based on potential impact
- to collect suggestions for key sustainability-supporting activities
- to agree on Stakeholder board consensus meeting

The annotated tentative agenda below can support the planning of the stakeholder board consultation meeting. The topics outlined in the template below (*Template 25. STEP XIII: Stakeholder board meeting: planning for sustainability beyond JACARDI – Annotated tentative agenda*) are relevant for the sustainability action planning and should be covered in the meeting.

JACARDI, WPX, Pilot xx	
Step XIII. Focus on key stakeholders' engagement in building sustainability	
STAKEHOLDER BOARD CONSULTATION MEETING: PLANNING FOR SUSTAINABILITY BEYOND JACARDI Annotated Tentative Agenda	
Introduction(s) and objectives of the meeting Key information on JACARDI Key information on sustainability as a principle	Presenters: Meeting organiser, Pilot Organizer, visible stakeholders (e.g., a representative of the Ministry of Health)
The key results, outcomes, and key findings of the pilot implementation and its sustainability-related achievements, as well as existing needs and gaps within the country/region that may benefit from the pilot's key findings	Presenters: The core pilot team
Session I: consultation with participants (1) on the needs of the country/regions relevant to the pilot key finding, (2) on the potentially supporting context characteristics, (3) on potential other key stakeholders not yet identifies, and (4) on potential communication opportunities.	Moderator + Rapporteur Participants: All Stakeholder board members
Session II: The identification and ranking of priority areas for the future use of the pilot's results and outcomes (1) within the setting of the pilot project, (2) for scaling up to other settings with similar target population/similar characteristics, (3) for transfer them to other target population, different settings or to include them in policies at the local, regional or national level.	

Session III: The identification and ranking of opportunities within the identified priority areas	
Session IV: Brainstorming on suggestions for key sustainability-supporting actions (including communication and dissemination) and related responsibilities to be included in the Sustainability Action Plan	
The following steps with information on the timeline of the Sustainability Action Plan development, including a consensus meeting of the Stakeholder board	Presenter: Meeting organiser/Pilot leader
The conclusion of the meeting	

Template 25. STEP XIII: Stakeholder board meeting: planning for sustainability beyond JACARDI – Annotated tentative agenda

The core pilot team should share the meeting materials with the invitees to ensure an efficient meeting. The materials can be prepared based on the final implementation report, if already available, or the notes covering the Final results and Discussion section of the Final implementation report. Overall insight into sustainability-related information within the final implementation plan is available in Appendix B of Annex VII. The most important aspect is that the materials are prepared with a focus on the **essentials important to the key stakeholders**. In addition, **appropriate language** should be used. The language used in the final implementation report is adjusted to the language that is usual for articles from peer-reviewed journals in medicine and thus may not be appropriate for the key stakeholders. The skills in managing that issue, among others, will be shared with core pilot teams in the Science-to-policy“ communication and interaction course (*Box 93. STEP XIII Capacity-building*).

The results of the stakeholder board meeting should be summarised in the template below (*Template 26. STEP XIII: Stakeholder board consultation meeting results*) (Annex VI).

JACARDI, WPX, Pilot xx		
Step XIII. Focus on key stakeholders’ engagement in building sustainability		
Step XIII. STAKEHOLDER BOARD CONSULTATION MEETING RESULTS		
Priority areas for the future continuation/sc ale-up/transfer of the pilot’s results, outcomes and key findings	List of priority areas	Ranking according to potential impact (high/mid/low)
	<ul style="list-style-type: none"> • ... • ... • ... • ... 	
Opportunities related to the priority areas	List of opportunities	Ranking according to potential impact (high/mid/low)

	<ul style="list-style-type: none"> • ... • ... • ... • ... 	
Key sustainability-supporting activities for Sustainability Action Plan 2027-28	PROPOSAL FOR ACTIVITIES	LEADING STAKEHOLDER, RESPONSIBLE STAKEHOLDER(s)

Template 26. STEP XIII: Stakeholder board consultation meeting results

The core pilot team should consider **the equity and diversity principle** (Chapter 3.4 ([link](#))). The following questions can be used to facilitate reflection.

Equity and diversity lens

Guiding questions

Was the key stakeholder analysis revisited and, if needed, revised?

Were the end-users/end beneficiaries meaningfully engaged throughout the pilot project, and were the voices of diverse groups impacted by the pilot heard? What improvements in this regard could be made during this step?

Were the 4C principles applied in the dissemination of results and sustainability actions during pilot project implementation? What improvements in this regard could be made during this step?

Box 91. STEP XIII Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹³³ below to integrate the equity and diversity principle in their work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx

¹³³ Only the part relevant for the current step is included, the whole matrix can be found in Annex IV.

Step XIII. Focus on key stakeholders' engagement in building sustainability, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
13.1 Revisit (and, if needed, revise) the key stakeholder analysis	a) Critical reflection applied within the core pilot team to review and revise the key stakeholders and their level of involvement, with consideration of diversity representation (e.g. experts and professionals, policymakers representing different disciplines and social groups, and persons with lived experiences).	b) Consultations conducted with diverse individuals, groups, or entities considered to be potentially directly or indirectly affected by the pilot to comprehensively review and revise relevant stakeholders.	c) Review and revision of key stakeholders carried out in co-design with diverse individuals, groups, or entities considered directly or indirectly affected by the pilot.	
13.2 Apply equity and diversity perspectives in the dissemination of results and sustainability activities	a) Critical reflection was applied within the core pilot team to identify priorities for future implementation, plans for dissemination of pilot results and sustainability activities.	b) Consultations were conducted with diverse end-users/end-beneficiaries and other stakeholders to identify priorities for future implementation, plans for dissemination of pilot results and sustainability activities.	c) Priorities for future implementation, plans for dissemination of pilot results and sustainability activities were identified in co-design with diverse end-users/end-beneficiaries and other stakeholders.	
13.3 Apply inclusivity and accessibility guidelines in material presented to the stakeholder board	a) Critical reflection was applied within the core pilot team in the development of materials presented to the stakeholder board, following the WP2 guidelines for inclusive and accessible	b) Consultations with diverse end-users/end-beneficiaries and other stakeholders were conducted during the development of materials presented to the stakeholder board, following the WP2 guidelines for	c) Materials presented to the stakeholder board were developed in co-design with diverse end-users/end-beneficiaries and other stakeholders, following the WP2 guidelines for inclusive and	

	communications (Annex III).	inclusive and accessible communications.	accessible communications	
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Box 92. STEP XIII Equity and diversity matrix

CAPACITY-BUILDING

The core pilot team learns about the development of the sustainability action plan (Step XIV) during the **“Science-to-policy” communication and interaction course** and during the **Learning Session 4**, which should ideally take place before or at the beginning of Step XIII. After attending these capacity-building activities, the core pilot team should be able to define the activities and other key elements of the sustainability action plan. More information on the capacity-building activities is provided in Chapter 3.6 ([link](#)).

Box 93. STEP XIII Capacity-building box

The core pilot team should also engage in **communication and dissemination** activities (Chapter 3.7 ([link](#))) if feasible.

REPORTING TIPS:

Timely reporting facilitates the work of core pilot teams, WP6-11 leadership teams and others within JACARDI. The deadline to deliver the approved Sustainability action plan (Step XV) is March 2027.

Taking notes in every step can make the preparation of the sustainability action plan much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11 and developed by WP6-11 leadership teams. They should help core pilot teams in compiling the relevant parts of the sustainability action plan.

Box 94. STEP XIII Reporting tips

3.9.14 Step XIV: Sustainability action plan

In this step, **the core pilot team prepares the draft sustainability action plan for two years after JACARDI**. The development of the plan is introduced in the capacity-building activities of Step XIII. The plan builds on all sustainability-related work completed in the previous steps. Particularly important are the identified priority areas (for the future continuation/scale-up/transfer of the pilot project results, outcomes and key findings) and opportunities (with potential impact on the uptake), and the sustainability-supporting activities that were drafted in Step XIII in collaboration with the stakeholder board. **The draft sustainability action plan should be developed in co-creation with the stakeholder board**, and the board should approve the finalised plan in Step XV.

The **objectives** of this step are to:

- to develop the draft sustainability action plan

The **operative objectives** of this step are:

- Proactively interact with respective WP6-11 leadership teams
- Consult country profiles with identified needs
- Check for the ideas in the best/validated practice
- Engage in communication and dissemination activities
- Integrate the equity and diversity perspective
- Review the sustainability action plan template and take notes to prepare relevant information in the defined format.
- Fill in the REDCap tool.

The **expected output** of this step is:

- Draft sustainability action plan is developed

The development of the sustainability action plan is not important only at the pilot level (to facilitate the potential future uptake of pilot results, outcomes, and key findings) but also forms the basis for the roadmaps that will be developed as the final products of the WP6-11 and may reinforce the sustainability of JACARDI's networks, knowledge, and impact.

STRUCTURE OF THE SUSTAINABILITY ACTION PLAN

The sustainability action plan follows a similar structure to the pilot implementation plan (Steps VI and IX), including defining a general objective, specific objectives, and activities. However, to serve the purpose, more importance is given to showing the development process, including the key stakeholders' active participation.

The **Sustainability action plan** includes the following sections:

- Title
- List of contributors
- Short summary
- Introduction
 - Burden of cardiovascular diseases and diabetes
 - JACARDI as a response of EU and EU countries
 - Needs and gaps of the country/region
 - Results and outcomes of the JACARDI pilot project

- Key sustainability supporting achievements of the JACARDI pilot project
- Process of development
 - Equity and diversity in action
 - Priority areas and their ranking
 - Opportunities
- Action plan
 - General objective and specific objectives
 - Activities
- Communication and dissemination

Box 95. Sustainability action plan structure

It is wise to acknowledge again that even though the same **REDCap tool** will be used to develop both the sustainability action plan and the final implementation report, the information between them will differ. The approach for reporting in the final implementation report is taken from the guidelines that support the publication of such information in peer-reviewed (medical) journals, and the language used should be adjusted to that particular type of reader. On the other hand, the sustainability action plans should be written for other types of readers, that is, for the key stakeholders (ideally – **with** them), using the structure and the language that is clear to them. In addition, the sustainability action plan has to be highly contextualised to the actual situation and needs of the country/region at that time point. It has to be developed and written so the key stakeholders can identify with it as much as possible since they will be responsible for its execution after JACARDI ends. So, the overlaps between the two reports do not exist.

For more guidance, please refer to Chapter 3.8 ([link](#)) and **Annex VII**.

When developing the sustainability action plan, the core pilot team should also consider the equity and diversity principle (Chapter 3.4 ([link](#))). The following question can be used to facilitate reflection.

Equity and diversity lens

Guiding question

Were the 4C principles applied during the development of the sustainability action plan?

Box 96. STEP XIV Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹³⁴ below to integrate the equity and diversity principle in their work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step XIV. Sustainability Action Plan, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments

¹³⁴ Only the part relevant for the current step is included, the whole matrix can be found in Annex IV.

14.1 Apply equity and diversity perspectives in the development of the sustainability action plan	a) Critical reflection was applied within the core pilot team in developing the sustainability action plan, including consideration of the impact and inclusivity of planned activities for diverse population groups.	b) The sustainability action plan was developed in consultations with diverse end-users/end-beneficiaries and other stakeholders, including consideration of the impact and inclusivity of planned activities for diverse population groups.	c) The sustainability action plan was developed in co-design with diverse end-users/end-beneficiaries and other stakeholders, including consideration of impact and inclusivity of planned activities for diverse population groups.	
14.2 Integrate equity and diversity perspectives in the sustainability action plan	a) Equity and diversity perspectives were integrated in the general objective of the sustainability action plan.	b) The sustainability action plan had at least one specific objective related to equity and diversity.	c) The sustainability action plan had an activity on equity and diversity under each specific objective.	
14.3 Integrate inclusive and accessible communications in the sustainability action plan	a) The sustainability action plan explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 (<i>Annex III</i>) and the WP5 JACARDI terminology glossary for internal and external communication (<i>Annex II</i>)	b) The sustainability action plan had a specific objective related to inclusive and accessible communications for pilot internal and external communication.	c) The sustainability action plan integrated an activity on inclusive and accessible communications for external and internal communication under each specific objective.	

Box 97. STEP XIV Equity and diversity matrix

The core pilot team should also engage in **communication and dissemination** activities (See Chapter 7 ([link](#))) if feasible.

REPORTING TIPS

Timely reporting facilitates the work of core pilot teams, WP6-11 leadership teams, and others within JACARDI. The deadline to deliver the approved sustainability action plan (Step XV) is March 2027; it is highly recommended that a draft sustainability action plan is prepared using the REDCap tool.

Taking notes in every step can make the preparation of the sustainability action plan much easier. The notes are typically collected in templates, adjusted to the needs of specific WP6-11, and developed by WP6-11 leadership teams. They should help core pilot teams compile the relevant parts of the sustainability action plan.

Box 98. STEP XIV Reporting tips

3.9.15 Step XV: Celebrate the success

In this step, the transition from JACARDI to future initiatives begins. The aim is to increase the visibility of the pilot's results, outcomes, and key findings already embedded in the sustainability action plan among those interested in and impacted by the pilot, as well as those with the power to support the pilot's sustainability.

The work builds on all the communication and dissemination activities that have taken place since the JA's beginning and has targeted diverse audiences both within and outside the JACARDI consortium. These activities have engaged a vast network of institutions and individuals, including high-level policy events, scientific conferences, stakeholder events with those most affected by the pilot, and social media communications. The best experiences and lessons learned from these activities should be considered when conducting Step XV.

The **objectives** of this step are:

- to organise a stakeholder board consensus meeting to reach a consensus on the sustainability action plan

The **operative objectives** of this step are:

- Launch the activities for communication and dissemination (as part of the sustainability action plan)
- Attend the final conference of JACARDI and, potentially, other planned national, regional, and local events
- Celebrate and co-create the way forward for JACARDI and its pilots.
- Equity and diversity perspectives should be considered throughout this step, applying the 4Cs principles when, for example, engaging diverse stakeholders, selecting speakers at dissemination events, visuals and written communications, and identifying the most appropriate dissemination channels.

The **expected output** of this step is:

- Stakeholder board consensus meeting organised, and the sustainability action plan is approved (Deadline: March 2027)

STAKEHOLDER BOARD CONSENSUS MEETING

Once the sustainability action plan has been co-created with the stakeholder board, **the core pilot team should organise a stakeholder board consensus meeting** to allow the board to approve and commit to the finalised plan.

The objectives of this consensus meeting are:

- to reach a consensus on the sustainability action plan
- to confirm buy-in
- to anchor the ownership
- to assure commitment to its execution
- to increase visibility.

For an efficient meeting, the core pilot team should share the final draft of the sustainability action plan with the board members in advance. In addition, the team may prepare a short fact sheet summarising the plan's key content. During the meeting, the representatives of key stakeholders can present their roles and responsibilities in implementing the plan.

The annotated tentative agenda below can support the planning of the stakeholder consensus meeting.

JACARDI, WPX, Pilot xx	
Step XV. Celebrating the success	
STAKEHOLDER BOARD CONSENSUS MEETING: TAKING SUSTAINABILITY ACTION PLAN ON BOARD Annotated Tentative Agenda	
Introduction(s) and objectives of the meeting	Presenters: Meeting organiser, Pilot organiser
Recap of the general outline of the Sustainability Action Plan with a focus on its general and specific objectives and the importance of proactive stakeholder involvement	Presenters: Core pilot team
Presentation I: Key stakeholder no. 1 presents their role in implementing the Sustainability Action Plan, adopting the responsibility for at least one concrete activity. (ensure representation of diversity among speakers)	Moderator: Meeting organiser Presenters: Representatives of key stakeholders Participants: All Stakeholder Board members
Presentation II: Key stakeholder no. 2 presents their role in implementing the Sustainability Action Plan, adopting the responsibility for at least one concrete activity. (ensure representation of diversity among speakers)	
Presentation III: Key stakeholder no. 3 presents their role in implementing the Sustainability Action Plan, adopting the responsibility for at least one concrete activity. (ensure representation of diversity among speakers)	
[Add agenda items as needed]	Moderator: Meeting organiser/Pilot organiser Participants: All Stakeholder Board members
Panel discussion ¹³⁵ acknowledging the work completed during JACARDI and the key stakeholders' future support for and ownership of the pilot's results and outcomes.	

Template 27. STEP XV: Stakeholder board consensus meeting - Annotated tentative agenda

COMMUNICATION AND DISSEMINATION ACTIVITIES

To launch the activities for communication and dissemination, the core pilot team and their key stakeholders should **organise local, regional, and/or national "Celebration Events,"** such as co-designed conferences, meetings, or policy dialogues. These events aim to communicate, disseminate, and advance the further adoption of the pilot's results and outcomes. In designing the "celebration events," the core pilot teams may employ the **core methodologies of the participatory leadership practice**¹³⁶, some of which are presented in the *table* below. These practices are designed to facilitate the engagement of various

¹³⁵ Consider adding a user/person with lived experience testimonial. The power of storytelling and testimonials of first-hand experience goes a long way.

¹³⁶ Participatory Leadership in the European Context, Workbook, Version 9.2, compiled and edited by Art of Hosting stewards: Maria Scordialos (Harà), Chris Corrigan, Toke Moller and Monica Nissén (InterChange), Mary-Alice Arthur (SOAR) and European Commission hosts: Matthieu Kleinschmager, Helen Titchen Beeth, Rainer von Leoprechting, Lena Ter Woort, Dirk Stockmans, Valda Liepina, Ursula Hillbrand.

groups in strategic conversations and to create conditions for unlocking the groups' collective wisdom in finding the best way to achieve a common purpose.

METHOD¹³⁷	PURPOSE
CIRCLE PRACTICE	Adaptable to a variety of groups, issues, and timeframes. Circle can be the process used for the duration of a gathering, particularly if the group is relatively small and time for deep reflection is a primary aim. Circle can also be used as a means for “checking in” and “checking out” or for making decisions together, particularly decisions based on consensus.
WORLD CAFÉ	Process used to foster interaction and dialogue with both large and small groups. Particularly effective in surfacing the collective wisdom of large groups of diverse people. Very flexible and adapts to many different purposes – information sharing, relationship building, deep reflection exploration and action planning.
OPEN SPACE	Useful in many contexts, including strategic direction-setting, envisioning the future, conflict resolution, morale building, consultation with stakeholders, community planning, collaboration and deep learning about issues and perspectives.
ACTION LEARNING	Question-based process used to explore complex problems and to come up with unexpected insights and possibilities. For use with small groups (minimum 5, maximum 8 people).
RITUAL DISSENT	Ritual Dissent is a workshop method designed to test and enhance proposals, stories, ideas, etc., by subjecting them to ritualised dissent (challenge) or assent (positive alternatives). In all cases, it is a forced listening technique, not a dialogue or discourse. Overall plans that emerge from the process are more robust than those surfaced by consensus-based techniques.

Table 7. Core methodologies of the participatory leadership practice (examples)

At the JACARDI consortium level, the Final conference will be a major opportunity to “Celebrate the success” and to provide visibility to all the work accomplished.

The equity and diversity perspective should be considered throughout this step, applying the 4Cs principles when, for example, engaging diverse stakeholders, selecting speakers at dissemination events, preparing visuals and written communications, and identifying the most appropriate dissemination channels.

¹³⁷ Source: Participatory Leadership in the European Context, Workbook, Version 9.2

Equity and diversity lens

Guiding question

Were the 4C principles considered during the final dissemination events?

Box 99. STEP XV Equity and diversity lens

In addition, the core pilot team can use the equity and diversity matrix¹³⁸ below to integrate equity and diversity principle in their work and actions. (→ [Box 15. How to use the equity and diversity matrix?](#))

JACARDI, WPX, Pilot xx				
Step XV. Celebrate the success, Equity and diversity matrix				
	Approaching	Meeting	Exceeding	Comments
15.1 Engage diverse stakeholders in planning final dissemination events	a) Diverse end-users/end-beneficiaries and other stakeholders were invited to final dissemination events.	b) Diverse end-users/end-beneficiaries and other stakeholders were consulted when planning final dissemination events.	c) Final dissemination events were co-designed with diverse end-users/end-beneficiaries and other stakeholders, and end-users/end-beneficiaries were included in pilot publications (if any).	
15.2 Consider representation among the speakers in the final dissemination events	a) Speakers at the final dissemination events represented different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	b) Speakers at the final dissemination events were moderately representative of the community the pilot aims to serve (i.e., 50% of key characteristics of the served community are represented within the team).	c) Speakers at the final dissemination events were representative of the community the pilot aims to serve (i.e., 75% or more of the key characteristics identified are represented within the team).	
15.3 Apply the principles of inclusive and accessible	a) Critical reflection was applied within the core pilot team when planning and	b) Diverse stakeholders were consulted when planning and	c) Planning and conducting final dissemination events were performed in	

¹³⁸ Only the part relevant for the current step is included, the whole matrix can be found in Annex IV.

communications in final dissemination events	conducting final dissemination events, following the WP2 guidelines for inclusive and accessible communications (<i>Annex III</i>).	conducting final dissemination events, following WP2 guidelines for inclusive and accessible communications.	co-design with diverse key stakeholders, following WP2 guidelines for inclusive and accessible communications.	
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Box 100. STEP XV Equity and diversity matrix

REPORTING TIPS

Communication and dissemination events performed in Steps XIII to XV should be reported based on recommendations from WP2 and WP6-11 leadership teams. Ideally, all events in this period should be made easily visible so that JACARDI’s presence is not hard to acknowledge.

Timely reporting facilitates the work of core pilot teams, WP6-11 leadership teams, and others within JACARDI. The deadline to deliver the approved Sustainability action plan (Step XV) is March 2027.

Box 101. STEP XV Reporting tips

4. Conclusions and recommendations

The JACARDI methodological framework represents a unique achievement in coordinating a harmonised, science-based, and equity-sensitive approach to implementing 143 pilots across 18 countries and six thematic areas. By integrating principles of implementation science with cross-cutting concepts such as sustainability and equity, the framework equips pilot teams with concrete, adaptable tools to design, monitor, and scale interventions in a structured yet flexible manner. The participatory and consensus-driven process that shaped the methodology has fostered ownership, coherence, and cross-country alignment, while allowing room for local contextualisation.

Acknowledging the inherent risk of shifts in local or national policy priorities, the JACARDI methodological framework promotes sustainability strategies that are not solely dependent on political continuity. By involving key stakeholders—including healthcare professionals, civil society, patient associations, and local actors, as well as local and national authorities such as Ministries of health—from the early stages of pilot design and throughout implementation, each pilot builds local ownership and relevance, which are crucial to sustaining actions despite changing policy landscapes. The participatory approach embedded in the methodological steps fosters the creation of flexible and context-sensitive Sustainability Action Plans, co-developed with those who are likely to carry the work forward. In addition, the inclusion of intermediary analyses and iterative adaptation cycles equips pilots with the tools to respond dynamically to external changes, ensuring that pilot actions remain aligned with the evolving needs and priorities of the communities they serve. Lastly, by anchoring implementation in evidence thanks to the context analysis activity, the methodological framework provides a robust foundation that can support the integration of pilot outcomes into broader strategic agendas, even in contexts of shifting political will.

To ensure the long-term availability and usability of the JACARDI methodological framework beyond the lifetime of the project, we recommend that its key components be further consolidated through a scientific publication. This would not only preserve the methodological heritage of the Joint Action but also allow it to be disseminated through permanent, peer-reviewed channels. Moreover, specific components of the overall methodological framework are also planning to independently publish their methodologies and results; for example, the European-level Context Analysis (Annex IV) and the integration of the equity and diversity lens (Annex II).

In addition, ongoing collaborations with the THCS Partnership—particularly in the area of methodological guidelines for implementation science—may offer an ideal platform to co-develop a shared summary of the framework. Such a joint output could serve as a reference for future initiatives and funding opportunities, ensuring that the value of the work carried out in JACARDI continues to inspire, inform, and guide long after the project ends.

In developing the JACARDI methodological framework, seven teams working across two WPs and constantly communicating and consensus-seeking across all WPs overcame several traps. We have shown the ability to work across different sciences and different fields and develop a common, single theoretical framework. For several aspects, the new tools were developed for use in JACARDI (Equity and diversity matrix, sustainability-supporting approaches covering all 48 months of JACARDI, Multidimensional assessment framework including a flowchart, and others). We substantially built on the previous experiences from similar JAs and projects. Principles of implementation science were massively used by succeeding in limiting the names of the tools, approaches, and methods to a minimum (following the result of JADECARE,

where implementation partners were asked to limit the use of acronyms of such tools as much as possible, “just tell us what to do”). We managed to convert the theory to the practical methodological guidelines and developed (generic) templates to cover most of the work that needs to be performed by the core pilot team while leaving the necessary flexibility for adaptation to the specific thematic area. We managed to develop two reporting templates for two main products – the Final implementation report and the Sustainability action plan. They have been double-checked to ensure that all important information the core pilot teams produce can be reported and further used. They have been many times checked for coherency, consistency, and completeness. And we managed to keep this work felt like a continuous journey of all teams, developing it, using it, and applying it.

The recommendation, therefore, stays that this constant flow among teams that develop and support the use of a certain aspect and the teams applying it in practice should be robust in both directions. Opportunities for discussions were many, and we should keep them. There were many challenges, and we managed to tackle several of them. However, we had failures, and we made mistakes. Luckily, a reflection process that should help us learn from our mistakes is in place. With so many individuals with open minds (and hearts) on board, we will be able to further reflect on the JACARDI methodological framework and the process of its development and refinement as the reality of the contexts within pilots’ settings hits.

Technical note:

This Methodological Framework should be regarded as the standard reference for the implementation and reporting of the JACARDI pilots. Nevertheless, given the dynamic nature of the project and the need to ensure full alignment with evolving requirements and adaptations, the framework may be subject to minor adjustments throughout the course of the project. Such adaptations will not affect the methodological foundation but will enhance consistency, accuracy, and responsiveness to the operational context. Accordingly, the framework represents a flexible yet robust structure, designed to balance methodological rigor with the practical demands of implementation.

In this context, the Booklet “To Guide the Pilot’s Journey” has been developed as a practical and operational tool. It serves to translate the framework into concrete guidance, offering a flexible instrument that accommodates necessary operational refinements and internal timeline adjustments, while remaining fully consistent with the overarching methodological approach.

Annexes





JACARDI

Joint action
cardiovascular diseases
and diabetes

ANNEX I: Detailed description of selected implementation science approaches

JACARDI WP Task 5.4



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Executive summary

JACARDI methodological framework is based on the principles of implementation science and proven tools designed and deployed in other Joint Actions (JA).

By focusing on the systematic integration of research findings into healthcare policies, programs and practices, implementation science ensures that evidence-based interventions are effectively adapted to local contexts. This approach maximises the impact of public health initiatives across diverse EU countries, addressing variability in healthcare systems and population needs. By grounding the project in implementation science, the framework becomes more adaptable, scalable and sustainable.

This document provides additional information on the implementation science approaches – tools and frameworks, that served as the basis for the development of the JACARDI methodological framework, including SWOT analysis methodology, CFIR (Consolidated Framework for Implementation Research), SCIROCCO maturity model, and Squire 2.0 (Standards for Quality Improvement Reporting Excellence) guidelines for reporting.

1. Introduction

1.1 Purpose and scope of the document

This document provides additional information on the implementation science approaches – tools and frameworks, that served as the basis for the development of the JACARDI methodological framework. The proposal was drafted based on the implementation principles and proven tools designed and deployed in other Joint Actions (JA), like JA CHRODIS¹, JA CHRODIS PLUS², JADECARE³ and CARE4DIABETES⁴ including the implementation strategy⁵, developed by Institute for Health Services Research – Kronikgune, now Biosistemak, Basque Country, Spain.

By focusing on the systematic integration of research findings into healthcare policies, programs and practices, implementation science ensures that evidence-based interventions are effectively adapted to local contexts. This approach maximises the impact of public health initiatives across diverse EU countries, addressing variability in healthcare systems and population needs. By grounding the project in implementation science, the framework becomes more adaptable, scalable and sustainable. In this context, reference frameworks used in the development of the JACARDI methodological framework include:

Model for improvement⁶, developed by Institute for Healthcare Improvement (IHI) is a simple yet powerful framework for accelerating improvement and has been used successfully in many industries, including thousands of health care organizations in numerous countries to improve countless different processes and outcomes.

The scaling-out methodology⁷, developed by the Biosistemak Institute for Health Systems Research of the Basque Country, Spain; promotes the replication of Good Practices (complex interventions consisting of several components, defined as being the parts that make the whole intervention and, in isolation or combination, can generate the power of the intervention) across European countries to enhance the transition of healthcare systems to digitally enabled, integrated, person-centred care.

CFIR⁸ (Consolidated Framework for Implementation Research) provides a framework of constructs arranged across five domains that have been associated with effective implementation and can be easily customized to diverse settings and scenarios. It promotes consistent use of constructs, systematic analysis, and organization of findings from implementation studies. The objective of CFIR is to provide researchers with a framework in which they can select the most relevant constructs in the particular field of their study and use them to diagnose the context of the implementation, evaluate the progress of this process, explain the results and improve the quality of the initiatives.

SWOT⁹ and SWOT-action planning. The SWOT analysis methodology is an analytical method which is used to identify and categorize significant internal (Strengths and Weaknesses) and external (Opportunities and Threats) factors faced either in a particular area, such as an organization, or a territory, such as a region,

¹ <https://chrodis.eu/>

² <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/projects-details/31061266/761307/3HP>

³ <https://www.jadecare.eu/>

⁴ <https://c4djointaction.eu/>

⁵ <https://ijic.org/articles/10.5334/ijic.8605>

⁶ <https://www.ihl.org/resources/how-to-improve>

⁷ <https://ijic.org/articles/10.5334/ijic.8605>

⁸ <https://cfirguide.org/>

⁹ <https://wikis.ec.europa.eu/display/ExactExternalWiki/SWOT+analysis+-+strengths%2C+weaknesses%2C+opportunities+and+threats>

nation, or city. This analysis allows revealing key enablers/positive forces and actual/potential barriers that need to be recognized and possibly addressed for the implementation of pilot project. It also enables participants to share their vision, make judgments in a structured way, build a common perception of the situation and develop a sense of ownership of the pilot project.

Theory of change¹⁰-action planning helps to identify solutions to effectively address the causes of problems that hinder progress and guide decisions on which approach should be taken, considering comparative advantages, effectiveness, feasibility and uncertainties that are part of any change process.

JADECARE Sustainability framework¹¹ identifies three core elements of sustainability for building up sustainable pilot projects: (1) sustainable practices are to be grounded in the health strategies and policy frameworks, with strong top-down and bottom-up connections; (2) holders of sustainability are needed to be present at different levels, facilitated by formal and informal networks; (3) culture of collaboration and consensus seeking is an essential value and engagement of partners is an unwritten rule.

SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence)¹² guidelines for reporting are intended as a guide to authors reporting on systematic, data-driven efforts to improve the quality, safety and value of healthcare. It was designed to increase the completeness and transparency of reporting of quality improvement work, and has contributed to the development of this body of literature by providing a guide to authors, editors, reviewers, educators and other stakeholders.

SCIROCCO Maturity model¹³ is an online participatory self-assessment tool that helps stakeholders to understand: (1) the local context and conditions for delivering integrated care in health and social care, including its strengths and weaknesses; (2) the readiness level of a country, region or organisation to adopt and scale-up integrated care; (3) the actions that more progressive regions have taken to be successful and enable information sharing, twinning and coaching to overcome barriers and accelerate results in demand-driven innovation.

Additional details on the underlying methodologies are provided in Annex 2. In addition, the Methodological framework uses proven tools designed and deployed in other Joint Actions (JA).

JA CHRODIS launched a comprehensive portal for health topics, focusing on providing well-founded information on chronic diseases, prevention, and healthy aging. This portal offers user-friendly resources and best practices in healthcare. By promoting health literacy and supporting policymakers, they aimed to improve people's quality of life and reduce the burden of chronic diseases to finally become a trusted source for all health-related questions.

JA CHRODIS PLUS identified solutions, tools and good practices that improve the care of people with chronic diseases and that can be adapted to the casuistry of various national and local settings across Europe. The key areas of the JA were: Integration into national policies, health promotion and disease prevention, multimorbidity care model, fostering the quality of care; and employment and chronic diseases.

¹⁰ <https://unsdg.un.org/sites/default/files/UNDG-UNDAF-Companion-Pieces-7-Theory-of-Change.pdf>

¹¹ JADECARE Deliverable 4.3 Characteristics of JADECARE practices, leading to sustainability and integration in national policies, available at <https://www.jadecare.eu/resources/>

¹² <https://www.squire-statement.org/index.cfm?fuseaction=Page.ViewPage&PageID=471>

¹³ https://scirocco-exchange-tool.inf.ed.ac.uk/en_gb/login/?redirect_to=https%3A%2F%2Fscirocco-exchange-tool.inf.ed.ac.uk%2Fen_gb%2F

JADECARE aimed to reinforce the capacity of health authorities to successfully address important aspects of health system transformation, in particular the transition to digitally enabled, integrated, person-centred care. In order to achieve this goal, JADECARE supported the transfer four evidence-based Good Practices selected by the Steering Group on Health Promotion and Prevention and Management of Non-Communicable Diseases of the European Commission, from original healthcare systems to other 21 healthcare systems across Europe.

CARE4DIABETES aims at reducing the burden of non-communicable diseases by providing a multidisciplinary lifestyle treatment intervention for type 2 diabetes with the potential to support Member States to promote new evidence-based policies and actions on patient empowerment, health promotion in people with type 2 diabetes, and cost-effective management of the disease, while improving the efficiency of health investments. For this means, the JA aims at transferring and implementing an identified evidence-based best practice across 12 Member States.

SCIROCCO Exchange¹⁴ was the EU Health Programme Funded Project aiming to improve the capacity of healthcare authorities to adopt and scale up integrated care. Building upon the preliminary achievements of the B3 Action Group on Integrated Care (of the European Innovation Partnership on Active and Healthy Ageing) that first developed the concept of the B3 Maturity Mode, the Scirocco Maturity Model was further refined and tested and supported by a validated online self-assessment tool for integrated care.

1.2 Structure of the document

This document is organised into several chapters: Executive summary, Introduction, Overview of selected implementation science approaches, and appendices. The overview section provides detailed description of the following implementation science approaches that were used in JACARDI:

- SWOT analysis methodology
- CFIR
- SCIROCCO maturity model
- Squire 2.0.

¹⁴ <https://www.sciroccoexchange.com/>

2. Overview of selected implementation science approaches

2.1 SWOT analysis methodology

The SWOT analysis methodology is an analytical method which is used to identify and categorize significant internal (Strengths and Weaknesses) and external (Opportunities and Threats) factors faced either in a particular area, such as an organization, or a territory, such as a region, nation, or city. This analysis helps an organization to determine how to allocate the resources to accomplish its goals.^{15,16}

It was originally developed for business and industry. It is widely used in the health sector too. The values of this method are its simplicity and applicability to different levels of operation.¹⁷

Performing a SWOT analysis allows to reveal key enablers/positive forces and actual/potential barriers that need to be recognized and possibly addressed for the implementation of the Local Good Practices at Next Adopter sites. It also enables participants to share their vision, make judgments in a structured way, build a common perception of the situation and develop a sense of ownership of the Local Good Practice.

The SWOT analysis is:

- *Flexible*: it can be applied to any context, program, and stage of implementation.
- *Simple*: although an expert facilitation to obtain the best of the SWOT analysis is required, the methodology is easy-to-use and accessible by non-technical stakeholders.
- *Structured*: the frame is well structured, making it easy to explore the different areas of analysis (S, W, O, T), to identify internal categories and to verify internal coherence.
- *Comparable*: being a structured method, it is possible to generate a meta-SWOT, comparing different analysis from different contexts.
- *Participatory*: the analysis can be performed by a group of experts and involve different stakeholders.

SWOT describes both internal attributes and external conditions (*Figure 1. Structure of a SWOT analysis*):

- **Strengths** are positive *internal* attributes that are within the organization's control. This section includes and identifies everything the organization does right when trying to achieve a specific goal, initiative or project.
- Weaknesses are negative *internal* attributes (also under the organization control). This section includes and identifies everything that keeps the organization from staying on track to achieving their goals, which need to be changed in order to achieve success. In this case, the Good Practice implementation.
- **Opportunities** are *external* positive conditions. They are outside the organization, but they can be of advantage to reach the projects goals and move the project forward. They may facilitate the implementation. They are often beyond the influence of a region or a local organisation, but it is important to know their possible influence. They include economics, technology, regulation and legislation, sociocultural changes.
- **Threats** are *external* conditions that may stand in the way or hinder the organization goals or project progress or implementation.

¹⁵ <https://wikis.ec.europa.eu/display/ExactExternalWiki/SWOT+analysis+-+strenqths%2C+weaknesses%2C+opportunities+and+threats>

¹⁶ Chapter 3. Assessing Community Needs and Resources | Section 14. SWOT Analysis: Strengths, Weaknesses, Opportunities, and Threats | Main Section | Community Tool Box [Internet]. [cited 2017 Nov 30]. Available from: <http://ctb.ku.edu/en/table-of-contents/assessment/assessing-community-needs-and-resources/swot-analysis/main>

¹⁷ "Idea: SWOT Analysis." The Economist (11 November 2009). Online at <http://www.economist.com/node/14301503>

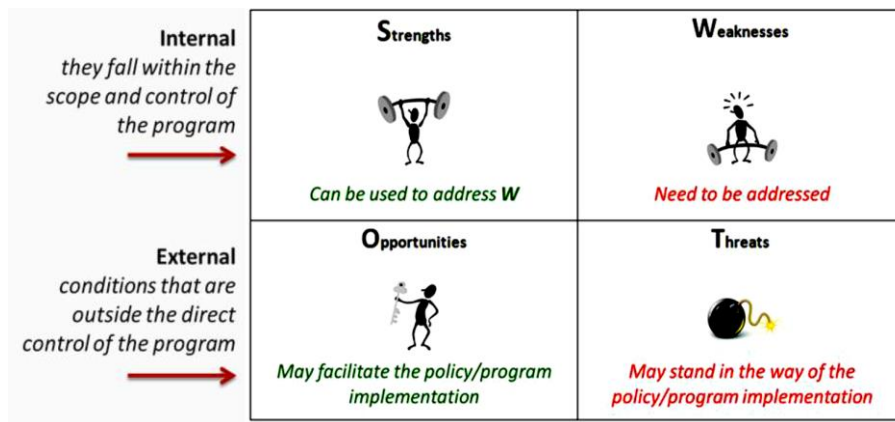


Figure 1. Structure of a SWOT analysis

The SWOT analysis addresses and highlights all the characteristics, relationships, and synergies among internal and with external variables of an initiative (i.e., policy or program). A two-by-two matrix is used to build a SWOT analysis, with horizontal pairings of internal (strengths and weaknesses) and external (opportunities and threats) factors, and vertical pairings of helpful (strengths and opportunities) and harmful (weaknesses and threats) factors in achieving an objective. Strengths, weaknesses, opportunities and threats can be scored according to what is seen as relevant regarding the Local Good Practice implementation and sustainability.

The timing of the SWOT analysis varies depending on the objectives. The analysis can be:

- Ex-ante: to improve planning and integration of a program in its context, **to perform a situation-analysis** and to evaluate the preconditions for the program implementation.
- Intermediate: to check the relevance and coherence of strategies, programmes and interventions, to re-evaluate if changes in S, W, O, T occurred in the man time, to explore elements that need to be addressed and to decide appropriate changes.
- Ex-post, for evaluation purpose.

In the frame of JACARDI, the SWOT analysis will be used ex-ante, preceding the implementation phase. The objective of the SWOT analysis is to use the knowledge an organization has about its internal and external environments and to formulate its strategy accordingly.

2.2 CFIR

Numerous interventions prove to be effective in research studies in health services, however, fail when they are intended to be transferred to different contexts and translated into results in patient care. It is estimated that two thirds of the efforts that organizations invest in implementing these changes do not obtain successful results. The barriers that hinder implementation affect various levels of health care provision: patient, care provision groups, health organization or policy. Consequently, there is a clear need to assess the extent to which the implementation of an intervention is effective in a specific context, with the aim of optimizing the benefits thereof, prolonging its sustainability and encouraging the dissemination of discoveries to other areas¹⁸.

The CFIR provides a framework of constructs arranged across five domains that have been associated with effective implementation and can be easily customized to diverse settings and scenarios. It promotes consistent use of constructs, systematic analysis, and organization of findings from implementation studies. The CFIR offers an overarching typology—a list of constructs to promote theory development and verification about what works where and why, across multiple contexts. The objective of CFIR is to provide researchers with a framework in which they can select the most relevant constructs in the particular field of their study and use them to diagnose the context of the implementation, evaluate the progress of this process, explain the results and improve the quality of the initiatives^{19, 20}.

The first version (*Figure 2. CFIR domains and constructs overview (2009)*) published in 2009 comprised of five major domains (the intervention, inner and outer setting, the individuals involved, and the process by which implementation is accomplished) and 39 constructs. The domains interact in rich and complex ways to influence implementation effectiveness.

¹⁸ Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci IS*. 2009 Aug 7;4:50.

¹⁹ Birken SA, Powell BJ, Pesseau J, Kirk MA, Lorenatto F, Gould NJ, et al. Combined use of the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF): a systematic review. *Implement Sci IS* [Internet]. 5 de enero de 2017; Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5217749/>

²⁰ Gomes B, Higginson IJ. Factors influencing death at home in terminally ill patients with cancer: systematic review. *BMJ*. 2006 Mar 2;332(7540):515–21.

CFIR domains and constructs (2009)		
Characteristics of the intervention		
1. Intervention Source	4. Adaptability	7. Design quality & packaging
2. Evidence Strength & quality	5. Trialability	8. Cost
3. Relative Advantage	6. Complexity	
Outer setting		
9. Patient needs & resources	11. Peer pressure	
10. Cosmopolitanism	12. External Policy & incentives	
Inner setting		
13. Structural characteristics	18. Compatibility	23. Readiness for implementation
14. Networks & communications	19. Relative priority	24. Leadership engagement
15. Culture	20. Organizational incentives & rewards	25. Available resources
16. Implementation climate	21. Goals and feedback	26. Access to knowledge & information
17. Tension for change	22. Learning climate	
Characteristics of the individuals		
27. Knowledge & beliefs about the intervention	29. Individual stage of change	31. Other personal attributes
28. Self-efficacy	30. Individual identification with organisation	
Process		
32. Planning	35. Formally appointed internal implementation leaders	37. External change-agents
33. Engaging	36. Champions	38. Executing
34. Opinion leaders		39. Reflecting & evaluating

Figure 2. CFIR domains and constructs overview (2009)

The Consolidated Framework for Implementation Research (CFIR) is one of the most commonly used determinant frameworks to assess these contextual factors; however, it has been over 10 years since publication and there is a need for updates.²¹ The 2022 Updated CFIR draws on more recent literature and feedback from users. User feedback was obtained from two sources: (1) a literature review with a systematic search; and (2) a survey of authors who used the CFIR in a published study.

²¹ Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. *et al.* The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation Sci* 17, 75 (2022). <https://doi.org/10.1186/s13012-022-01245-0>

CFIR domains and constructs (2020)		
Innovation		
A. Innovation sources	D. Innovation adaptability	G. Innovation design
B. Innovation evidence-base	E. Innovation trialability	H. Innovation cost
C. Innovation relative advantage	F. Innovation complexity	
Outer setting		
A. Critical incidents	E. Policies & laws	1. Societal pressure
B. Local attitudes	F. Financing	2. Market pressure
C. Local conditions	G. External pressure	3. Performance-measurement pressure
D. Partnerships & connections		
Inner setting		
<i>Regardless of implementation and/or delivery of the innovation</i>		
A. Structural characteristics	B. Relational connections	2. Recipient-centeredness
1. Physical infrastructure	C. Communications	3. Deliverer-centeredness
2. Information technology infrastructure	D. Culture	4. Learning-centeredness
3. Work infrastructure	1. Human equity-centeredness	
<i>Specific to the implementation and/or delivery of the innovation .</i>		
E. Tensions for change	I. Mission resources	3. Materials & Equipment
F. Compatibility	J. Available resources	Access to Knowledge & Information
G. Relative priority	1. Funding	
H. Incentive systems	2. Space	
Individuals		
<i>ROLES</i>		
A. High-level Leaders	D. Implementation Facilitators	G. Other Implementation
B. Mid-level Leaders	E. Implementation Leads	H. Innovation Deliverers
C. Opinion Leaders	F. Implementation Team Members	I. Innovation Recipients
<i>CHARACTERISTICS</i>		
A. Need	C. Opportunity	
B. Capability	D. Motivation	
Implementation process		
A. Teaming	D. Planning	G. Doing
B. Assessing needs	E. Tailoring strategies	H. Reflecting & evaluating
1. Innovation deliverers	F. Engaging	1. Implementation
2. Innovation recipients	1. Innovation deliverers	2. Innovation
C. Assessing context	2. Innovation recipients	I. Adapting

Figure 3. CFIR domain and constructs (2020)

Though the CFIR provides relatively detailed definitions for each construct, it is essential for users to fully operationalize constructs by adapting and using language that is meaningful for the context and individuals involved in implementing and delivering the innovation²².

Moreover, an Outcomes Addendum to the CFIR is proposed to offer clear conceptual distinctions between types of outcomes for use with the CFIR, and perhaps other determinant implementation frameworks as well²³.

Extensive descriptions of the constructs and outcomes addendum are included in the *Appendix A*. Updated CFIR constructs, in case needed.

²² Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. et al. The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation Sci* 17, 75 (2022). <https://doi.org/10.1186/s13012-022-01245-0>.

²³ Damschroder, L.J., Reardon, C.M., Opra Widerquist, M.A. et al. Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR Outcomes Addendum. *Implementation Sci* 17, 7 (2022). <https://doi.org/10.1186/s13012-021-01181-5>

2.3 SCIROCCO

SCIROCCO exchange was the EU health programme funded project aiming to improve the capacity of healthcare authorities to adopt and scale up integrated care²⁴. The central component is SCIROCCO exchange maturity model and tool which is an online participatory self-assessment tool that helps stakeholders to understand:

- the local context and conditions for delivering integrated care in health and social care, including its strengths and weaknesses;
- the readiness level of a country, region or organisation to adopt and scale-up integrated care;
- the actions that more progressive regions have taken to be successful and enable information sharing, twinning and coaching to overcome barriers and accelerate results in demand-driven innovation.

The SCIROCCO exchange maturity model (*Figure 4. SCIROCCO exchange maturity model*) considers the environment in which an intervention has developed, or into which will be implemented. The main goal of the model is to provide a multi-dimensional benchmark of the maturity of a context. As an ancillary technique the model helps recognizing the maturity requirements of healthcare systems to deliver integrated care to facilitate or guide the situational analysis.

The model has been derived from interviews that took place in 12 regions²⁵ within European countries responsible for health and care delivery that are part of the European innovation partnership on active and healthy ageing (EIP on AHA)²⁶. The many activities that need to be managed in order to deliver integrated care were grouped into 12 'dimensions':

1. Readiness to change
2. Structure and governance
3. Information and eHealth services
4. Standardization and simplification
5. Finance and funding
6. Removal of inhibitors
7. Population approach
8. Citizen empowerment
9. Evaluation methods
10. Breadth of ambition
11. Innovation management
12. Capacity building

²⁴ <https://www.sciroccoexchange.com>

²⁵ Attica (Greece), Basque Country (Spain), Catalonia (Spain), Delta (Netherlands), Olomouc region (Czech republic), Galicia (Spain), Northern Ireland (UK), Puglia (Italy), Saxony (Germany), Scotland (UK), Skane (Sweden), South Denmark (Denmark).

²⁶ https://ec.europa.eu/eip/ageing/home_en



Figure 4. SCIROCCO exchange maturity model

Extensive descriptions of the dimensions are included in the *Appendix B. SCIROCCO maturity model*, in case needed.

2.4 SQUIRE 2.0

The SQUIRE 2.0 guidelines (*Figure 5. Outline of the SQUIRE 2.0 guidelines*) are intended as a guide to authors reporting on systematic, data-driven efforts to improve the quality, safety and value of healthcare. It was designed to increase the completeness and transparency of reporting of quality improvement work, and has contributed to the development of this body of literature by providing a guide to authors, editors, reviewers, educators and other stakeholders.

SQUIRE 2.0 is designed to apply across the many approaches used for systematically improving the quality, safety and value of healthcare. Methods range from iterative changes using PDSA cycles in single settings to retrospective analyses of large-scale programs to multisite randomized trials.

It contains 18 items that respond to two general sections and four key questions:

- Title and abstract
- Why did you start?
- What did you do?
- What did you find?
- What does it mean?
- Other information

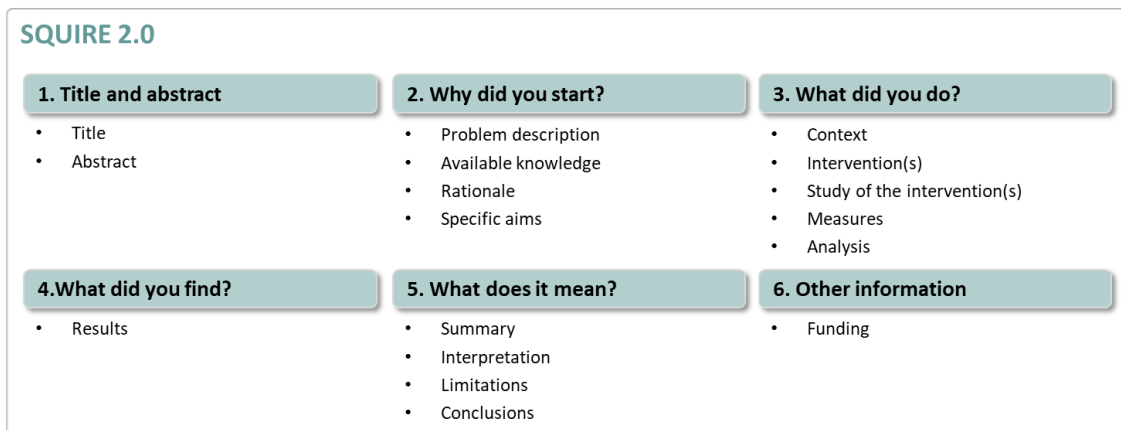


Figure 5. Outline of the SQUIRE 2.0 guidelines

SQUIRE 2.0 is intended for reporting the range of methods used to improve healthcare, recognizing that they can be complex and multidimensional. It provides common ground to share these discoveries in the scholarly literature.

A major challenge in the reporting of systematic efforts to improve healthcare is the multiplicity of terms used to describe the work. Terms such as quality improvement, implementation science and improvement science refer to approaches that have many similarities but can also connote important (and often debated) differences^{27, 28}.

²⁷ Goodman D, Ogrinc G, Davies L, Baker GR, Barnsteiner J, Foster TC, et al. Explanation and elaboration of the SQUIRE (Standards for Quality Improvement Reporting Excellence) Guidelines, V.2.0: examples of SQUIRE elements in the healthcare improvement literature. *BMJ Qual Saf.* 2016 Apr 27;bmjqs-2015-004480.

²⁸ Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised Publication Guidelines from a Detailed Consensus Process. *Can J Diabetes.* 2015 Oct 1;39(5):434–9.

Appendices

Appendix A. Updated CFIR constructs

I. INNOVATION DOMAIN

Innovation: The “thing” being implemented, e.g., a new clinical treatment, educational program, or city service.

[Document the innovation being implemented, e.g., innovation type, innovation core vs. adaptable components, using a published reporting guideline. Distinguish the innovation (the “thing” that continues when implementation is complete) from the implementation process and strategies used to implement the innovation (activities that end after implementation is complete).]

Construct Name	Construct Definition <i>The degree to which:</i>
A. Innovation Source	The group that developed and/or visibly sponsored use of the innovation is reputable, credible, and/or trustable.
B. Innovation Evidence-Base	The innovation has robust evidence supporting its effectiveness.
C. Innovation Relative Advantage	The innovation is better than other available innovations or current practice.
D. Innovation Adaptability	The innovation can be modified, tailored, or refined to fit local context or needs.
E. Innovation Trialability	The innovation can be tested or piloted on a small scale and undone.
F. Innovation Complexity	The innovation is complicated, which may be reflected by its scope and/or the nature and number of connections and steps.
G. Innovation Design	The innovation is well designed and packaged, including how it is assembled, bundled, and presented.
H. Innovation Cost	The innovation purchase and operating costs are affordable.

II. OUTER SETTING DOMAIN

Outer Setting: The setting in which the Inner Setting exists, e.g., hospital system, school district, state. There may be multiple Outer Settings and/or multiple levels within the Outer Setting (e.g., community, system, state).

Construct Name	Construct Definition <i>The degree to which:</i>
A. Critical Incidents	Large-scale and/or unanticipated events disrupt implementation and/or delivery of the innovation.
B. Local Attitudes	Sociocultural values (e.g., shared responsibility in helping recipients) and beliefs (e.g., convictions about the worthiness of recipients) encourage the Outer Setting to support implementation and/or delivery of the innovation.
C. Local Conditions	Economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation and/or delivery of the innovation.
D. Partnerships & Connections	The Inner Setting is networked with external entities, including referral networks, academic affiliations, and professional organization networks.
E. Policies & Laws	Legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation.
F. Financing	Funding from external entities (e.g., grants, reimbursement) is available to implement and/or deliver the innovation.
G. External Pressure	External pressures drive implementation and/or delivery of the innovation. Note: Use this construct to capture themes related to External Pressures that are not included in the subconstructs below.

- 1. Societal Pressure** Mass media campaigns, advocacy groups, or social movements or protests drive implementation and/or delivery of the innovation.
- 2. Market Pressure** Competing with and/or imitating peer entities drives implementation and/or delivery of the innovation.
- 3. Performance-Measurement Pressure** Quality or benchmarking metrics or established service goals drive implementation and/or delivery of the innovation.

Project Outer Setting(s): [Document the actual Outer Setting in the project, e.g., type, location, and the boundary between the Outer Setting and the Inner Setting.]

Construct Name	Construct Definition <i>The degree to which:</i>
Note:	<i>Constructs A – D exist in the Inner Setting regardless of implementation and/or delivery of the innovation, i.e., they are persistent general characteristics of the Inner Setting.</i>
A. Structural Characteristics	Infrastructure components support functional performance of the Inner Setting. Note: Use this construct to capture themes related to Structural Characteristics that are not included in the subconstructs below.
1. Physical Infrastructure	Layout and configuration of space and other tangible material features support functional performance of the Inner Setting.
2. Information Technology Infrastructure	Technological systems for tele-communication, electronic documentation, and data storage, management, reporting, and analysis support functional performance of the Inner Setting.
3. Work Infrastructure	Organization of tasks and responsibilities within and between individuals and teams, and general staffing levels, support functional performance of the Inner Setting.
B. Relational Connections	There are high quality formal and informal relationships, networks, and teams within and across Inner Setting boundaries (e.g., structural, professional).
C. Communications	There are high quality formal and informal information sharing practices within and across Inner Setting boundaries (e.g., structural, professional).
D. Culture	There are shared values, beliefs, and norms across the Inner Setting. Note: Use this construct to capture themes related to Culture that are not included in the subconstructs below.
1. Human Equality-Centeredness	There are shared values, beliefs, and norms about the inherent equal worth and value of all human beings.
2. Recipient-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of recipients.
3. Deliverer-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of deliverers.
4. Learning-Centeredness	There are shared values, beliefs, and norms around psychological safety, continual improvement, and using data to inform practice.
Note:	<i>Constructs E – K are specific to the implementation and/or delivery of the innovation.</i>
E. Tension for Change	The current situation is intolerable and needs to change.
F. Compatibility	The innovation fits with workflows, systems, and processes.
G. Relative Priority	Implementing and delivering the innovation is important compared to other initiatives.
H. Incentive Systems	Tangible and/or intangible incentives and rewards and/or disincentives and punishments support implementation and delivery of the innovation.
I. Mission Alignment	Implementing and delivering the innovation is in line with the overarching commitment, purpose, or goals in the Inner Setting.
J. Available Resources	Resources are available to implement and deliver the innovation. Note: Use this construct to capture themes related to Available Resources that are not included in the subconstructs below.
1. Funding	Funding is available to implement and deliver the innovation.
2. Space	Physical space is available to implement and deliver the innovation.
3. Materials & Equipment	Supplies are available to implement and deliver the innovation.

K. Access to Knowledge & Information Guidance and/or training is accessible to implement and deliver the innovation.

III. INNER SETTING DOMAIN

Inner Setting: The setting in which the innovation is implemented, e.g., hospital, school, city. There may be multiple Inner Settings and/or multiple levels within the Inner Setting, e.g., unit, classroom, team.

Project Inner Setting(s): [Document the actual Inner Setting in the project, e.g., type, location, and the boundary between the Outer Setting and the Inner Setting.]

IV. INDIVIDUALS DOMAIN

Individuals: The roles and characteristics of individuals.

ROLES SUBDOMAIN

Project Roles: [Document the roles applicable to the project and their location in the Inner or Outer Setting.]

Construct Name	Construct Definition <i>The degree to which:</i>
A. High-level Leaders	Individuals with a high level of authority, including key decision-makers, executive leaders, or directors.
B. Mid-level Leaders	Individuals with a moderate level of authority, including leaders supervised by a high-level leader and who supervise others.
C. Opinion Leaders	Individuals with informal influence on the attitudes and behaviors of others.
D. Implementation Facilitators	Individuals with subject matter expertise who assist, coach, or support implementation.
E. Implementation Leads	Individuals who lead efforts to implement the innovation.
F. Implementation Team Members	Individuals who collaborate with and support the Implementation Leads to implement the innovation, ideally including Innovation Deliverers and Recipients.
G. Other Implementation Support	Individuals who support the Implementation Leads and/or Implementation Team Members to implement the innovation.
H. Innovation Deliverers	Individuals who are directly or indirectly delivering the innovation.
I. Innovation Recipients	Individuals who are directly or indirectly receiving the innovation.

CHARACTERISTICS SUBDOMAIN

Project Characteristics: [Document the characteristics applicable to the roles in the project based on the COM-B system or role-specific theories.]

Construct Name	Construct Definition: <i>The degree to which:</i>
A. Need	The individual(s) has deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation.
B. Capability	The individual(s) has interpersonal competence, knowledge, and skills to fulfill Role.
C. Opportunity	The individual(s) has availability, scope, and power to fulfill Role.
D. Motivation	The individual(s) is committed to fulfilling Role.

V. IMPLEMENTATION PROCESS DOMAIN

Implementation Process: The activities and strategies used to implement the innovation.

Project Implementation Process: [Document the implementation process framework and/or activities and strategies being used to implement the innovation. Distinguish the implementation process used to implement the innovation (activities that end after implementation is complete) from the innovation (the “thing” that continues when implementation is complete).]

Construct Name	Construct Definition: <i>The degree to which individuals:</i>
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A. Teaming	Join together, intentionally coordinating and collaborating on interdependent tasks, to implement the innovation.
B. Assessing Needs	Collect information about priorities, preferences, and needs of people. Note: Use this construct to capture themes related to Assessing Needs that are not included in the subconstructs below.
1. Innovation Deliverers	Collect information about the priorities, preferences, and needs of deliverers to guide implementation and delivery of the innovation.
2. Innovation Recipients	Collect information about the priorities, preferences, and needs of recipients to guide implementation and delivery of the innovation.
C. Assessing Context	Collect information to identify and appraise barriers and facilitators to implementation and delivery of the innovation.
D. Planning	Identify roles and responsibilities, outline specific steps and milestones, and define goals and measures for implementation success in advance.
E. Tailoring Strategies	Choose and operationalize implementation strategies to address barriers, leverage facilitators, and fit context.
F. Engaging	Attract and encourage participation in implementation and/or the innovation. Note: Use this construct to capture themes related to Engaging that are not included in the subconstructs below.
1. Innovation Deliverers	Attract and encourage deliverers to serve on the implementation team and/or to deliver the innovation.
2. Innovation Recipients	Attract and encourage recipients to serve on the implementation team and/or participate in the innovation.
G. Doing	Implement in small steps, tests, or cycles of change to trial and cumulatively optimize delivery of the innovation.
H. Reflecting & Evaluating	Collect and discuss quantitative and qualitative information about the success of implementation. Note: Use this construct to capture themes related to Reflecting & Evaluating that are not included in the subconstructs below.
1. Implementation	Collect and discuss quantitative and qualitative information about the success of implementation.
2. Innovation	Collect and discuss quantitative and qualitative information about the success of the innovation.
I. Adapting	Modify the innovation and/or the Inner Setting for optimal fit and integration into work processes.

An **Outcomes Addendum** to the CFIR is proposed to offer clear conceptual distinctions between types of outcomes for use with the CFIR, and perhaps other determinant implementation frameworks as well²⁹.

I. ANTECEDENT ASSESSMENTS	
Name	Definition
A. Acceptability	The extent to which an innovation is perceived as “agreeable, palatable, or satisfactory” (Proctor, 2009).
B. Appropriateness	The “perceived fit, relevance, or compatibility of the innovation [...] for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem” (Proctor, 2009).
C. Feasibility	The extent to which an innovation “can be successfully used or carried out within a given agency or setting” (Proctor, 2009).
D. Implementation Climate	The extent to which the Inner Setting has an implementation climate.
E. Implementation Readiness	The extent to which the Inner Setting is ready for implementation.
II. IMPLEMENTATION OUTCOMES	

²⁹ Damschroder, L.J., Reardon, C.M., Opra Widerquist, M.A. *et al.* Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR Outcomes Addendum. *Implementation Sci* 17, 7 (2022). <https://doi.org/10.1186/s13012-021-01181-5>

Name	Definition
A. Anticipated Implementation Outcomes	Outcomes based on perceptions or measures of the likelihood of future implementation success or failure, i.e., implementation outcomes that have not yet occurred. These outcomes are forward-looking; constellations of CFIR determinants across domains predict these outcomes.
1. Adoptability	The likelihood key decision-makers will decide to put the innovation in place/innovation deliverers will decide to deliver to innovation.
2. Implementability	The likelihood the innovation will be put in place or delivered.
3. Sustainability	The likelihood the innovation will be put in place or delivered over the long-term.
B. Actual Implementation Outcomes	Outcomes based on perceptions or measures of current (or past) implementation success or failure, i.e., implementation outcomes that have occurred. These outcomes are backward-looking; constellations of CFIR determinants across domains explain these outcomes.
1. Adoption	The extent key decision-makers decide to put the innovation in place/innovation deliverers decide to deliver the innovation.
2. Implementation	The extent the innovation is in place or being delivered.
3. Sustainment	The extent the innovation is in place or being delivered over the long-term.
III. INNOVATION OUTCOMES	Outcomes that capture the success or failure of the innovation, based on the impact of the innovation on three important constituents: Innovation Recipients, Innovation Deliverers, and Key Decision-Makers. Impact is defined by: Reach ("The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program.") x Innovation Effectiveness ("The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes.")
Name	Definition
A. Innovation Recipient Impact	Recipient Reach x Innovation Effectiveness
B. Innovation Deliverer Impact	Deliverer Reach x Innovation Effectiveness
C. Key-Decision Maker (or System) Impact	Key-Decision Maker Reach x Innovation Effectiveness

Appendix B. SCIROCCO maturity model

1. Readiness to Change

Objectives:

If the existing systems of care need to be re-designed to provide a more integrated set of services, this will require change across many levels, the creation of new roles, processes and working practices, and new systems to support information sharing and collaboration across care teams. This will be disruptive and may be viewed negatively by workers, press and public, so a clear case needs to be made for those changes, including a justification, a strategic plan, and a vision of better care.

- Creating a compelling vision, with a real sense of urgency, and enlisting stakeholder support including political leadership, management, care professionals, public and press.
- Accepting the reality that care systems are unsustainable and need to change.
- Publishing a clear description of the issues, the choices that need to be made, and the desired future state of the care systems, stating what will be the future experience of care.
- Creating a sense of urgency to ensure sustained focus, and building a 'guiding coalition' for change.

Assessment scale:

- 0 – No acknowledgement of compelling need to change
- 1 – Compelling need is recognised, but no clear vision or strategic plan
- 2 – Dialogue and consensus-building underway; plan being developed
- 3 – Vision or plan embedded in policy; leaders and champions emerging
- 4 – Leadership, vision and plan clear to the general public; pressure for change
- 5 – Political consensus; public support; visible stakeholder engagement.

2. Structure & Governance

Objectives:

The broad set of changes needed to deliver integrated care at a regional or national level presents a significant challenge. It needs multi-year programmes with excellent change management, funding and communications, and the power to influence and (sometimes) mandate new working practices. This means alignment of purpose across diverse organisations and professions, and the willingness to collaborate and put the interest of the overall care system above individual incentives. It also means managing the introduction of eHealth services to enable integrated care in a way that makes them easy to use, reliable, secure, and acceptable to care professionals and citizens alike.

- Enabling properly funded programmes, including a strong programme, project management and change management; establishing ICT or eHealth competence centres to support roll-out; distributed leadership, to reduce dependency on a single heroic leader; excellent communication of goals, progress and successes.
- Managing successful eHealth innovation within a properly funded, multi-year transformation programme.
- Establishing organisations with the mandate to select, develop and deliver eHealth services.

Assessment scale:

- 0 – Fragmented structure and governance in place
- 1 – Recognition of the need for structural and governance change
- 2 – Formation of task forces, alliances and other informal ways of collaborating
- 3 – Governance established at a regional or national level

- 4 – Roadmap for a change programme defined and broadly accepted
- 5 – Full, integrated programme established, with funding and a clear mandate.

3. ICT & eHealth Services

Objectives:

Integrated care requires, as a foundational capability, sharing of health information and care plans across diverse care teams that lead progressively to systems for enabling continuous collaboration, measuring and managing outcomes, and enabling citizens to take a more active role in their care. This means building on existing eHealth services, connecting them in new ways to support integration, and augmenting them with new capabilities, such as enhanced security and mobility.

- Essential components to enable information-sharing, based on secure and trusted services.
- ‘Digital first’ policy (where possible, move phone and face-to-face services to digital services to reduce dependence on staff and promote self-service).
- Availability of fundamental building blocks to enable eHealth and eServices (‘infostructure’).
- Confidentiality and security designed into patient records, registries, online services etc.
- Enabling of new channels for healthcare delivery to replace face-to-face and telephone contact.

Assessment scale:

- 0 – ICT systems are not designed to support integrated care
- 1 – ICT and eHealth services to support integrated care are being piloted
- 2 – ICT and eHealth services to support integrated care are deployed but there is not yet region wide coverage
- 3 – ICT and eHealth services to support integrated care are planned and deployed widely at large scale but use of these services is not mandated
- 4 – Mandated or funded use of regional/national eHealth infrastructure across the healthcare system
- 5 – Universal, at-scale regional/national eHealth services used by all integrated care stakeholders.

4. Standardisation & Simplification

Objectives:

When considering eHealth services and how they can support the information sharing and collaboration needs of integrated care, the task can be made easier if the number of different systems in use, and the formats in which they store data, can be simplified. Practically, this means trying to consolidate data centres, standardising on fewer systems, and agreeing on what informatics standards will be used across a region or country.

- Simplification of infrastructure; fewer integration points to manage; easier interoperability.
- Consolidation of applications and data centres into fewer sites.
- Regional standardisation on fewer (or single) solutions.
- Ability to view and exchange medical data from different systems across diverse care settings.

Assessment scale:

- 0 – No standards in place or planned that support integrated care services
- 1 – Discussion of the necessity of ICT to support integrated care and of any standards associated with that ICT
- 2 – An ICT infrastructure to support integrated care has been agreed together with a recommended set of information standards – there may still be local variations

3 – A recommended set of agreed information standards at regional/national level; some shared procurements of new systems at regional/national level; some large-scale consolidations of ICT underway

4 – A unified set of agreed standards to be used for system implementations specified in procurement documents; many shared procurements of new systems; consolidated data centres and shared services widely deployed

5 – A unified and mandated set of agreed standards to be used for system implementations fully incorporated into procurement processes; clear strategy for regional/national procurement of new systems; consolidated datacentres and shared services (including the cloud) is normal practice.

5. Funding

Objectives:

Changing systems of care so that they can offer better integration requires initial investment and funding; a degree of operational funding during transition to the new models of care; and on-going financial support until the new services are fully operational and the older ones are de-commissioned. Ensuring that initial and on-going costs can be financed is an essential activity that uses the full range of mechanisms from regional/national budgets to ‘stimulus’ funds, European Union investment funds, public-private partnerships (PPP) and risk-sharing mechanisms).

Assessment scale:

0 – No additional funding is available to support the move towards integrated care

1 – Funding is available but mainly for the pilot projects and testing

2 – Consolidated innovation funding available through competitions/grants for individual care providers and small-scale implementation

3 – Regional/national (or European) funding or PPP for scaling-up is available

4 – Regional/national funding for on-going operations is available

5 – Secure multi-year budget, accessible to all stakeholders, to enable further service development.

6. Removal of Inhibitors

Objectives:

Even with political support, funded programmes and good eHealth infrastructure, many factors can still make integrated care difficult to deliver, by delaying change or limiting how far change can go. These include legal issues with data governance, resistance to change from individuals or professional bodies, cultural barriers to the use of technology, perverse financial incentives, and lack of skills. These factors need to be recognised early, and a plan developed to deal with them, so as to minimise their impact.

- Actions to remove barriers: legal, organisational, financial, skills.
- Changes to the law concerning e.g., medical acts, information governance, data sharing –factors which may hold up innovation.
- Creation of new organisations or collaborations to encourage cross-boundary working (‘normative integration’).
- Changes to reimbursement to support behavioural change and process change.
- Education and training to increase understanding of ICT and speed up solution delivery.

Assessment scale:

0 – No awareness of the effects of inhibitors on integrated care

1 – Awareness of inhibitors but no systematic approach to their management is in place

- 2 – Strategy for removing inhibitors agreed at a high level
- 3 – Implementation Plan and process for removing inhibitors have started being implemented locally
- 4 – Solutions for removal of inhibitors developed and commonly used
- 5 – High completion rate of projects & programmes; inhibitors no longer an issue for service development

7. Population Approach

Objectives:

Integrated care can be developed to benefit those citizens who are not thriving under existing systems of care, in order to help them manage their health and care needs in a better way, and to avoid emergency calls and hospital admissions and reduce hospital stays. This is a practical response to meeting today's demands. Population health goes beyond this, and uses methods to understand where future health risk (and so, demand) will come from. It offers ways to act ahead of time, to predict and anticipate, so that citizens can maintain their health for longer and be less dependent on care services as they age.

- Understanding and anticipating demand; meeting needs better.
- Improving the resilience of care systems by using existing data on public health, health risks, and service utilisation.
- Taking steps to divert citizens into more appropriate and convenient care pathways based on user preferences.
- Predicting future demand and taking steps to reduce health risks through technology-enabled public health interventions.

Assessment scale:

- 0 – Population health approach is not applied to the provision of integrated care services
- 1 – A population risk approach is applied to integrated care services but not yet systematically or to the full population
- 2 – Risk stratification is used systematically for certain parts of the population (e.g. high-use categories)
- 3 – Group risk stratification for those who are at risk of becoming frequent service users
- 4 – Population-wide risk stratification started but not fully acted on
- 5 – Whole population stratification deployed and fully implemented.

8. Citizen Empowerment

Objectives:

Health and social care systems are under increasing pressure to respond to demands that could otherwise be handled by citizens and carers themselves. The evidence suggests that many individuals would be willing to do more to participate in their own care if easy-to-use services, such as appointment booking, self-monitoring of health status, and alternatives to medical appointments, were available to them. This means providing services and tools that enable convenience, offer choice, and encourage self-service and engagement in health management.

Assessment scale:

- 0 – Citizen empowerment is not considered as part of integrated care provision
- 1 – Citizen empowerment is recognised as important part of integrated care provision but effective policies to support citizen empowerment are still in development

2 - Citizen empowerment is recognised as important part of integrated care provision, effective policies to support citizen empowerment are in place but citizens do not have access to health information and health data

3 - Citizens are consulted on integrated care services and have access to health information and health data

4 – Incentives and tools exist to motivate and support citizens to co-create healthcare services and use these services to participate in decision-making process about their own health

5 – Citizens are fully engaged in decision-making processes about their health, and are included in decision-making on service delivery and policy-making.

9. Evaluation Methods

Objectives:

As new care pathways and services are introduced to support integrated care, there is a clear need to ensure that the changes are having the desired effect on quality of care, cost of care, access and citizen experience. This supports the concept of evidence-based investment, where the impact of each change is evaluated, ideally by health economists working in universities or in special agencies. Health technology assessment (HTA) is an important method here, and can be used to justify the cost of scaling up good practices to regional or national level.

- Establishing baselines (on cost, quality, access etc.) in advance of new service introduction.
- Systematically measuring the impact of new services and pathways using appropriate methods (e.g., observational studies, incremental improvement, clinical trials).
- Generating evidence that leads to faster adoption of good practice.

Assessment scale:

0 – No evaluation of integrated care services is in place or in development

1 – Evaluation of integrated care services exists, but not as a part of a systematic approach

2 – Evaluation of integrated care services is planned to take place and be established as part of a systematic approach

3 – Some integrated care initiatives and services are evaluated as part of a systematic approach

4 – Most integrated care initiatives are subject to a systematic approach to evaluation; published results

5 – A systematic approach to evaluation, responsiveness to the evaluation outcomes, and evaluation of the desired impact on service redesign (i.e., a closed loop process).

10. Breadth of Ambition

Objectives:

Integrated care includes many levels of integration, such as integration between primary and secondary care, of all stakeholders involved in the care process, or across many organisations. It may be developed simply for healthcare needs (i.e., vertical integration) or it may include social workers, the voluntary sector, and informal care (i.e., horizontal integration). The broader the ambition, the more numerous and diverse the stakeholders who have to be engaged. Similarly, integration may include all levels of the system or may be limited to clinical information sharing. The long-term goal should be fully integrated care services which provide a complete set of seamless interactions for the citizen, leading to better care and improved outcomes.

- Integration supported at all levels within the healthcare system – at the macro (policy, structure), meso (organisational, professional) and micro (clinical) levels.
- Integration between the healthcare system and other care services (including social, voluntary, informal, family services).
- Seamless transition for the patient between and within care services.

Assessment scale:

- 0 – Integrated services arise but not as a result of planning or the implementation of a strategy
- 1 – The citizen or their family may need to act as the integrator of service in an unpredictable way
- 2 – Integration within the same level of care (e.g., primary care)
- 3 – Integration between care levels (e.g., between primary and secondary care)
- 4 – Integration includes both social care service and health care service needs
- 5 – Fully integrated health & social care services.

11. Innovation Management

Objectives:

Many of the best ideas are likely to come from clinicians, nurses and social workers who understand where improvements can be made to existing processes. These innovations need to be recognised, assessed and, where possible, scaled up to provide benefit across the system. At the same time, universities and private sector companies are increasingly willing to engage in open innovation, and innovative procurement, in order to develop new technologies, test process improvements and deliver new services that meet the needs of citizens. There is also value in looking outside the system to other regions and countries that are dealing with the same set of challenges, to learn from their experiences. Overall, this means managing the innovation process to get the best results for the systems of care, and ensuring that good ideas are encouraged and rewarded.

- Adopting proven ideas faster.
- Enabling an atmosphere of innovation from top to bottom, with collection and diffusion of best practice.
- Learning from inside the system, as well as from other regions, to expand thinking and speed up change.
- Involving universities and private sector companies in the innovation process (i.e., ‘open innovation’).
- Using innovative procurement approaches (Pre-Commercial Procurement, IPP, PPP, Shared Risk, Outcome-Based Payment)
- Using European projects (e.g., Horizon 2020, EIP, CEF).

Assessment scale:

- 0 – No innovation management in place
- 1 – Innovation is encouraged but there is no overall plan
- 2 – Innovations are captured and there are some mechanisms in place to encourage knowledge transfer
- 3 – Formalised innovation management process is planned and partially implemented
- 4 – Formalised innovation management process is in place and widely implemented
- 5 – Extensive open innovation combined with supporting procurement & the diffusion of good practice is in place

12. Capacity Building

Objectives:

Capacity building is the process by which individual and organisations obtain, improve and retain the skills and knowledge needed to do their jobs competently. As the systems of care are transformed, many new roles will need to be created and new skills developed. These will range from technological expertise and project management, to successful change management. The systems of care need to become 'learning systems' that are constantly striving to improve quality, cost and access. They must build their capacity so as to become more adaptable and resilient. As demands continue to change, skills, talent and experience must be retained. This means ensuring that knowledge is captured and used to improve the next set of projects, leading to greater productivity and increasing success.

- Increasing skills; continuous improvement.
- Building a skill base that can bridge the gap and ensure that the capacity needs are understood and addressed by ICT where appropriate
- Providing tools, processes and platforms to allow organisations to assess themselves and build their own capacity to deliver successful change.
- Creating an environment where service improvements are continuously evaluated and delivered for the benefit of the entire care system.

Assessment scale:

0 – Integrated care services are not considered for capacity building

1 – Some systematic approaches to capacity building for integrated care services are in place

2 – Cooperation on capacity building for integrated care is growing across the region

3 – Systematic learning about integrated care and change management is in place but not widely implemented.

4 – Systematic learning about integrated care and change management is widely implemented; knowledge is shared, skills retained and there is a lower turnover of experienced staff.

5 – A 'person-centred learning healthcare system' involving reflection and continuous improvement.



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JACARDI

Joint action
cardiovascular diseases
and diabetes

ANNEX II: Methodological and explanatory framework for the integration of the equity and diversity perspectives in JACARDI

JACARDI WP Task 5.3

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Annex III (Inclusive and accessible communications guidelines) was prepared as a joint effort between WP2 and WP Task 5.3. The contributors to this specific annex are mentioned at the beginning of that document.

Glossary of Acronyms

Acronym	Description
DALYs	Disability adjusted life years
SEP	Socioeconomic position
SES	Socioeconomic status
SDH	Social determinants of health
T2D	Type 2 diabetes
T1D	Type 1 diabetes

Keywords

Equity, diversity, inclusion, critical reflection, social inequalities, cardiovascular diseases, diabetes

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Executive summary

One of the cross-cutting aims of JACARDI is the integration of equity and diversity perspectives in all its structures. The purpose of the Methodological and explanatory framework for the integration of the equity and diversity principle in JACARDI (explanatory framework) is to provide the project partners with a shared understanding on the rationale and practical principles and pathways for meeting this joint aim. The explanatory framework is based on the 4C principles (Critical reflection, Context and data, Co-design, and inclusive and accessible Communication) identified based on previous literature, focus group interviews with JACARDI WP leadership teams, and previous experiences of task contributors in initiating change and integration of equity and diversity perspectives in complex settings. This framework provides justification on the importance of equity and diversity perspectives in reducing the burden of CVD and diabetes; outlines the theoretical underpinnings of the explanatory framework and previous work on the topic; describes the 4C principles for integrating equity and diversity perspectives in JACARDI, as well as outlines implementation and monitoring of the explanatory framework.

1. Introduction

Inequalities in non-communicable diseases in Europe persist, with largest inequalities in disability adjusted life years (DALYs) observed in cardiovascular diseases (CVD) and diabetes (Andrade et al., 2023). There is strong evidence on the significant contribution of upstream (i.e. macro level) societal and structural factors in generation of health inequities, surpassing the single effect of health behaviours, access to care, and disease management (Brown et al., 2004; Mensah 2020), and leading to the concept of “socially transmitted conditions” (Allen & Feigl, 2017). There is also increasing awareness of the role of a life course approach (Stringhini et al., 2016) and of the intersectional nature of social inequities, calling for diversity inclusive health policy and praxis (Kumar et al., 2021). There are 54 million persons (12% of total EU population) that have been born outside of their current country of residence (OECD & European Commission, 2023). An estimated 101 million persons aged 16 or older in the EU have some level of disability (European Council, 2024). An estimated 9% identify themselves as LGBT+ according to a global survey conducted in 30 countries (IPSOS, 2023).

Awareness of the deeply embedded discriminative societal structures that cause both factual and invisible barriers in equal access to resources, as well as on the contribution of experiences of racism and discrimination to health inequities has increased over the past decade. Despite increasing awareness of the urgency for action, the mismatch between acknowledgement of the need for application of intersectional approach that comprehensively considers population cultural and ethnic diversity with practice has pertained (Kumar et al., 2021). Addressing this mismatch, and in alignment with the European Commission priority to integrate diversity and inclusion perspectives in health equity measures and policy, JACARDI aims to cross-cuttingly integrate equity and diversity perspectives in its methodological framework and actions. Mainstreaming diversity and inclusion are essential for updating policies and practices to better meet the needs of the increasingly diverse populations in European countries. To address this need, JACARDI has developed the methodology for systematic and transversal integration of diversity and inclusion perspectives in all its structures and work on health inequities.

1.1 Purpose and scope of the document

The purpose of this explanatory framework is to promote a shared vision and understanding across project partners on application of the equity and diversity perspectives in the Joint Action on CARdiovascular diseases and Diabetes (JACARDI). The explanatory framework constitutes the basis for transversally (i.e. cross-cuttingly or horizontally) integrating the diversity and equity approach in the project, especially from the perspective of work packages (WP) 6-11 and their pilots. Equity refers to identifying and eliminating obstacles that lead to unequal distribution of resources and opportunities, with the aim of ensuring fair treatment and equal opportunities for all. Diversity refers to the presence of different characteristics or social dimensions within a group, organization, or community, for example age, gender, race, ethnicity, sexual orientation, socioeconomic status, physical and cognitive abilities, religious beliefs and cultural background. Another central concept related to equity and diversity is inclusion, which refers to the sense of belonging and being heard at individual, community, societal and political levels in society. In JACARDI, equity and diversity perspectives are addressed through consideration of social and commercial determinants of health, with a particular focus on gender, and population cultural and ethnic diversity. The principles of the explanatory framework can be flexibly applied to work with any underrepresented social groups.

Cross-cutting integration of the equity and diversity perspectives contributes to achieving the overarching aim of JACARDI, which is to support European Union (EU) countries in reducing the burden of cardiovascular diseases (CVD) and diabetes, as well as related risk factors, through more equitable and sustainable health systems. Integration of equity and diversity perspectives is anticipated to reduce the burden of CVD and diabetes among groups at greater social disadvantage, which contributes to reducing inequities also at the population level. The importance for more comprehensive consideration of equity and diversity perspectives is justified through increasing population diversity in the EU and widening social inequalities particularly among underrepresented and socially disadvantaged population groups.

The main objectives for activities related to integration of equity and diversity in JACARDI are that:

1. All partners understand the importance of applying the equity and diversity perspectives in their work and have concrete tools and support for application of equity and diversity perspectives in practice.
2. Partners actively apply equity and diversity perspectives in pilots and thus contribute to designing more inclusive and equitable practices and health systems.
3. To develop and monitor structures for systematic integration of equity and diversity in complex cross-country settings.

1.2 Structure of the document

This document is divided into six chapters: Executive summary, Introduction, Development process, Methodological and explanatory framework for the integration of the equity and diversity perspectives in JACARDI, Conclusions; and Appendices. The development process section provides an overview of how the explanatory framework was developed. The section on the methodological and explanatory framework presents a summary of outputs of task 5.3 by M12.

1.3 Relation to other work in the project

The explanatory framework supports JACARDI WPs and pilots in adherence to the cross-cutting aim of integrating equity and diversity perspectives that has been agreed to be one of the core themes in JACARDI at the grant proposal stage. The framework has been integrated in the JACARDI XV methodological steps outlined in D5.1. The task was also harmonised with other tasks in WP5.

2. Development process of the explanatory framework

The explanatory framework was developed based on the review of literature and theory and focus group interviews with JACARDI WP leadership teams at the start of the project.

2.1 Social inequalities in cardiovascular diseases and diabetes

2.1.1 Cardiovascular diseases

A recent umbrella review (Teshale et al., 2023) identified four macro categories for the association of social determinants of health (SDH) with CVD incidence, prevalence, and mortality: early childhood circumstances, social and community context, neighbourhood and built environment, and the socioeconomic circumstances. Adverse childhood circumstances, such as neglect, abuse, and parental low socio-economic level are associated with adverse health and social outcomes in later stages of life, including higher risk for CVD and diabetes. Social and community contexts are associated with CVD through multiple interacting psychological, physiological, emotional and behavioural mechanisms. Living in a socially deprived neighbourhood is associated with greater exposure to stress, poorer access to health services and unhealthy lifestyles through poorer access to recreational services, healthy, culturally appropriate and affordable foods, greater exposure to road traffic and lesser walkability. Mechanisms underlying the association between socioeconomic circumstances (e.g. education, income, employment, homelessness and food insecurity), include exposure to chronic stress, lower health literacy, barriers to timely health service access, poorer risk factor and disease management, and greater exposure to harmful behaviours (e.g. consumption of unhealthy foods, smoking, alcohol and drug abuse) (Teshale et al., 2023). The impact of individual and area-based level SES on coronary heart disease outcomes has been reported to be higher in countries without universal health coverage (Schröder et al., 2016).

Although a consistent body of literature has reported marked sex differences in biological characteristics, treatment and outcomes of CVD, a gender-sensitive approach is not yet widely adopted in either prevention or clinical management (Grant & Sanghavi, 2024; Mahowald et al., 2024). An interactive effect between sex, post-discharge timing and readmission rates following episodes of heart failure was reported, with higher readmission rates among women within the first year of the episode and higher readmission rates among men upon longer follow-up (Hoang-Kim et al., 2020). Men were also more likely than women to be cared for by a cardiologist, to undergo investigations for heart failure and to be referred to specialized clinics after an emergency department visit or hospitalization (Chan et al., 2022). While these findings may be attributable to the sex differences in aetiology of heart failure, prejudice that heart failure is predominantly a male syndrome may cause delays in recognizing and managing the condition among women.

There is also growing evidence on higher risk for adverse CVD outcomes among sexual and gender minorities, where intrapersonal (self-stigma, concealment), interpersonal (discrimination, violence), and structural (social and legal barriers) stressors are considered the main drivers of CVD disparities (Caceres et al., 2020). However, a full understanding of the social and biological determinants of risk among these minorities is still needed.

CVD prevalence and mortality differ significantly among migrant origin groups in Europe, both to their advantage and disadvantage, compared with the majority population in the country of migration and

depending on the CVD outcome examined. Differences have been reported for example depending on country of origin and country of residence, length of residence, as well as the complex interaction between genetic and pre- and post-migration related exposures such as socioeconomic circumstances, access to health services, and physical and psychosocial stressors (Agyemang & van den Born, 2022). An interaction between gender and migrant origin has also been reported for the behavioural profile of immigrants (Khlaf et al., 2020) and for mediators of CVD occurrence, such as blood pressure and cholesterol levels (Dalla Zuanna et al., 2023).

2.1.2 Diabetes

There is extensive and consistent evidence on higher risk for type 2 diabetes (T2D) among socially disadvantaged population groups compared with those holding greater societal power and privilege. Lower socioeconomic position (SEP), measured through characteristics of the built environment and other individual and community level social factors in addition to SES, is associated with higher T2D incidence, prevalence and mortality (Agardh et al., 2011; Chatzi et al., 2020; Espelt et al., 2011; Hill-Briggs et al., 2021). Household-based indicators of cultural and economic resources also show an independent impact on diabetes outcomes (Vandenhede et al., 2013). Diabetes self-management has been reported to be associated with higher levels of social support (Strom & Egede, 2012) and health literacy levels (Kim & Lee, 2016). Using an intersectional perspective, a modifying effect of the presence of urban parks on inequalities in T2D was found, with higher inequalities in areas with higher park density (Plans-Beriso et al. 2024). This is explained as partly due to the phenomenon called “greentrification”, whereby green areas increase the desirability and prices of housing, thus leading to the attraction of population groups with higher SEP and the displacement of groups with lower SEP. These findings call for introducing also an environmental justice perspective in policies addressing the prevention of chronic diseases.

Women (Agardh et al., 2011; Plans-Beriso et al., 2024), persons with disabilities (Chatzi et al., 2020), and migrants (Agyemang et al., 2021; Meeks et al., 2015) have been reported to be at greater risk for social inequalities in diabetes occurrence and progression. Similarly to CVD, gender differences in exposures, manifestations, clinical picture, and management of T2D have been reported, highlighting the need for gender sensitive approaches in treatment of T2D (Kautzky-Willer et al., 2016). The prevalence of type 2 diabetes among migrants in Europe significantly exceeds that observed within their countries of origin. People with migrant origin also tend to develop T2D earlier in life and at lower body weight levels than Europeans, indicating unique risk factors among these groups (Agyemang et al., 2021). Additionally, some risk factors like metabolic syndrome are more prevalent among migrants (Skogberg et al., 2017). Prevalence of T2D among migrants varies also by country and region of origin, reported to be highest among Persons of South Asian, Middle Eastern/North African, Sub-Saharan African, Western Pacific, and South/Central American origin (Meeks et al., 2015). Migrant origin women, particularly those of South Asian, East Asian, and Middle Eastern/North African origin have been reported to be more likely in developing gestational diabetes than Finnish origin women (Bastola, 2021). Factors such as socioeconomic status, lifestyle changes post-migration, and genetic predispositions play significant roles in these disparities. Understanding these ethnic disparities is vital for tailoring effective antenatal care and improving outcomes for diverse populations in Western countries (Kinnunen et al., 2018; Kragelund Nielsen et al., 2020).

In the case of Type-1 diabetes (T1D), the evidence on the association between SEP and the risk of childhood diabetes is inconsistent, also due to the weaker quality of the relevant studies (Lopez-Doriga Ruiz_

P et al, 2023). A very large cohort study, including all children born in Norway from 1974 to 2013 followed up to 15 years of age, found a U-shaped relationship between maternal socioeconomic position and risk of T1D, which could partly explain the inconsistency of previous studies (Lopez-Doriga Ruiz P et al, 2024). In fact, they found a lower T1D incidence in children of mothers with the highest educational qualifications and in those of mothers with elementary occupations, particularly those involving social mixing, such as cleaners and helpers; furthermore, among fathers, neither education nor occupation was significantly associated with T1D in their children. On the other hand, the association of a lower SEP with poorer management and control of the disease is confirmed also for T1D (Lindner LME et al, 2018).

2.2 Theoretical underpinnings of the explanatory framework

The explanatory framework for integration of equity and diversity perspectives in JACARDI draws its theoretical base from the WHO Commission on Social Determinants of Health (2008) framework, the model for social basis of disparities in health (Diderichsen et al., 2001; Diderichsen et al., 2012), the intersectional framework (Crenshaw, 1991; Krieger, 2001), the development of life course epidemiology (Blane 2007), and the model of the commercial determinants of health (Gilmore et al., 2023). The explanatory framework emphasizes the role of macro level factors in generation of health inequities, intersectional nature of social identities and the complex interaction between macro level and individual characteristics. Visualisation of this theoretical base is presented in *Figure 1. Theoretical base for the integration of equity and diversity perspectives*.

The macro-social, economic, political and environmental factors include and influence the overall amount, the distribution and social relevance of individual, family and community resources. These factors provide the context (i.e. the green background) for the complex interactions between individual-level social determinants (ex. age, sex, gender, migrant status, ethnicity, income, education and occupation) and exposures influencing health outcomes throughout the life course. In particular, the life course perspective highlights that the individuals' social position and health depend on parental social position, through mechanisms of biological and social programming, as well as on disadvantages accumulating and/or intersecting during the lifespan.

Within the structural factors also lie the commercial determinants of health, defined as “the systems, practices, and pathways through which commercial actors drive health and equity” (Gilmore et al., 2023). Commercial determinants refer to the conditions, actions and omissions by commercial actors that arise in the context of the provision of goods or services for payment, and involve the complex interaction between political, economic and social systems. In this sense commercial determinants can have either a direct or indirect, positive or negative impact to health and global health, and can significantly affect equity in health. For example, the 2019 Global Burden Study estimates that just four commercial products (tobacco, alcohol, ultra-processed food, and fossil fuels), account for at least 34% of total deaths or 41% of deaths from non-communicable diseases (Gilmore et al., 2023); these products in turn play a major role in the generation of inequalities in chronic diseases. Other commercial practices driving inequities in health are e.g. the privatization of services such as education and healthcare (Diderichsen F et al, 2021).

Social determinants of health are conditions in which people are born, grow, live, work and age, and which are shaped by the distribution of wealth, power, prestige, and resources at global, national and local levels. In this explanatory framework, individual characteristics such as gender, ethnicity and migrant origin are

considered to act as independent social determinants of health that are simultaneously in a complex interaction with other social determinants of health. The explanatory framework thus emphasizes the intersectional nature of social determinants of health (yellow box). Intersectionality refers to the complex, overlapping, and interrelated social categories (ex. ethnicity, migrant status, power, economic resources, social networks, gender, age, health status and health literacy among multiple others) that affect an individual's identity, social position, and health (Crenshaw 1991; Krieger 2001). Intersectionality also reflects the power dynamics within the social, economic, political and environmental context within which the individual is situated. The relative importance of any given social category depends on their contextual or situational circumstances, which in turn determine whether a social category creates an advantage, is neutral, or creates a disadvantage for the individual's health (Hill Collins & Bilge 2020).

The orange box represents the different mechanisms of ill-health production:

- differential exposure: socially patterned distribution of individual, contextual and environmental exposures (lifestyles, occupational risks, psychosocial factors, material circumstances, environmental exposure, access to prevention);
- differential vulnerability to exposure and disease progression: socially patterned ability to cope with exposures and therefore differential incidence and severity; socially patterned clinical course and outcomes due to differential opportunities and access to prevention, treatment and self-management;
- social consequences: the backward impact of ill-health on the individual social position and consequently on exposures.

The key mediating role of the context in creating or compensating for disadvantage, and even creating an advantage, places contextual factors (also referred to as upstream factors) as priority areas for interventions aiming at promoting equity and diversity. It is imperative to critically examine the role of social, economic, political and environmental factors in creating inequities in the distribution of status, wealth and power in the society.

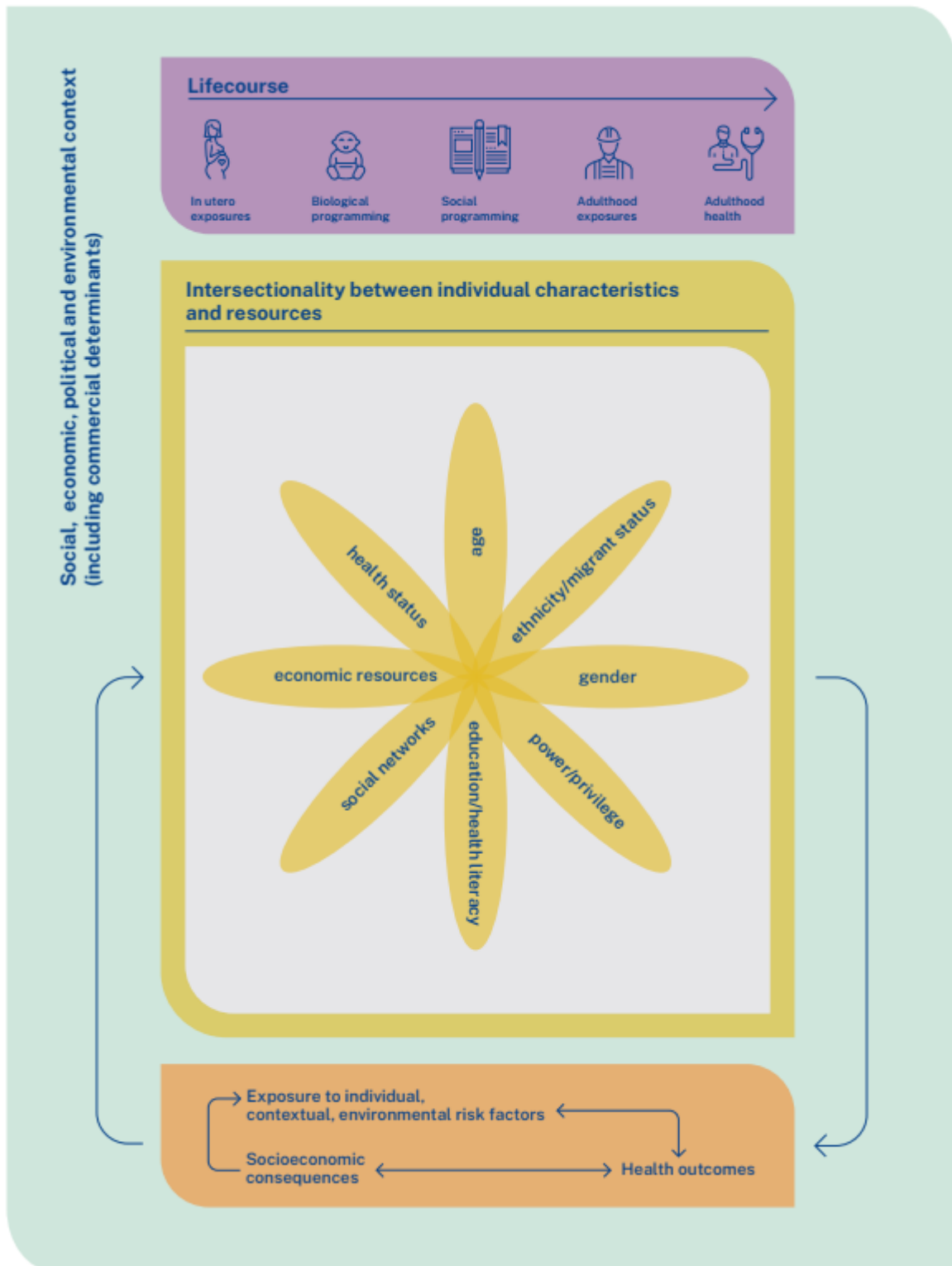


Figure 1. Theoretical base for the integration of equity and diversity perspectives

2.3 Focus group interviews with WP leaders

Focus group interviews carried out at the beginning of the project (3-15.11.2023) to understand how familiar the topics of equity and diversity were within the leadership team and to hear views on barriers and facilitators for practical implementation of this cross-cutting theme in JACARDI. Five focus group interviews with 24 WP leaders were conducted. The size of each focus group varied from three to seven participants. All JACARDI WPs were represented in the interviews. The interviews lasted from 1 hour 45 minutes to 2 hours. A rapid analysis of results was performed.

Cultural and ethnic diversity, and other social determinants of health were generally seen as crucial for reducing inequity and promoting health by the WP leaders. However, many were unsure how especially diversity perspectives could be addressed in practice. Concerns were raised whether it would be possible to obtain a shared understanding on main concepts and terminology within JACARDI. There were also mixed thoughts among WP leaders on the relevance of commercial determinants of health for JACARDI. Overall, cultural and ethnic diversity and other social determinants, as well as commercial determinants were viewed as very broad topics, and all WP leaders perceived that they could make a connection between these and find relevance to the themes of their WPs at least to some extent. WP leaders perceived the JACARDI project's broad scope and magnitude as a valuable opportunity for exchange of expertise and mutual learning across partner countries. At the same time, some raised concerns whether the cross-cutting themes of cultural and ethnic diversity, and other social and commercial determinants of health, are very broad, making it challenging to know what topics are relevant. A clear need for practical support in addressing the cross-cutting themes of JACARDI was also communicated by the WP leaders.

3. Methodological and explanatory framework for the integration of the equity and diversity perspectives in JACARDI

The theory of change for integrating equity and diversity perspectives in JACARDI is described in *Figure 2. Theory of change for integrating equity and diversity perspectives in JACARDI*. To address the first key concern of WP leaders raised during the focus group interviews on the need of a shared understanding across partners, this explanatory framework based on the 4Cs principles was developed, supported by the equity and diversity terminology glossary. To address the second key concern raised by WP leaders on the broad scope of the cross-cutting themes of cultural and ethnic diversity and other social and commercial determinants, the equity and diversity maturity matrix was developed as a practical tool to guide pilots in applying the 4Cs principles in JACARDI. While at the grant proposal stage, this practical tool was planned to be in a checklist format, it evolved into matrix format to provide even more practical examples to how equity and diversity perspectives can be applied by pilots at different levels of comprehensiveness considering their previous experience in considering these perspectives and available resources. The third key concern raised by WP leaders was the need for practical support. The identified solutions for meeting these needs are capacity-building sessions, the equity and diversity maturity matrix and other practical tools like the inclusive and accessible communications checklist, one-on-one sessions with WP leaders, as well as workshops and peer-learning sessions for pilots.



Figure 2. Theory of change for integrating equity and diversity perspectives in JACARDI

3.1 The 4Cs principles of the equity and diversity explanatory framework

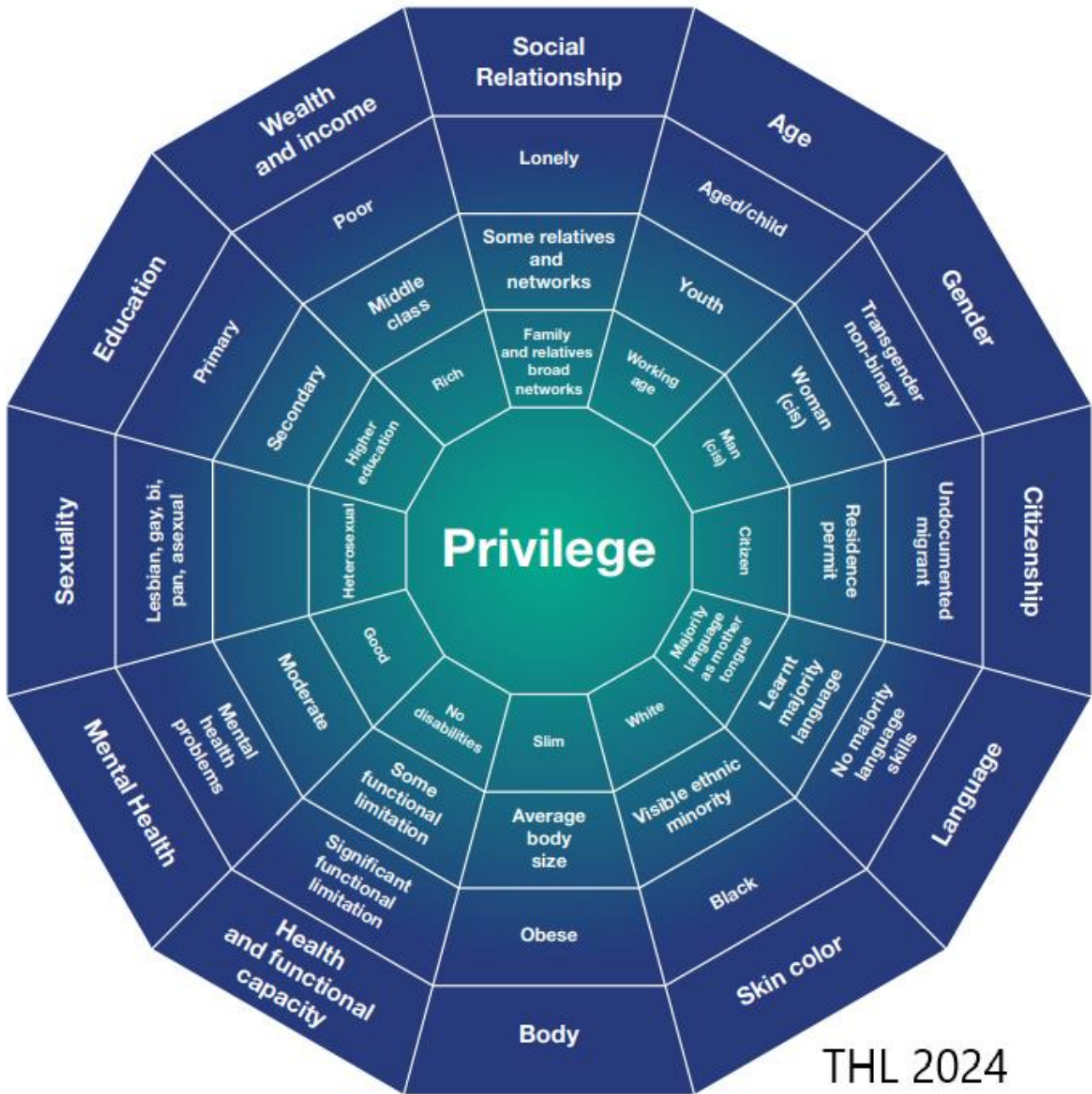
The 4C principle (Critical reflection, Co-design, Context and data, and inclusive and accessible Communication) outlines the key pathways for integration of equity and diversity perspectives in JACARDI and thus constitute the core concepts of the explanatory framework for integration of equity and diversity perspectives. Critical reflection is the core underlying principle for all activities aiming at integrating equity and diversity perspectives, whereas co-design, context and data, and inclusive and accessible communications are concrete pathways and areas where it should be especially applied. The 4C principle was designed to be a simple framework to guide consideration of the key areas related to equity and diversity within JACARDI.

3.1.1 Critical reflection

The underlying principle and key pathway in this explanatory framework to understanding the complex interactions between individual-level social determinants and exposures influencing health outcomes throughout the life course, is through developing **critical reflection** skills. Critical reflection, also referred to as cultural humility, is a continuous, life-long process of critical self-reflection to examine one's own biases, prejudices and stereotypes, as well as one's own position of power in relation to others (Trevalon & Murray-Garcia 1998). Cultural humility advocates for giving the power to populations we aim at serving, with the presumption that these communities already have the knowledge and capability to take responsibility for issues concerning themselves.

The wheel of privilege (*Figure 3. The wheel of privilege*) is one of the multiple ways of visualising how the power dynamics are distributed within the society. It is used as a starting point to explore one's own position of power in relation to others and how these effect daily interactions and decisions. Additionally, it can be used to catalyse thought processes on which social groups are there in the society. It is however important to note that not all social groups are exhaustively represented in this wheel of privilege but are rather examples of the different social groups in the society. The wheel of privilege depicts sub-groups within the society belonging to broader social categories. The sub-groups closer to the inner circle hold the most power and privilege in the society. The degree of power and privilege grows with an increasing number of social characteristics within the inner circle of the wheel of privilege.

Cultivation and engagement with critical reflection is the key pathway for facilitating finding purpose and meaning in the activities aiming for integration of equity and diversity perspectives among JACARDI partners. Change is person-centered and person-driven. For a paradigm shift to occur towards developing more equitable and diversity inclusive actions and systems, it is imperative that those in the position of power to initiate change are willing to apply the equity and diversity lens in their activities. In JACARDI, cultural humility is applied especially in the following three key areas of pilot implementation: 1) context and data; 2) co-design; 3) inclusive and accessible communications.



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Figure 3. The wheel of privilege

3.1.2 Co-design

Co-design is a collaborative approach that involves actively engaging end users/end beneficiaries, professionals, and other relevant stakeholders in the design of projects and products, including health interventions, health promotion activities, and healthcare services (Vargas et al., 2022). There are multiple other terms used in relation to co-design, including coproduction, co-creation, patient engagement, meaningful engagement, participatory methods, and citizen participation (Moll et al. 2020; WHO 2023). Co-

design promotes development of solutions that better meet the needs of the intended target populations, thus contributing to more holistic and impactful measures for reducing health inequities (Thomas et al., 2021).

Co-design is particularly relevant in health-related projects, as health is deeply personal and diverse in experience, influenced for example by cultural, socioeconomic, and individual factors (Thomas et al., 2021). Traditional top-down health promotion and intervention approaches often neglect the nuanced challenges faced by specific communities. Co-design applies a bottom-up approach, allowing for a deeper understanding of diverse perspectives, challenges, and experiences (Nickel & vom dem Knesebeck, 2020). Involving underrepresented communities in the design process can contribute to building trust and empowering communities to take agency and to actively shape solutions that resonate with their needs and preferences. Such an approach reduces the risk of epistemic injustice, which relates to unjust discrimination and exclusion of especially groups in vulnerable situations in decisions concerning them (Osborne et al., 2022).

Despite significant potential advantages in co-design, caution and critical reflection must be applied to avoid further strengthening inequities and other undesired outcomes (King et al. 2022). Moll et al. (2020) suggest application of critical reflection particularly in the following three domains of the co-design process: 1) the starting point (own prejudices, biases and privilege, ensuring respectful transactions, giving the power to the communities, ensuring meaningful engagement in light of time and resource pressures); 2) deciding what approaches and tools will be used (ensuring a wide representation of persons in question and other stakeholders, what does inclusive participation mean in practice, tools and techniques that will be used to engage, deciding on participatory methods that would be suitable and effective to bring out the diverse experiences, how joint understanding and way forward will be achieved); 3) identifying what are the desired results and how they will be reached (how the undesired results like tokenism and strengthening existing injustices and inequities can be avoided, sustainability of desired results, how can the quality of transactions be improved and how can trust, mutual respect and accountability be ensured).

To facilitate equitable participation and open dialogue, the principles of safer spaces should be followed. This includes respecting everyone's physical and psychological space, being open-minded and holding no preconceptions, no physical discrimination, being respectful in own communication and of opinions of others, letting others have a say and to participate, and interfere in any kind of inappropriate behaviour (Equality 2022). Building capacity in equity and diversity and honing the skills of critical reflection are essential for reducing adverse unintended outcomes of co-design.

Co-design is relevant for pilot implementation from conceptualising the problem to considering sustainability and scalability of the pilot. Meaningful engagement of stakeholders, and especially communities the pilot wants to serve, should occur at early stages of pilot situation analysis. In the Grant Agreement, it is mentioned that pilots are advised to form a stakeholder board that can be consulted throughout pilot planning, implementation and evaluation. To more comprehensively hear the voices of the communities we wish to serve, it is advised to assemble for consultations/workshops groups of diverse end users/end beneficiaries, representative of the community the pilot wants to serve, to identify the key themes and discourses that should be taken into account in the pilot. This would be beneficial for collecting a better representation of diverse views to inform pilot actions and reduces potential power imbalances that are more

likely to be present in “mixed” stakeholder boards involving also professionals and decision-makers. Ideally, the general and specific objectives are defined in co-design with the communities we aim to serve. Co-design facilitates conduct of a comprehensive needs assessment that allows to identify barriers and facilitators (strengths) to implementing the pilot, providing nuanced insights into the context and biases in the data (Osborne et al. 2022). It is also needed for matching diverse needs based on local wisdom with available data. Finally, co-design should be applied during evaluation of the pilot, when compiling the sustainability action plan, and considering scalability of the pilot.

3.1.3 Context and data

The social and economic context regulates the distribution of power and privilege, as well as available resources (Krieger 2001). The context is, therefore, of key importance from the intersectional perspective as it entails the power dynamics in the society and how these affect an individual’s identity, social position, and health. It is important to note that the advantages and disadvantages arising from the intersectional perspective are contextual in nature. A person’s degree of advantage or disadvantage compared to others can change with changes in the context (Hill Collins & Bilge 2020).

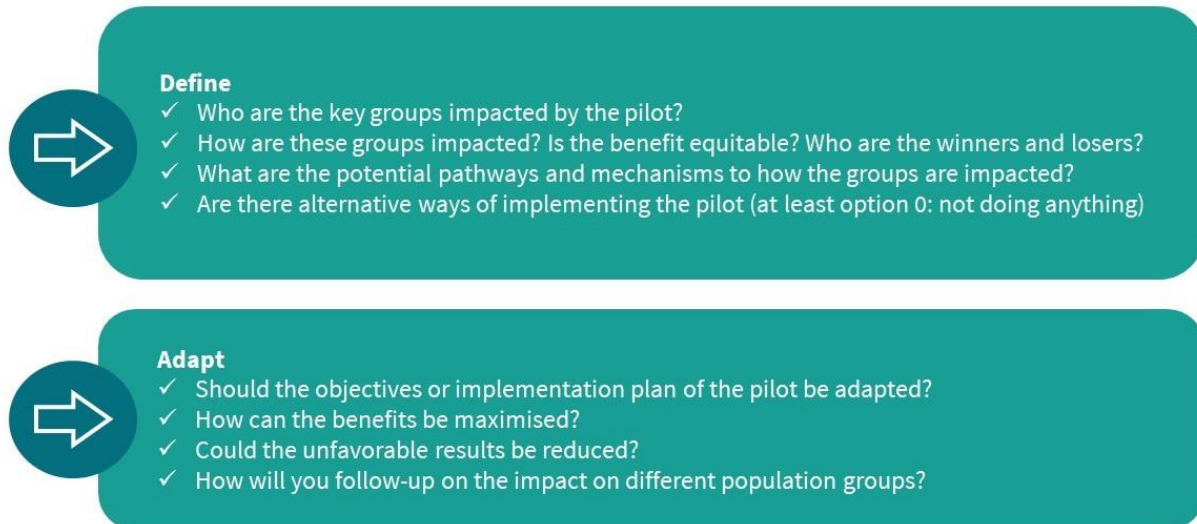
Application of critical reflection to examine the contextual factors that create visible or invisible barriers to participation and equitable distribution of resources and opportunities for diverse social groups can facilitate design of more equitable and diversity inclusive actions. Conducting the impact assessment on different population groups contributes to the development of universal measures and reduces the risk of unintentionally creating barriers for some population groups. Critical reflection can start with reflecting on who all are impacted by the planned action and how these groups are impacted. It is also important to consider whether planned actions entail barriers to participation for some population groups and how these could be addressed. When considering the impact on different population groups, intersectionality should also be considered. For example, it could be considered how do the planned actions impact women with disabilities, older ethnic minority women with limited digital skills, persons with functional limitations living in rural areas and so on. Figure 4 (*Figure 4. Key considerations during pilot impact assessment for diverse population groups*) summarises the key questions to consider when conducting an impact assessment.

Data is needed to conduct an impact assessment. Data refers to any type of information (e. g. quantitative, qualitative, observational) that we may use to inform our priorities and actions. Data plays an important role in shaping health policy and practice, and it is a general consensus that health policy should be evidence-based. Professionals responsible for resourcing data collection and those responsible for health monitoring and maintaining datasets have significant power in influencing what data is available and applied for decision making. Data availability influences what groups and health indicators are given visibility (Kihlström et al. manuscript under review). If the data is not available, it renders the phenomenon unseen and therefore not identifiable as a priority for policy and practice - “no data, no problem”. Additionally, critical reflection can be applied to consider other possible biases in the data, including selectivity of participants, and how different methodological choices in data collection and measurement may influence results.

New data can be gathered to fill the gaps in available data to strengthen understanding on who are the main groups impacted and how these groups are impacted. Data can be gathered for example through co-design workshops with end users/end beneficiaries, health professionals, non-governmental organisations, and

other relevant stakeholders; interviews and surveys.

Pilot impact assessment for different population groups



THL 2023

Figure 4. Key considerations during pilot impact assessment for diverse population groups

3.1.4 Inclusive and accessible communications

Communication can be viewed as a process of sending or receiving information and making meanings (Turner & West 2018). Communication takes place all the time, including verbal and nonverbal communication. It occurs at multiple levels, for example within the project team, within our own organisation, as well as with partners, collaborators, and other stakeholders. Through communication, we express our thoughts, priorities, and values. Therefore, communication holds the power to reinforce or break down harmful stereotypes and include or exclude persons or communities. This is why from an equity and diversity perspective, it is imperative to be mindful of our communication, so that it is accessible and inclusive for diverse population groups. Inclusive and accessible communication promotes equity and diversity and builds trust. It is reciprocal by nature and is done in collaboration with stakeholders. Furthermore, inclusive and accessible communication is a basic human right (United Nations, 1948), which is further supported by the European Accessibility Act (European Union 2019), and Equality and Anti-Discrimination Laws (Cazenave & Bellantoni 2022) and other legislations.

For communication to be inclusive and accessible, critical reflection should be applied to ensure that the information is suitable for everyone despite their abilities, genders, cultural and ethnic background, or life situations. Critical reflection should be applied to consider for example how the communication is made and who decided what is to be communicated; what (all different) messages and meanings the communication brings across; who is reached directly or indirectly by the communication; and where and when the

communication is disseminated (Calado 2021).

In addition to being a key pathway in the JACARDI 4C principles for considering equity and diversity perspectives, inclusive and accessible communications are a cross-cutting theme in all JACARDI communications (WP2). The guidelines and checklist (Annex III) emphasise application of critical reflection particularly in the following circumstances: 1) communication planning; 2) use of inclusive language; 3) inclusive use of visuals; 4) digital accessibility; 5) inclusivity in events.

3.2 Equity and diversity terminology glossary and maturity matrix

The equity and diversity terminology glossary can be found in Appendix A. This glossary has been integrated into the joint WP5 terminology glossary ([JACARDI Teams](#)¹). The equity and diversity maturity matrix has been developed and integrated within the JACARDI methodological framework, led by WP5 task 5.4 and WP4. This practical tool provides concrete examples on how the 4C principles of equity and diversity can be applied in practice at each of the methodological steps and at three different levels of comprehensiveness (approaching, meeting, exceeding). It also serves as an important tool to examine how application of equity and diversity perspectives evolved during JACARDI. The equity and diversity matrix can be found in Appendix B and the supporting questions integrated within the harmonised stepwise methodology document can be found in Appendix C.

3.3 Capacity building on equity and diversity

Capacity building is carried out throughout the JACARDI project through masterclasses that deepen the understanding of the JACARDI partners on the concepts related to the 4C principles for integrating equity and diversity perspectives, as well as consultations and workshops for WP leaders and pilots that support adherence to the explanatory framework and application of the related practical tools.

The first series of four masterclasses related to the JACARDI 4C principles for consideration of equity and diversity perspectives was held in January to February 2024. Recordings and further readings on the topics of the masterclasses can be found in the [JACARDI Teams](#). The dates, trainers, topics, number of participants and the total score for the masterclass among those who filled out the feedback form are provided in [Table 1. Summary of the masterclasses on 4C principles held from January to February 2024](#). Each masterclass was evaluated on a scale from 1-5 (1=strongly disagree, 2=disagree, 3=do not agree nor disagree, 4=agree, 5=strongly agree). Participant feedback was asked on the following four areas: 1) relevance of the content of the session for the participant's work; 2) perceived practical applicability of knowledge gained during the masterclass; 3) whether participation in the master class was worth their time; 4) satisfaction with technical arrangements. The average for each of these questions was used to calculate the total average for each of the masterclasses. In open feedback, participants particularly appreciated clarity, conciseness, and practical examples. There was different level of familiarity with the basic concepts introduced during the masterclasses, and many expressed the need for still more examples on practical application of the 4C principles in pilot implementation and further capacity building to gain a more comprehensive understanding. The need for clear guidelines was also expressed.

¹This link is not accessible if someone from outside JACARDI project needs to access it.

In addition to the masterclasses, one-on-one consultations between task 5.3 leaders and technical WP leaders were held during spring 2024 to further align understanding how equity and diversity principles can be applied from the perspective of specific WPs. The equity and diversity experts working in task 5.3 will continue to be available for consultations for both WP leaders and pilots through workshops and capacity building/learning sessions throughout JACARDI. WPs are encouraged to reach out when support is needed, and the equity and diversity experts will also aim at being regularly in contact with WP leadership to identify what kind of support would be beneficial.

Date	Trainer	Topic	Number of participants	Number who gave feedback	Average score (1-5)
10.01.2024	Janne Sørensen , University of Copenhagen (Denmark), JACARDI Scientific Advisory board member	Critical reflection	94	57	4.3
24.01.2024	Richard Osborne , WP6 lead, Sante Publique (France); Swinburne University of Technology (Australia).	Co-design	97	49	4.4
07.02.2024	Natalia Skogberg , WP5 task 5.3 lead, WP2 co-lead, Finnish Institute for Health and Welfare (THL); Teresa Spadea , WP5 task 5.3 co-lead; Epidemiology Unit ASL TO3 (Italy)	Context and data	91	30	4.3
21.02.2024	Sinikka Kytö , WP2, Finnish Institute for Health and Welfare (THL)	Inclusive and accessible communications	84	30	4.4

Table 1. Summary of the masterclasses on 4C principles held from January to February 2024

4. Conclusions and recommendations

Structured cross-cutting consideration of equity and diversity perspectives in JACARDI is a novel approach, which requires development of new methodologies and tools. The tools have been developed so that they are as concrete as possible not only to support implementation, but also to facilitate monitoring and reporting to the funding body on how the structured cross-cutting consideration of equity and diversity perspectives mentioned in the grant agreement have been carried out in practice. The methodology and tools also need to be assessed and further developed based on feedback from the users (i.e. pilots and WPs) and therefore any feedback received on these within JACARDI is highly useful. The methodology and tools for equity and diversity developed in JACARDI are likely to be of relevance also for future projects.

Monitoring whether and how the application of the explanatory framework and tools provided may have induced a shift in the equity and diversity perspectives is carried out by task 5.3 through:

- focus group interviews with WP leaders and co-leaders at the beginning and end of JACARDI, gathering feedback from masterclasses
- mapping out the process of development and implementation through review of documents and the stages of progress of pilots in integration of equity and diversity principles based on the data collected through the equity and diversity matrix at the beginning of project when developing the pilot implementation plan, as well as during the first, second and final report phases. Furthermore, it will be examined to what extent equity and diversity topics are integrated in the sustainability action plan and in dissemination plans of pilot results.

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Appendices

Appendix A: WP5 task 5.3 terminology glossary

The glossary has been tailored to the purposes of JACARDI task 5.3. Key references can be found in the reference list at the end of the glossary.

A

Anti-racism Active and conscious action against all forms of racism. Anti-racism means working to reduce ethnic discrimination, the effects of discriminatory practices, and negative prejudice.

C

Citizenship A legal status of belonging to a particular country that determines civil and political rights, duties, and responsibilities. Citizenship is a narrower concept than *nationality* (see below).

Co-design Meaningful, participatory, and inclusive involvement of all relevant stakeholders, including persons with lived experiences (i.e. end users or end beneficiaries), professionals, and other relevant groups in designing products, services, and policies. Sometimes also referred to as *co-creation*.

Commercial determinants of health Actions, conditions and decisions made by for-profit companies that can either directly or indirectly harm or promote population health.

Commercial determinants of health are in complex interaction with political, economic, and social systems.

Critical reflection (cultural humility) A continuous, life-long process of acknowledging our limitations in knowledge and challenging our biases, prejudices, and stereotypes, as well as our position of power in relation to others.

Culture A broad term that refers to a set of shared values, beliefs, customs, behaviors, symbols, and artifacts that characterize a group or society. Culture can change with time and plays a key role in shaping social identities, and perceptions of one's surroundings and of others.

Cultural and ethnic diversity Presence of various ethnicities, and cultural backgrounds within different communities, organizations, or within society. It encompasses distinct traditions, languages, religions, origins, cultures, customs, and values that contribute to a diversity of human experiences.

D

Diabetic See person with diabetes

Discrimination A person is treated worse than others or is put in a worse position based on a personal characteristic without an acceptable reason.

Diversity The presence of different characteristics or social dimensions within a group, organization, or community. Examples of social dimensions are age, gender, race, ethnicity, sexual orientation, socioeconomic status, physical and cognitive abilities, religious beliefs, and cultural background.

E

End user/End beneficiary The individual, community, or organization i.e., relevant stakeholder that will ultimately use or benefit in some way from the developed product, service, or measure.

Ethnicity Shared cultural, linguistic, religious, or ancestral heritage of a group of people.

Equality The even distribution of rights, resources, and/or opportunities to all.

Equity The fair treatment and equal distribution of resources and opportunities across individuals or social groups (e.g. based on social, economic, demographic, and geographic characteristics).

G

Gender transformative leadership Breaking down structural gender-related power imbalances and discriminatory practices leading to gender inequalities in the professional setting.

I

Inequality The uneven distribution of rights, resources and/or opportunities among some individuals or social groups, regardless of the reasons behind it.

Inequity The unjust and avoidable inequality in the distribution of rights, resources, and/or opportunities across individuals or social groups (e.g. based on social, economic, demographic, and geographic characteristics).

Inclusion Securing material resources, abilities and rights for equal and meaningful participation in the society and decisions concerning oneself.

Inclusive and accessible communication Principles and practices that ensure suitability of information for everyone, regardless of their abilities (including digital skills), gender, background, or life situation. It considers that the language and/or visuals used do not reinforce prejudices, stereotypes, or discriminatory views towards certain individuals or social groups.

Intersectional/intersectionality An approach that examines the complex interaction of the social context and related societal power relations with overlapping, interrelated, and compounding social categories (e.g. race, ethnicity, class, gender, sexuality, age, ability among multiple others), which all together influence the individual's identity, social position, and health. Not to be confused with Intersectoral (see below).

Intersectoral Actions that involve several sectors of society and policy. In the health domain, intersectoral (or multisectoral) approaches aim to address the (non-medical) social and economic factors that influence the health of a population at the local, national, and global levels (see *Social determinants of health*).

Internalised racism The consciously or unconsciously acquired beliefs, thoughts and actions of the individual's own or their group's inferiority compared to the majority population.

M

Migrant A person who has moved geographically either within the same country or across country borders. In JACARDI, migrant refers to international migrants who have, for any reason, moved across country borders from their country of origin, i.e. who are international migrants. Children of migrants born in the country of migration can be referred to as persons of migrant descent.

N

Nationality The status of belonging to a particular nation, defined as a group of people organized in one country, who identify with each other based on shared culture and history.

National minorities A population group that is smaller in size compared with the majority population in the country or region, which preserve their own culture, traditions, religion, or language.

P

Persons in vulnerable situations Persons with limited possibilities to protect themselves from harm and exploitation. The term *persons in vulnerable situations* emphasises the role of the situation on the individual's vulnerability. It is a more inclusive term compared to the term *vulnerable populations* that suggests vulnerability to be a defining characteristic of the person.

Person with diabetes A more inclusive term compared with the commonly used term *diabetic* because it considers diabetes as just one of the characteristics of the person, rather than as a defining characteristic.

Persons with lived experiences Individuals and communities, who have first-hand experience on the given subject, and who are the end users or end beneficiaries for the planned actions. From the perspective of JACARDI, the lived experiences of relevance are living with or being affected by diabetes and/or cardiovascular diseases.

Prejudice A preconceived notion or viewpoint shaped prior to familiarity with a person, subject, or phenomenon. Prejudices can stem from factors like ignorance or stereotypes and might also exist subconsciously. These biases frequently target entire groups, such as a minority or a religious group.

Proportionate universalism The principle stating that actions must be universal, but with a scale and intensity that is proportionate to the level of disadvantage, i.e. proportionately targeted to reduce the steepness of the gradient (see *Social gradient in health*).

R

Racism The intentional or unintentional thoughts or actions that are based on the notion of inferiority of some groups based on, for example, their ethnicity, skin colour, culture, religion, mother tongue or nationality. Racism can occur within human interactions and communication, and it can be experienced by an individual or by groups. Racism can also be embedded within systems, such as policies and practices.

Reciprocity The principles and practices that ensure that all parties involved in the collaboration benefit from the cooperation.

Representation In the context of population diversity, representation refers to the visibility or absence of minorities and their voices in the society, such as in decision-making, visual material and the media.

S

Social determinants of health (SDH) are the non-medical factors that influence health outcomes. Conditions in which people are born, grow, live, work and age, and which are shaped by the distribution of wealth, power and resources at global, national and local levels. In the context of the JACARDI project, ethnicity/migrant origin are considered as independent social determinants of health and to be in complex interaction with other social determinants of health.

Social gradient in health It refers to the global phenomenon that shows that health inequalities are observed along a social scale, whereby usually people in a more disadvantaged social position have worse health than people in more advantaged positions. This is observed both within and between countries and implies that health inequities affect the entire population.

Socioeconomic (or social) position (SEP) is a broad concept related to the factors that produce stratification within a society and define the position of an individual according to hierarchies of wealth, power, prestige, and access to resources. It is often incorrectly used interchangeably with the narrower concept of socioeconomic status (SES), measured as a combination of education, income and occupation.

Stakeholder board An advisory board consisting of different individuals, groups, institutions, organisations, or other entities that show an interest for the activity, program, intervention or policy relevant to your field; are either directly or indirectly affected by the planned or implemented actions, decisions, or outcomes; or are important advocates for continuation and potential scalability of results when JACARDI ends. Persons with lived experiences should be included into the stakeholder board and it must be ensured that their participation is equitable to that of experts, professionals, and policy makers.

Structural inequalities Disparities in resources, opportunities, and power embedded in societal structures and institutions, leading to an advantage or disadvantage for certain groups.

Stereotypes A perception of a person or a group based on a generalisation of other persons perceived to belong to a similar group.

T

Transversal Cross-cutting. In JACARDI, transversal consideration of equity and diversity refers to cross-cuttingly integrating these perspectives at all levels and structures of the project.

V

Vulnerability See *persons in vulnerable situations*.

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Appendix B: WP5 task 5.3 equity and diversity matrix

Equity and diversity are cross-cutting themes in JACARDI. This equity and diversity maturity matrix is a practical tool for pilots, providing concrete examples for integration of equity and diversity perspectives at different levels of comprehensiveness. The steps in the matrix correspond with the XV steps of the JACARDI harmonised methodology for pilots. The equity and diversity matrix draws from the 4Cs principles identified as core components for integration of equity and diversity in JACARDI: Critical reflection; Context and data; Co-design; and inclusive and accessible Communications.

How to use the equity and diversity matrix?

The core pilot team will use the matrix to describe the pilot's consideration of equity and diversity. The different levels in the equity and diversity matrix provide concrete examples on how this can be done at different levels of comprehensiveness. Ideally, the pilots will use the matrix as a guiding tool when planning their activities. Pilots will report consideration of equity and diversity at the four key points of pilot implementation:

Steps I-VI: when compiling a pilot implementation plan (Webropol questionnaire, by M12)

Steps VII-VIII: intermediary reporting 1 (Integrated within general reporting)

Steps IX-XI: intermediary reporting 2 (Integrated within general reporting)

Step XII-XV: final reporting (Integrated within general reporting, by March 2027)

The steps in the equity and diversity matrix have three levels: approaching, meeting, exceeding. The pilots need to describe the level that best describes their activities. This will vary depending on the resources and previous experiences in equity and diversity perspectives among the core pilot team. For some, being at the approaching level will be an important step towards integration of equity and diversity, while some will reach the exceeding level. Use the comments field to provide additional information. If it is difficult to identify the appropriate level, a description of activities can be added in the open text field.

Pilot responses will be used to identify supporting activities for integrating equity and diversity perspectives, reporting to HADEA and at General Assemblies, and in publications related on equity and diversity in JACARDI.

Equity and diversity matrix outline:

STEP I: JACARDI core pilot team

- 1.1 Compose a diverse core pilot team
- 1.2 Strengthen capacity in equity and diversity within the core pilot team

STEP II: Definition of the problem and the general objective

- 2.1 Apply equity and diversity principles in the definition of the problem and the general objective

STEP III: Situation analysis at the site of the implementation including key stakeholder analysis

- 3.1 Conduct a pilot-level stakeholder analysis
- 3.2 Meaningfully engage diverse stakeholders
- 3.3 Identify the impact on diverse end users/ end beneficiaries

STEP IV Refinement of the general objective

- 4.1 Engage diverse stakeholders in refinement of the general objective

STEP V Definition of specific objectives

- 5.1 Apply the equity and diversity perspectives in the definition of specific objectives
- 5.2 Consider equity and diversity when selecting EU best practices/other evidence-based practices

STEP VI Pilot implementation plan No 1

- 6.1 Engage diverse stakeholders in development of the pilot implementation plan
- 6.2 Integrate equity and diversity perspectives in the pilot implementation plan
- 6.3 Integrate equity and diversity perspectives in the pilot communication

STEP VII Roll-out of actions and monitoring

- 7.1 Identify how equity and diversity principles will be monitored
- 7.2 Apply equity and diversity perspectives during roll-out of actions
- 7.3 Continue strengthening capacity in equity and diversity within the pilot team
- 7.4 Consider core pilot team composition

STEP VIII Intermediate report No 1

- 8.1 Engage diverse stakeholders in evaluation of intermediate results
- 8.2 Integrate equity and diversity perspectives in intermediate reporting
- 8.3 Integrate equity and diversity perspectives in intermediate reporting on pilot communication

IX Pilot implementation plan No 2

- 9.1 Engage diverse stakeholders in development of pilot implementation plan
- 9.2 Integrate equity and diversity perspectives in the pilot implementation plan
- 9.3 Integrate equity and diversity perspectives in the pilot communication

X Roll out of actions and monitoring

- 10.1 Monitor (and if needed revise) equity and diversity principles
- 10.2 Apply equity and diversity perspectives during roll-out of actions
- 10.3 Continue strengthening capacity in equity and diversity within the pilot team
- 10.4 Consider core pilot team composition

XI Intermediate report No 2

- 11.1 Engage diverse stakeholders in evaluation of intermediate results
- 11.2 Integrate equity and diversity perspectives in intermediate reporting
- 11.3 Integrate equity and diversity perspectives in intermediate reporting on pilot communication

XII Final implementation report

- 12.1 Return results to the community and engage diverse stakeholders in evaluation of results
- 12.2 Integrate equity and diversity perspectives in reporting
- 12.3 Integrate equity and diversity perspectives in reporting on pilot communication

XIII Focus on the key stakeholders' engagement in building sustainability

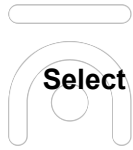
- 13.1 Revisit (and if needed revise) the key stakeholder analysis
- 13.2 Apply equity and diversity perspectives in dissemination of results and sustainability actions
- 13.3 Apply inclusivity and accessibility guidelines in material presented to the stakeholder board

XIV Sustainability action plan

- 14.1 Apply equity and diversity perspectives in development of the sustainability action plan
- 14.2 Integrate equity and diversity perspectives in the sustainability action plan
- 14.3 Integrate inclusive and accessible communications in the sustainability action plan

XV Celebrate the success

- 15.1 Engage diverse stakeholders in planning final dissemination events
- 15.2 Consider representation among the speakers in the final dissemination events
- 15.3 Apply the principles of inclusive and accessible communications in final dissemination events



JACARDI

Joint action

cardiovascular diseases and diabetes

Select the level best describing your activities. Use the comments field to provide additional information.

	Approaching	Meeting	Exceeding	Comments
STEP I: JACARDI Core pilot team				
1.1. Compose a diverse core pilot team	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	b) The core pilot team consists of professionals from different disciplines and social groups (e.g. age, gender, ethnicity), and is moderately representative of the community the pilot aims to serve (i.e. 50% of key characteristics of the served community are represented within the team).	c) The core pilot team consists of professionals from diverse disciplines, social groups, and is representative of the community the pilot aims to serve (i.e. 75% or more of the key characteristics identified are represented within the team).	
1.2. Strengthen capacity in equity and diversity within the core pilot team	A) The core pilot team members understand and can explain the 4Cs principle and the relevance of equity and diversity in JACARDI to other partners and this is demonstrated through integrating equity and diversity perspectives in the pilot implementation plan.	b) The core pilot team members understand how to include equity and diversity perspectives in their pilot implementation but need support (e.g. consultations, workshops) of equity and diversity subject matter experts on how to apply them in practice.	c) The core pilot team members feel empowered to apply sufficiently concrete equity and diversity aspects in their implementation plans in an autonomous manner, and actively seek opportunities to strengthen their capacity in equity and diversity beyond JACARDI structures, for example through external seminars, trainings and independent readings.	

	Approaching	Meeting	Exceeding	Comments
Step II: Definition of the problem and the general objective				
2.1 Apply equity and diversity principles in the definition of the problem and the general objective	a) Definition of the problem and general objective were defined based on critical reflection of available quantitative and qualitative data on population demographic, socioeconomic, and ethnic and cultural diversity.	b) In addition to using available quantitative and qualitative data, definition of the problem and the general objective involved consultations (e.g. workshops, interviews) with health professionals and end users.	c) In addition to using available quantitative and qualitative data, definition of the problem and the general objective involved meaningful engagement of health professionals and end users through co-design .	
Step III: Situation analysis at the site of the implementation including key stakeholder analysis				
3.1 Conduct a pilot-level stakeholder analysis	a) Critical reflection was applied to identify diverse stakeholders during the pilot-level stakeholder analysis conducted internally by the core pilot team.	b) Consultations were conducted with diverse individuals, groups, or entities considered to be potentially directly or indirectly affected by the pilot to comprehensively identify all relevant stakeholders.	c) The pilot level analysis was carried out in co-design with diverse individuals, groups, or entities considered directly or indirectly affected by the pilot.	
3.2 Meaningfully engage diverse stakeholders	a) The pilot-level stakeholder board was established together with stakeholders and is diverse in its composition (e.g. experts and professionals, policy makers representing different disciplines and social groups, and persons with lived experiences).	b) In addition to the pilot-level stakeholder board , groups of diverse end users/end beneficiaries, representative of the community the pilot wants to serve, was assembled for relevant consultations/workshops to identify the key themes and discourses that should be taken into account in the pilot.	c) In addition to the pilot-level stakeholder board and groups of diverse end users/end beneficiaries , the pilot flexibly assembled other groups on specific topics (e.g. constituting of specific professional groups or groups that have relevant insights in some current theme related to pilot implementation) to gain more comprehensive insights that benefit the pilot.	

	Approaching	Meeting	Exceeding	Comments
3.3 Identify the impact on diverse end users/ end beneficiaries	a) Impact on diverse end users/ end users was identified through critical reflection on existing data and good practices.	b) Impact on diverse end users/ end beneficiaries was identified through critical review of existing data and good practices and consultations with diverse end users and other relevant stakeholders.	c) Impact on diverse end users/ end beneficiaries was identified through critical review of existing and new data and good practices, and meaningful engagement through co-design with diverse end users and other relevant stakeholders.	
STEP IV Refinement of the general objective				
4.1 Engage diverse stakeholders in refinement of the general objective	a) The general objective was refined with the pilot team, applying critical reflection in consideration of equity and diversity among the end users/ end beneficiaries.	b) The general objective was refined based on consultations with diverse stakeholders and end users/ end beneficiaries.	c) The general objective was refined in co-design with diverse stakeholders and end users/ end beneficiaries.	
Step V Definition of specific objectives				
5.1 Apply the equity and diversity perspectives in the definition of specific objectives	a) Specific objectives were defined within the pilot team, based on critical reflection on equity and diversity among the end users/ end beneficiaries.	b) Specific objectives were defined based on consultations with diverse end users/ end beneficiaries and other stakeholders.	c) Specific objectives were defined in co-design with diverse end users/ end beneficiaries and other stakeholders.	
5.2 Consider equity and diversity when selecting EU best practices/other evidence-based practices	a) Critical reflection considering equity and diversity perspectives was applied when selecting previous good practices (either from the EU Best Practices Portal or other evidence-based practices).	b) EU Best practices/other evidence-based practices were selected based on critical reflection and consultations with diverse stakeholders.	c) EU best practices/other evidence-based practices were selected based on critical reflection and co-design with diverse stakeholders.	

	Approaching	Meeting	Exceeding	Comments
STEP VI Pilot implementation plan No 1				
6.1 Engage diverse stakeholders in development of the pilot implementation plan	a) Key stakeholders/ the stakeholder board was informed on relevant parts of the pilot implementation plan.	b) Key stakeholders/the stakeholder board was consulted when developing the pilot implementation plan.	c) Key stakeholders/the stakeholder board was meaningfully engaged through co-design when developing the pilot implementation plan.	
6.2 Integrate equity and diversity perspectives in the pilot implementation plan	a) Equity and diversity perspectives were integrated in the general objective of the pilot implementation plan.	b) The pilot implementation plan had at least one specific objective related to equity and diversity.	c) The pilot implementation plan had an action point on equity and diversity under each specific objective.	
6.3 Integrate equity and diversity perspectives in the pilot communication	a) The pilot implementation plan explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 and the WP5 JACARDI terminology glossary for internal and external communication in the pilot implementation plan.	b) The pilot implementation plan had a specific objective related to inclusive and accessible communications for pilot internal and external communication.	c) The pilot implementation plan integrated an action point on inclusive and accessible communications for external and internal communication under each specific objective.	
VII Roll-out of actions and monitoring				
7.1 Identify how equity and diversity principles will be monitored	a) Plans for monitoring the principles of equity and diversity during roll-out of actions were identified based on critical reflection within the pilot team.	b) Plans for monitoring equity and diversity principles during roll-out were identified in consultations with diverse end users/end beneficiaries and other stakeholders.	c) Plans for monitoring equity and diversity principles during roll-out were identified in co-design with diverse end users/ end beneficiaries and other stakeholders and based on the pilot implementation plan.	

	Approaching	Meeting	Exceeding	Comments
7.2 Apply equity and diversity perspectives during roll-out of actions	a) Critical reflection was applied within the core pilot team during roll-out of actions (e.g. how are different groups affected; are some groups unintentionally left behind; are relevant and diverse stakeholders meaningfully involved; are pilot communications inclusive and accessible for the target populations).	b) Consultations with diverse end users/ end beneficiaries and other stakeholders took place to support the roll-out of the project.	c) The roll-out was conducted in co-design with diverse end users/end beneficiaries and other stakeholders during the project's roll-out.	
7.3 Continue strengthening capacity in equity and diversity within the pilot team	a) The core pilot team members understand and can explain the 4Cs principle and the relevance of equity and diversity in JACARDI to other partners and this is demonstrated through integrating equity and diversity perspectives in the pilot implementation plan.	b) The core pilot team members understand how to include equity and diversity perspectives in their pilot implementation but need support (e.g. consultations, workshops) of equity and diversity subject matter experts on how to apply them in practice.	c) The core pilot team members feel empowered to apply sufficiently concrete equity and diversity aspects in their implementation plans in an autonomous manner, and actively seek opportunities to strengthen their capacity in equity and diversity beyond JACARDI structures, for example through external seminars, trainings and independent readings.	
7.4 Consider core pilot team composition	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the pilot aims to serve.	c) The core pilot team consists of professionals from diverse disciplines, social groups, and is representative of the community the pilot aims to serve (i.e. all of the key characteristics identified are represented within the team).	

	Approaching	Meeting	Exceeding	Comments
	community the pilot aims to serve.			
VIII Intermediate report No 1				
8.1 Engage diverse stakeholders in evaluation of intermediate results	a) Critical reflection was applied within the core pilot team to consider whether there is a need for changes at action level or specific objectives levels that would further strengthen equity and diversity perspectives in the pilot, and these were described and assessed in the intermediate report. Relevant stakeholders were informed of key aspects of the intermediate report.	b) Consultations were conducted with diverse end users/ end beneficiaries and other stakeholders to consider whether there is a need for changes at general objectives or specific objectives level that would further strengthen equity and diversity perspectives in the pilot, and these are described and assessed in the intermediate report.	c) Diverse end users/ end beneficiaries and other stakeholders were meaningfully engaged through co-design to consider whether there is a need for changes at action level or specific objectives level that would further strengthen equity and diversity perspectives in the pilot, and these were described and assessed in the intermediate report.	
8.2 Integrate equity and diversity perspectives in intermediate reporting	a) Equity and diversity perspectives were reported under the general objective .	b) A specific objective related to equity and diversity (other than inclusive and accessible communications) was reported.	c) An action point related to equity and diversity (other than inclusive and accessible communications) was reported in relation to each specific objective.	
8.3 Integrate equity and diversity perspectives in intermediate reporting on pilot communication	a) The report explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 and the WP5 JACARDI terminology	b) A specific objective related to inclusive and accessible communications for pilot internal and external communication was reported.	c) An action point on inclusive and accessible communications for external and internal communication was reported in relation to each specific objective.	

	Approaching	Meeting	Exceeding	Comments
	glossary for internal and external communication.			
IX Pilot implementation plan No 2				
9.1 Engage diverse stakeholders in development of pilot implementation plan	a) Implementation plan No 2 compiled by the pilot team and stakeholder board was informed on relevant revisions of the pilot implementation plan.	b) Stakeholder board was consulted when developing the pilot implementation plan No 2.	c) Stakeholder board was meaningfully engaged through co-design when developing the pilot implementation plan No 2.	
9.2 Integrate equity and diversity perspectives in the pilot implementation plan	a) Equity and diversity perspectives were integrated in the general objective of the pilot implementation plan No 2.	b) The pilot implementation plan had at least one specific objective related to equity and diversity of the pilot implementation plan No 2.	c) The pilot implementation plan had an action point on equity and diversity under each specific objective of the pilot implementation plan No 2.	
9.3 Integrate equity and diversity perspectives in the pilot communication	a) The pilot implementation plan explicitly mentioned the inclusive and accessible communications checklist produced by WP2 and the WP5 JACARDI terminology glossary for internal and external communication in the pilot implementation plan.	b) The pilot implementation plan had a specific objective related to inclusive and accessible communications for pilot internal and external communication.	c) The pilot implementation plan integrated an action point on inclusive and accessible communications for external and internal communication under each specific objective.	

	Approaching	Meeting	Exceeding	Comments
X Roll out of actions and monitoring				
10.1 Monitor (and if needed revise) equity and diversity principles	A) Equity and diversity perspectives monitored were identified based on critical reflection within the pilot team.	B) Equity and diversity perspectives monitored were identified in consultations with diverse end users/end beneficiaries and other stakeholders.	c) Equity and diversity perspectives monitored were identified in co-design with diverse end users/ end beneficiaries and other stakeholders.	
10.2 Apply equity and diversity perspectives during roll-out of actions	a) Critical reflection was applied within the core pilot team during roll-out of actions (e.g. how are different groups affected; are some groups unintentionally left behind; are relevant and diverse stakeholders meaningfully involved; are pilot communications inclusive and accessible for the target populations).	b) Consultations with diverse end users/ end beneficiaries and other stakeholder took place to support the roll-out of the project.	c) The roll-out was done in co-design with diverse end users/end beneficiaries and other stakeholders during the project's roll-out.	
10.3 Continue strengthening capacity in equity and diversity within the pilot team	A) The core pilot team members understand and can explain the 4Cs principle and the relevance of equity and diversity in JACARDI to other partners and this is demonstrated through integrating equity and diversity perspectives in the pilot implementation plan.	b) The core pilot team members understand how to include equity and diversity perspectives in their pilot implementation but need support (e.g. consultations, workshops) of equity and diversity subject matter experts on how to apply them in practice.	c) The core pilot team members feel empowered to apply sufficiently concrete equity and diversity aspects in their implementation plans in an autonomous manner, and actively seek opportunities to strengthen their capacity in equity and diversity beyond JACARDI structures, for example through external	

	Approaching	Meeting	Exceeding	Comments
			seminars, trainings and independent readings.	
10.4 Consider core pilot team composition	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	a) The core pilot team consists of professionals from different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	c) The core pilot team consists of professionals from diverse disciplines, social groups, and is representative of the community the pilot aims to serve (i.e. all of the key characteristics identified are represented within the team).	
XI Intermediate report No 2				
11.1 Engage diverse stakeholders in evaluation of intermediate results	a) Critical reflection was applied within the core pilot team to consider whether there is a need for changes at action level or specific objectives levels that would further strengthen equity and diversity perspectives in the pilot, and these were described and assessed in the intermediate report. Relevant stakeholders were informed of key aspects of the intermediate report.	b) Consultations were conducted with diverse end users/ end beneficiaries and other stakeholders to consider whether there is a need for changes at general objectives or specific objectives level that would further strengthen equity and diversity perspectives in the pilot, and these are described and assessed in the intermediate report.	c) Diverse end users/ end beneficiaries and other stakeholders were meaningfully engaged through co-design to consider whether there is a need for changes at action level or specific objectives level that would further strengthen equity and diversity perspectives in the pilot, and these were described and assessed in the intermediate report.	
11.2 Integrate equity and diversity perspectives in intermediate reporting	a) Equity and diversity perspectives were reported under the general objective .	b) A specific objective related to equity and diversity (other than inclusive and accessible communications) was reported.	c) An action point related to equity and diversity (other than inclusive and accessible communications) was reported in	

	Approaching	Meeting	Exceeding	Comments
			relation to each specific objective.	
11.3 Integrate equity and diversity perspectives in intermediate reporting on pilot communication	a) The report explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 and the WP5 JACARDI terminology glossary for internal and external communication.	b) A specific objective related to inclusive and accessible communications for pilot internal and external communication was reported.	c) An action point on inclusive and accessible communications for external and internal communication was reported in relation to each specific objective.	
XII Final implementation report				
12.1 Return results to the community and engage diverse stakeholders in evaluation of results	a) Evaluation of results was conducted based on critical reflection within the core pilot team and relevant stakeholders , including end users and end beneficiaries were informed of results.	b) Consultations were conducted with diverse end users/ end beneficiaries when interpreting and evaluating results.	c) Results were interpreted and evaluated in co-design with diverse end users/ end beneficiaries.	
12.2 Integrate equity and diversity perspectives in reporting	a) Equity and diversity perspectives were reported under the general objective .	b) A specific objective related to equity and diversity (other than inclusive and accessible communications) was reported.	c) An action point related to equity and diversity (other than inclusive and accessible communications) was reported in relation to each specific objective.	
12.3 Integrate equity and diversity perspectives in reporting on pilot communication	a) The report explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 and the WP5 JACARDI terminology	b) A specific objective related to inclusive and accessible communications for pilot internal and external communication was reported.	c) An action point on inclusive and accessible communications for external and internal communication was reported in relation to each specific objective.	

	Approaching	Meeting	Exceeding	Comments
	glossary for internal and external communication.			
XIII Focus on the key stakeholders' engagement in building sustainability				
13.1 Revisit (and if needed revise) the key stakeholder analysis	a) Critical reflection applied within the core pilot team to review and revise the key stakeholders and their level of involvement, with consideration of diversity representation (e.g. experts and professionals, policy makers representing different disciplines and social groups, and persons with lived experiences).	b) Consultations conducted with diverse individuals, groups, or entities considered to be potentially directly or indirectly affected by the pilot to comprehensively review and revise relevant stakeholders.	c) Review and revision of key stakeholders carried out in co-design with diverse individuals, groups, or entities considered directly or indirectly affected by the pilot.	
13.2 Apply equity and diversity perspectives in dissemination of results and sustainability actions	a) Critical reflection was applied within the core pilot team to identify priorities for future implementation, plans for dissemination of pilot results and sustainability actions.	b) Consultations were conducted with diverse end users/ end beneficiaries and other stakeholders to identify priorities for future implementation, plans for dissemination of pilot results and sustainability actions.	c) Priorities for future implementation, plans for dissemination of pilot results and sustainability actions were identified in co-design with diverse end users/ end beneficiaries and other stakeholders.	
13.3 Apply inclusivity and accessibility guidelines in material presented to the stakeholder board	a) Critical reflection was applied within the core pilot team in development of materials presented to the stakeholder board, following the WP2 guidelines for inclusive	b) Consultations with diverse end users/ end beneficiaries and other stakeholders were conducted during development of materials presented to the stakeholder board, following the WP2 guidelines for inclusive and accessible communications.	c) Materials presented to the stakeholder board were developed in co-design with diverse end users/ end beneficiaries and other stakeholders, following the WP2 guidelines for inclusive and accessible communications.	

	Approaching	Meeting	Exceeding	Comments
	and accessible communications.			
XIV Sustainability action plan				
14.1 Apply equity and diversity perspectives in development of the sustainability action plan	a) Critical reflection was applied within the core pilot team in developing the sustainability action plan, including consideration of impact and inclusivity of planned actions for diverse population groups.	b) The sustainability action plan was developed in consultations with diverse end users/ end beneficiaries and other stakeholders, including consideration of impact and inclusivity of planned actions for diverse population groups.	c) The sustainability action plan was developed in co-design with diverse end users/ end beneficiaries and other stakeholders, including consideration of impact and inclusivity of planned actions for diverse population groups.	
14.2 Integrate equity and diversity perspectives in the sustainability action plan	a) Equity and diversity perspectives were integrated in the general objective of the sustainability action plan.	b) The sustainability action plan had at least one specific objective related to equity and diversity.	c) The sustainability action plan had an action point on equity and diversity under each specific objective.	
14.3 Integrate inclusive and accessible communications in the sustainability action plan	a) The sustainability action plan explicitly mentioned the use of inclusive and accessible communications checklist produced by WP2 and the WP5 JACARDI terminology glossary for internal and external communication in the pilot implementation plan.	b) The sustainability action plan had a specific objective related to inclusive and accessible communications for pilot internal and external communication.	c) The sustainability action plan integrated an action point on inclusive and accessible communications for external and internal communication under each specific objective.	

	Approaching	Meeting	Exceeding	Comments
XV Celebrate the success				
15.1 Engage diverse stakeholders in planning final dissemination events	a) Diverse end users/ end beneficiaries and other stakeholders were invited into final dissemination events.	b) Diverse end users/ end beneficiaries and other stakeholders were consulted when planning final dissemination events.	c) Final dissemination events were co-designed with diverse end users/ end beneficiaries and other stakeholders, and end users/ end beneficiaries were included in pilot publications (if any).	
15.2 Consider representation among the speakers in the final dissemination events	a) Speakers at the final dissemination events represented different disciplines and social groups , representing at least two key characteristics of the community the pilot aims to serve.	b) Speakers at the final dissemination events were moderately representative of the community the pilot aims to serve (i.e. 50% of key characteristics of the served community are represented within the team).	c) Speakers at the final dissemination events were representative of the community the pilot aims to serve (i.e. 75% or more of the key characteristics identified are represented within the team).	
15.3 Apply the principles of inclusive and accessible communications in final dissemination events	a) Critical reflection was applied within the core pilot team when planning and conducting final dissemination events, following the WP2 guidelines for inclusive and accessible communications.	b) Diverse stakeholders were consulted when planning and conducting final dissemination events, following WP2 guidelines for inclusive and accessible communications.	c) Planning and conducting of final dissemination events were performed in co-design with diverse key stakeholders, following WP2 guidelines for inclusive and accessible communications.	

Appendix C: Equity and diversity lens questions

Methodological step	Guiding questions on equity and diversity
STEP I: JACARDI core pilot team	Is there diversity within the core pilot and is it representative of the communities the pilot aims to serve? Does the core pilot team actively apply the 4C principles of equity and diversity (Critical reflection; Co-design; Context and data; inclusive and accessible Communications)?
STEP II: Definition of the problem and general objective	Were the problem and the general objective defined based on critical reflection and co-design with the end users/ end beneficiaries and other main stakeholders?
STEP III: Situation analysis at the site of the implementation including key stakeholders' analysis	Was the pilot-level stakeholder analysis conducted in co-design with diverse groups affected by the pilot? Was a diverse pilot stakeholder board established? Were diverse groups of end users representative of the community the pilot wants to serve assembled for relevant consultations/workshops to identify the key themes and discourses that should be taken into account in the pilot? Were the 4C principles considered during the situation analysis (e.g. in communication and meaningful engagement of stakeholders through co-design, identification of impact of pilot on diverse groups)?
STEP IV: Refinement of general objective	Was the general objective refined based on critical reflection within the core pilot team and in co-design with end users and other diverse stakeholders to optimally meet the needs of the community the pilot aims at serving?
STEP V: Definition of specific objectives	Were the 4C principles applied in definition of specific objectives (incl. co-design with diverse stakeholders)? Were the 4C principles considered when selecting best practices or other evidence-based practices?
STEP VI: Pilot implementation plan No 1	Was the pilot implementation plan co-designed with the stakeholder board? Were the 4C principles of equity and diversity integrated throughout the pilot implementation plan?
STEP VII: Roll-out of actions and monitoring	Were the 4C principles applied in monitoring of objectives and roll-out of actions? Did the core pilot team continue strengthening capacity in equity and diversity and was representation considered?
STEP VIII: Intermediate report No 1	Were diverse stakeholders engaged in evaluation of intermediate results? Were the 4C principles of equity and diversity integrated in intermediate reporting?
STEP IX: Pilot implementation plan No 2	Were diverse stakeholders engaged in development of the pilot implementation plan? Were the 4C principles of equity and diversity integrated throughout the pilot implementation plan?
STEP X: Roll out of actions and monitoring	Were the 4C principles applied in monitoring of objectives and roll-out of actions? Did the core pilot team continue strengthening capacity in equity and diversity and was representation considered?

STEP XI: Intermediate report No 2	Were diverse stakeholders engaged in evaluation of intermediate results? Were the 4C principles of equity and diversity integrated in intermediate reporting?
STEP XII: Final implementation report	Were the end users engaged in interpreting and evaluation of results? Were the 4C principles applied in dissemination of results?
STEP XIII: Focus on the key stakeholders' engagement in building sustainability	Was the key stakeholder analysis revisited and if needed revised? Were the 4C principles applied in dissemination of results and in sustainability actions?
STEP XIV: Sustainability action plan	Were the 4C principles applied during the development of sustainability action plan?
STEP XV: Celebrate the success	Were the 4C principles considered during the final dissemination events?





JACARDI

Joint action
cardiovascular diseases
and diabetes

ANNEX III

JACARDI WP 2 and
WP Task 5.3



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Guidelines and a checklist for inclusive and accessible communication in the JACARDI project



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Introduction

This document provides principles and guidelines for inclusive and accessible communication in the EU Joint Action on CARdiovascular diseases and Diabetes (JACARDI) project, drawing from guidelines and recommendations developed in EU and WHO, other EU-projects and extensive work of the Finnish Institute for Health and Welfare's (THL) experts on inclusive and accessible communication.

The aspects of inclusive and accessible communication are essential parts of modern communication. In JACARDI's communication, one of the aims is to communicate as inclusively and accessibly as possible while also increasing awareness of these perspectives. The goal is that different target groups can relate to our messages. To achieve this goal communication should be:

- reciprocal and based on active listening to audiences
- respectful, sensitive and take into account the diversity of the population
- clear and understandable and utilize multiple channels.
- Multilingual communication should also be considered as needed.

The checklist is designed for communication experts working in different levels of the project (project, WPs, pilots). In addition, everyone working on the project benefits from using this checklist when producing internal or external communication (presentations, texts, social media, events etc.).

Definition of inclusive and accessible communications

Inclusive and accessible communications refer to principles and practices which ensure that information is suitable for everyone despite of one's abilities, genders, background, or life situations.

According to Calado (2021) inclusive communication is reflecting on

- HOW we build our communication
- WHAT messages (besides the one we intend) the communication can bring forward
- WHO are the direct and indirect targets of the communication
- WHERE and WHEN the communication is shared.

Benefits of using inclusive and accessible communications

Inclusive and accessible communications promote equity in access to information, as well as allow to reach a broader audience. It also creates trust and adds sense of belonging.

Equity in health, social, cultural, and ethnic diversity, and improvement of data availability are cross-cutting themes in the JACARDI project. Communication is an important tool in promoting equity and diversity by ensuring that the main messages of JACARDI, as well as activities and results of each WP are effectively communicated and disseminated to the relevant target audiences, and that messages are conveyed according to the specific requirements of the communication channels.

Legislative underpinnings of inclusive and accessible communications

The legislative measures are designed to ensure that communication is not only available to a wide range of people but is also understandable and usable by everyone, regardless of their abilities or characteristics.

Accessible and inclusive communication is a fundamental human right. Article 19 of the Universal Declaration of Human Rights recognizes that: “Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers” (United Nations, 1948)

The European Accessibility Act (Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services) and supportive standards aim to make a wide range of digital goods and services, provided within the EU, accessible to persons with a disability.

There are also Equality and Anti-Discrimination Laws, Accessibility Standards, Disability Rights Legislation, Inclusive Language Policies, Government Guidelines and International Standards which obligate and guide organisations to act in a specific way.

[Read more about a detailed summary example from Accessible and inclusive public communication: Panorama of practices from OECD countries p. 15.](#)

How to use this guideline?

Use this guideline when you start planning your communication and are developing written or spoken materials, website, presentations, documents, products, events.

This guideline is divided into six sections. Every section has an introduction chapter and after that questions and tips to support your work.

Before you start reading the document, please take a moment and go through the short checklist (next). The checklist will help you understand what you already know and what you still need to familiarise yourself with.

Short checklist

- Have you thought about your own attitudes and biases? Are you aware of them?
- Do you know your audience well enough? Have you involved them in the planning of your project, event or communications?
- Have you clarified goals and timetable for your communication?

- Have you chosen the channels and languages? Have you planned alternative strategies to reach people that cannot read or write?
- Have you planned how to ask feedback and implement?
- Is your language easy to understand for everyone?
- Are you consciously avoiding negative stereotypes?
- Are you aware of recommendations for language considering genders, persons with disabilities and/or different ethnic backgrounds?
- Do you use person-first language?
- Do you follow the principles of plain language when writing your text?
- Are you going to need translations? Do you know who could check the translations?
- Do your images represent diversity (gender and gender expression, ethnicity, age, weight etc.)?
- Are you breaking stereotypes with your choice of visuals?
- Do your documents and web pages comply with accessibility requirements? Have you checked accessibility by using accessibility checker?
- Have you added alt-text to the images? Have you paid attention to colour contrast?
- Do you have captions in your video or transcription in your podcast?
- Are you using a sufficiently large font size?
- Have you ensured the accessibility of tables?
- Have you adopted or created principles for safer spaces?
- Do you know what to do if you or someone encounters hate speech or harassment?
- Do you know what to do if your message or communication offends someone?

1. Communication planning

When planning communication, start by considering what you want to say, to whom, in which channels and when. Find out the behaviour and needs of the target audience. Always involve the target audience already in the planning phase of communication when it is possible. Also, consider the available resources (e.g., time, money) and align actions accordingly.

You can involve the audience in different stages of communication:

- planning and guidance,
- wording communication and choosing topics,
- communication itself (e.g. interviews, blogs, speeches, video appearances),
- testing the message and giving feedback
- disseminating the message in the audience's own channels.

1.1. Assess the behaviour and needs of the audience

Questions to consider:

- Who is the audience in your communication?
 - What does the audience know about the topic? What do you know?
 - How well do you know audience?
 - Are you excluding some part of the audience? Is there something you don't know yet?
 - How do you evaluate the success of your communication?
-
- Note that there is always diversity among wide target audiences for example, age, ethnicity, gender and persons identifying as LGBTQIA+ (lesbian, gay, bisexual, transgender, queer or questioning, intersex, asexual, and more), persons with disabilities. Think how you can reach people within your audience as well as possible.
 - Search the necessary information by getting to know your audience's needs. Useful methods for that are for example co-design methods and workshops with audiences. Also pay attention to existing knowledge gaps (what do you NOT know).
 - Use existing data to gather information about your audience, for example survey data. Remember to be critical on data biases, for example who is represented and what groups are possibly rendered invisible by the data.
 - Be aware of your own assumptions and biases. A good resource for deepening your understanding of own assumptions and biases is the openly available [Online course on anti-racism for professionals developed by the Finnish Institute for Health and Welfare \(THL\)](#)
 - Evaluate the success of your communication by looking at pre-set goals. Also monitor for example statistics and feedback received.

1.2. Modify the content of your message and choose appropriate channels

Questions to consider:

- What do you want to say? What does your audience need to know? What do you want to achieve, what is your goal?
 - What channels does your audience use? Which channels will you choose? Which channels are available for your organisation?
 - Which languages do you need to use?
 - When is a good time to communicate?
-
- Make your point clear to yourself. Involve the target audience in communication planning for example by asking how best to communicate with them and which would be the best ways to spread information in their community. If your target group is very wide, try to consider different needs and values. You can reach members of your target audience or a specific community, for instance, by contacting NGOs or through snowball sampling. Read more in the next chapter 1.3.
 - It is advisable to communicate the same message in different channels. Design and edit your key point(s) to fit the format and audiences of for example social media, press release, print, video. Make use of audio and visuals as well and producing materials also for those who cannot read or who don't have access to a computer, TV or mobile phone (e.g. leaflets, cartoons).
 - Consider the channels and, for instance, social media groups where you might not be used to communicating, but where the target audience is present.
 - In addition to the official languages in your country, also select languages that your audience uses: what are the most spoken languages in your country? Assess the needs for sign languages or braille and widely spoken minority languages.
 - In addition to plain language (see definition below) use easy language if needed. Easy language is designed for individuals with cognitive or learning disabilities, limited literacy, or for whom the language being used may be a barrier. Assess which better suits your audience needs: Easy or plain language communication or translating the message into multiple languages.
 - Test your message and ask for feedback. Involve stakeholders, communities, and target audiences in designing, commenting and implementing your communication. Consider getting feedback from a diverse audience (persons with different age, genders, ethnic background, disabilities).
 - Never outsource communication products without specifying accessibility and inclusion requirements in the contract terms.
 - Time your messaging appropriately because timing influences how a target audience reacts to messages. Consider different cultural holidays (for example Easter, Eid, Diwali). Consider how to incorporate cultural diversity during different health day thematic communication and address the theme from this perspective.
 - When producing multilingual material, find out what already exists. If you start to produce material make it as long-lasting as possible: consider how to present rapidly changing information. For example, contact details

may change quickly, so it is advisable to direct the user to a website where updated contact information can be found.

- If you order translations for your text, remember to check the completed translation. If possible, ask an expert or a native speaker to check your text.
- In addition to translations, also consider the suitability of the material for different audiences, such as different cultures. Test and ask for feedback on the material from the audience.
- During the COVID-19 epidemic in Finland, multilingual and multi-channel crisis communication was developed. Read more to apply these lessons in your own work.
 - [Coping of persons with disabilities and migrant origin populations in serious disruptions and emergencies : Emergency action plans supporting preparedness \(THL\)](#)
 - [Master multilingual communications! A guide to multilingual organisational communications in the event of disruptions \(the Finnish Red Cross\)](#)

1.3 Involving audience in producing communication

Question to consider:

- How can you involve your audience and use participatory methods in communication?
- How does the participant benefit for participation?

- Seek understanding by listening actively. Have an open, curious, humble and honest attitude towards the audience/participants knowledge. Remember that knowledge based on peoples' lived experiences is valuable.
- Make contacts and build trust in communities. Building trust takes time and requires maintenance of relationships. Culturally diverse communities and organisations are often aware of and understand the needs and wishes of local minorities, migrants and the channels for reaching people. These actors are often also perceived as reliable sources of information in communities, which means that people may be more open to listening to information that comes through them. It is a good practice to ask for help, for example, from a professional of integration work or health when trying to reach locally operating organisations. Take into consideration that diversity is also present in each cultural group and language group.
- You can also organise community hearings via an open call, recruit culturally diverse staff, and implement multilingual and multi-channel communications when participating people in a vulnerable situation.
- When developing cooperation, use an interpreter where required.
- Make sure to clarify the aims and objectives of the co-operation at all stages so that no unrealistic expectations arise.
- Make sure participants represent diversity in areas such as age, gender, and background.
- Inform the participants about your organisation and the project, as well as the issue to be developed and the objectives. Introduce the participant's role so they know what they are participating, what is expected and who else is participating.
- Co-operation must be reciprocal. Note that people who are participating should also benefit from collaboration and receive appropriate compensation for their participation. This can be for example a fair compensation for

travel expenses. Direct distribution of money is not advised, unless there's a budget for it in the project. Also tell the participants how to monitor the results and effectiveness of the work.

- If the person involved in the process expresses needs for help, advise them to the right sources of help.
- Remember to thank the participants for their contribution for example with a letter or thank-you event. Share expressions of appreciation outside the process, for example by thanking participants in an interview with a local newspaper or in your communication channels.
- Read more recommendations from chapter 5 Inclusivity of events when planning to host an event or a meeting for participating audience.
- When collecting data from your audience, such as registrations for webinars, it's important to adhere to the General Data Protection Regulation (GDPR). [Data protection under GDPR \(Your Europe\)](#).

2. Use of inclusive language

According to SIEM-project (2022) inclusive language refers to the use of language which is free of words, phrases or tones that reflect prejudiced, stereotyped, or discriminatory views of particular people or groups. It does not deliberately or inadvertently exclude people from being seen as part of a group.

It avoids irrelevant details and acknowledges positive qualities. It is also clear and understandable and considers multilingual aspects.

2.1. Creating more equitable reality by using inclusive language

Questions to consider:

- Are you familiar with current terms?
- Do you use as specific terms as possible and avoid stereotypes and generalizations?

- Check principles and practices for respectful language use. Some principles are written in this document next, but you can also read more for example [Inclusive communication in the GSC \(EU\), which is available in 24 languages BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV](#).
- Remember that language and terminology changes all the time, it is not stable, so consider that your word choices are up to date.
- Language is never neutral, evaluate your word choices critically.
- Deliberately plan the tone of your message.
- Avoid setting up oppositions and using othering language. Do not categorize people into 'us' and 'them.' When discussing people, carefully consider when and how to use words like 'normal,' 'ordinary,' 'similar,' or 'different,' as well as 'other' and 'distinct.' Avoid using expressions like 'both,' 'either' or 'opposite genders'.
- When conveying a message through storytelling, ensure that you avoid unnecessarily perpetuating stereotypes and prejudices about individuals and groups. The power of stories is very strong.
- If you are unsure which is the right term, ask for help. If your message pertains to specific individuals, inquire about the term, title, or pronoun the person prefers to be addressed by. If you don't know the pronouns

- someone uses, you can use their name in texts. Ask if they would like their family relationships, disabilities, background, or nationality to be mentioned and what words they prefer to be used regarding those aspects.
- Pay attention to speaking about different people with equal respect. For example, if you use a surname for one person, use surnames for all others mentioned in the same context. For instance, you cannot refer to a young woman performing operational work by her first name if an older male manager is mentioned by his surname in the same context.
 - Also participate people from different minority groups (e.g. gender minorities and persons with disability) and ask for feedback.

2.2. Gender-sensitive language

Questions to consider:

- Are you aware of the gendered aspects of language?
-
- Gender-neutral language treats women, men, and non-binary people equally and does not perpetuate stereotypical perceptions of gender roles. It also considers those of a non-binary gender. When weighing up gender-neutral alternatives, always be aware of any possible ambiguity or shift in meaning and choose accordingly.
 - Gender equality in language is attained when women and men – and those who do not conform to the binary gender system – are addressed through language as persons of equal value, dignity, integrity and respect. (EIGE).
 - Avoid the generic masculine pronoun (for example instead of using his, use his or her, or change the sentence to a plural).
 - Remember gender diversity. If the matter concerns all genders, do not only talk about men and women.
 - Do not provide irrelevant information about people's gender.
 - Avoid using gendered nouns (avoid policeman > prefer police officer)
 - Ensure that your language actively promotes gender equality by not trivializing or subordinating women.
 - Also break stereotypes dealing with families, remember there are a lot of variation in families and their ways to divide household chores.
 - Learn more and see more examples:
 - [EIGE toolkit on gender sensitive communication](#)
 - [Inclusive communication in the GSC \(EU\), available in 24 languages BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV.](#)

2.3. Persons with disabilities and diseases

Questions to consider:

- Are you using sensitive language while you are speaking with persons with some disabilities?
- Does your communication see the person behind disability or disease?

- Use language that is person centered. Use person first language: a person with a disability, person with diabetes (instead of diabetic as a noun), a person in a vulnerable situation.
- Emphasize each person's individuality and capabilities rather than defining them by a condition.
- Avoid phrases like 'suffers from' and passive 'victim' words.
- Avoid terms that define the disability as a limitation. There is variation among individuals in how they want to emphasize the role of disability in their own identity. Aim for neutrality in expression, avoiding reinforcing the taboo nature and negativity surrounding disabilities.
- In addition to the individual, also consider the circumstances in society, recognizing that disability is not a problem, but rather, it is an obstructive society.
- If the disability in question is not relevant, refrain from defining the group through it. Actively highlight that groups are not homogeneous.
- When referring to people with disabilities in your communication, acknowledge “invisible” disabilities, such as learning disabilities, mental conditions, or chronic pain.
- According to the recommendations for diabetes related language use made by the Association of Diabetes Care & Education Specialists (ADCES) and the American Diabetes Association (ADA) diabetes related language is:
 - neutral, non-judgmental, and based on facts, actions or physiology/biology.
 - free from stigma
 - strengths-based, respectful, inclusive and imparts hope
 - fosters collaboration between patients and providers
 - person-centered.
 - Read more about language and diabetes:
 - [Speaking the language of diabetes: Language Guidance for Diabetes-Related Research, Education and Publications \(ADCES\)](#)
 - [Language matters: language and diabetes \(NHS England\)](#)

2.4. Ethnic and cultural diversity

Questions to consider:

- Does your language consider people from different ethnic backgrounds in a respectful manner?
- How do you consider intercultural aspects in your communication?

- Use person-first language.
- Avoid assumptions and generalizations about different nationalities and cultures.
- Be aware and actively deconstruct hierarchies such as whiteness as a norm.
- Use specific terms if you refer to a person's cultural background, ethnicity or nationality or migrant definition. If you need to refer to a person's ethnic background or nationality, be as specific as you can. For example,

instead of a general term such as 'Asian' which covers a broad range of people, use more specific terms such as 'Indian', 'Pakistani', 'Japanese' or 'Chinese', etc. if you can.

- Use terms and definitions related to migration correctly (e.g., asylum seeker, refugee, immigrant, resident, citizen).
- Use minority definitions correctly, for example a person with roma origin, The Roma, Romani communities.
- Remember that communities are multiple, not homogenous.
- Do not victimize, marginalize, or represent individuals or communities as helpless.
- Do not make assumptions about anyone's religion or other beliefs based on their appearance or country of birth.
- Recognize the differences between language, culture, ethnicity, nationality, and religion. For example, 'Somali' refers to someone of Somali background who speaks the Somali language, and its meaning is not the same as the term 'Muslim,' which refers to a person practicing Islam.
- [List of concepts \(Migration and cultural diversity, THL\)](#)
- [Cultural competence and cultural sensitivity \(Migration and cultural diversity, THL\)](#)
- [Media and Migration - Ethical Journalism Network](#)

2.5. Understandable and clear language

Questions to consider:

- Do you use clear and understandable language or plain language?
- Is your message as clear as possible?
- Are you avoiding jargon? Are there idioms which might be hard to understand?

- Organise information so the most important points come first.
- Use short sentences and familiar words.
- Avoid jargon.
- If you use idioms, make sure that everybody understands them.
- Write out the abbreviations.
- Use active instead of passive.
- Consider text structure: Use headings and subheadings and bullet points for lists.
- Use images and icons to help illustrate the content.
- Use of plain, understandable, and clear language also helps people who are practicing language (non-native speakers, people who are practicing new language etc.). Aside from multilingual communication, the use of plain language helps people understand the message more easily.
- [Read more about Clear and Understandable Content \(WCAG2\)](#)
- Assess the needs for easy language and Easy Read documents which are for people who have difficulty reading and understanding written information. Documents presented in Easy Read allow information to be more easily accessed by people that have difficulty reading, for example people with intellectual disabilities or people who are learning language. [Easy-to-read \(Inclusion Europe\)](#)

3. Inclusive use of visuals

Images and illustrations are an essential part of communication. Through the selection of visuals, one can enhance clarity in messaging, foster inclusivity, and break down stereotypes. By choosing diverse images, people can better relate to your message.

3.1. Representing diversity in image selection

Questions to consider:

- How does the picture make you feel? What are your initial impressions? Do you like it? Why? Why not?
 - Does the image strengthen your presumptions?
 - Is there diversity? Is there inclusiveness?
 - What is the message? Does it correspond to the message you want to get across?
- Consider the topic and your objectives to messages and select suitable image. Consider also that you are representing real people and communities who you are talking about. Ensure that there is diversity among people: use images that include representatives of minority groups in communication aimed at everyone.
 - Ensure that your image selection doesn't represent gender, age, ethnic and other groups in a stereotypical way. Instead, be creative and dismantle harmful norms. If you are not sure, what the harmful norms may be, consult your stakeholders or target audiences.
 - Consider positions people have: who is in active role, who is assisting and who is the expert?
 - Pay attention to the technical aspects of the images: Who is in focus? Who is in the foreground and background? Ensure that there is variation in these technical aspects of the images, for instance, among different genders and age.
 - If possible, hire a photographer to take customized photos for you instead of stock photos.
 - Use AI (e.g. ChatGPT, DALL-E) as a tool for getting ideas and inspiration to your visuals carefully. Avoid creating photos by using AI or at least be aware of and consider potential risks of creating false impressions or reinforcing stereotypes because the information that AI uses might be discriminatory and biased. Read more for example: [Reproducing inequality: How AI image generators show biases against women in STEM \(UNDP Serbia\)](#)
 - Be extra careful while you are illustrating sensitive topics (e.g. mental health problems, sexuality, violence). Make sure you are not reinforcing stereotypes by considering who you are representing. When illustrating sensitive topics like violence, realistic images can cause distress for those who have personal experiences related to the subject.
 - Discuss the use of images and ask for feedback for example from your colleagues and target groups.

3.2. Add accessibility of your messages through infographics and icons

Questions to consider:

- How could you consider inclusivity in infographics and avoid stereotypes?
 - Have you considered digital accessibility in your infographics?
- Disassemble stereotypical color and icon choices, such as depicting women with a red skirt icon and men with a blue trouser icon.

- Check sufficient color contrast and font size.
- Use image captioning: text near an image can help provide more context. Image captioning is recognised by screen readers. Do describe what you are captioning. This is important for people who don't have access to the image itself. They must be able to understand what picture you are captioning. Be sure to be clear and elaborative on your caption. (SIEM)
- Avoid text within an image if you want the text to be able to be identified by screen readers. Text-as-image is not ideal for people who use magnifiers, as magnifying text within an image could result in a pixelated result. If you must use text-as-image, consider using alt-text or image captioning and SVG (Scalable Vector Graphics). (SIEM)
- Design with colourblind people in mind. To avoid any complications, graphic designers should always use a non-colour identifier (such as icons of various shapes or text descriptions). (SIEM)

4. Digital accessibility

Accessibility means that as many different people as possible have the opportunity to access information regardless of their abilities, characteristics, or life situation. This means that in addition to cognitive accessibility (such as clear language, easy to perceive content) and social accessibility, attention must also be paid to technical accessibility. Accessibility is based on EU directives aimed at removing barriers to accessing information. Paying attention to accessibility helps those who use assistive tools, but it also benefits everyone else because accessibility makes communication clearer and reachable in different situations.

The standards for accessibility have been set in the Web Content Accessibility Guidelines (WCAG). Methods of implementing accessibility vary across different countries. In this chapter you can read some guidelines to enhance and implement accessibility.

Read more about accessibility:

- [Accessibility standardization \(European Commission\)](#)
- [Web Content Accessibility Guidelines \(WCAG\)](#)
- [Accessibility overview \(Webaccessibility.fi\)](#)

4.1. Making documents (pdf, word), presentations (PPT), forms, and web pages that comply with accessibility requirements

- Check the principles for clear and understandable language (chapter 3).
- Check guidelines for making different documents accessible:
 - [Make your PowerPoint presentations accessible to people with disabilities \(Office accessibility, Microsoft\)](#)
 - [Make your Word documents accessible to people with disabilities \(Office accessibility, Microsoft\)](#)

- [Create accessible PDF's \(Office accessibility, Microsoft\)](#)
It is always easier to prepare source file accessible and after that save the file as pdf-format by these instructions.
- [Improve accessibility with the Accessibility Checker \(Microsoft\)](#)
- Use appropriate tools in documents; for instance, when adding headings, select the correct heading level from the text settings, or when adding an image, use the 'insert image' option. Avoid typing everything in capital letters or italics. Use bold for emphasis but do so moderately.
- In terms of accessibility, it might be easiest to create a web page from the text within the document, as it eliminates the need for a separate accessibility check of the document. Evaluate the publishing format on a case-by-case basis.

4.2. Adding alternatives for people with visual impairments or deaf people

- To enable the access to visual content for everyone, include alternative texts that can be read by a screen reader with visuals. A good alternative text helps people who cannot see it, understand the information communicated by the photo. Alt-text should be a short description of the visual, try to catch main point or idea or key results. Don't use phrase "image/photo of...".
- To enable the access to audio content for deaf people, add transcripts, subtitles, international sign language or other sign language interpretation. For example, include subtitles/ caption or transcripts for videos, and transcripts for podcast.
- Consider the use of colors and the contrast between text and background so that text is readable for a visually impaired person. Use contrast checker tools to ensure sufficient contrast, for example [WebAim Contrast Checker](#).

4.4 Considering accessibility in social media

- Write the posts using clear text. Check the recommendations for inclusive use of language and visuals.
- Use inclusive images and add alt-text them.
- Add captions for videos.
- If you use hashtags which consist of more than one word, use capitalization to differentiate the words eg. #DiabetesPrevention instead of #diabetesprevention.
- Use emojis but use them in moderation. Use of emojis can clarify your message. Never use emojis to replace words. Emojis can be placed, for example, at the end of the sentence rather than in the middle because screen readers always read out them.
- Avoid using strobing, flashing or "Slam" transitions in videos.
- Read more: [Creating Accessible Social Media Content – GAAD Toolkit](#)

5. Inclusivity in events

The success of an event is enhanced by ensuring that everyone has the opportunity to participate. Inclusivity should be considered from the planning phase to the actual event. Ways inclusivity can be increased are through speaker selection, attention to language usage and image choices, as well as considering improvements in physical accessibility.

5.1. Planning the program

Questions to consider:

- How to make sure your event program is promoting inclusiveness?
- Ensure that the representatives of minorities are invited to participate as experts in discussions, not solely as individuals sharing their personal experiences. The involvement of experiential experts should be carefully considered, especially in situations where a person from a minority group is expected to publicly share their experiences. Can sharing experiences further expose someone to vulnerability, such as becoming a target for hate speech or triggering traumatic experiences?
 - Ask the person the term, title, and/or pronoun they wish to be referred to as.
 - It's good to describe the nature of the event to the speakers in advance and assist them in considering how they would like to introduce themselves in this context. Individuals should be given the opportunity to introduce themselves if they wish. If the speaker needs a support person can also be offered. Speakers' travel expenses and meals can also be covered to enable the participation of those with low incomes.

5.2. Taking participants' needs into account in practical arrangements

Questions to consider

- What kind of needs might the audience have?
 - Are you familiar with principles for safer space which aim to improve the inclusion of vulnerable people and groups of people in particular?
- Put yourself in the shoes of the participants. Consider the benefits, barriers and questions of participation from the participant's perspective.
 - Plan a budget and allocate money for supplies, travel, catering, and admission fees (especially when participating people with lived experience).
 - Depending on an event arrange childcare so that parents of small children can also participate (especially when participating people with lived experience).
 - Offer different ways to participate in workshops, for example, in addition to active participation, assess if it is also possible to observe or for example draw pictures.
 - Get familiar with and implement the principles of safer spaces: [Principles for safer events at THL](#) Make sure all participants accept the principles when registering. Feedback collected after the event provides an opportunity to comment anonymously on the safety and accessibility of the event. An effort should be made to investigate situations that may emerge afterwards so far as possible.
 - Intervene to harassment. Plan and prepare in advance how to handle different disruptive situations by for example allocating roles and responsibilities and having a set of simple guidelines.
 - Ensure the accessibility of the space, making it suitable for people with physical disabilities, visual impairments, and hearing impairments. Assess if you need an interpreters.

- When presenting, explain verbally everything that is in your presentation and avoid leaving graphs or images up to the interpretation of your audience, since there might be someone with a learning disability or a visual impairment.
- Make your presentation accessible and instruct speakers to make their presentations accessible ([check how to make PowerPoint accessible, Microsoft](#)).
- Ensure that posters are not hung too high.
- Don't start your speech with the greeting "Welcome ladies and gentlemen!", prefer "Welcome all!"

6. Difficult situations

It's important to acknowledge that themes considering inclusivity may evoke different emotions in people. Individuals promoting inclusivity might, for instance, become targets of hate speech or harassment. Or communities you are dealing with may counter hate speech. That's why it's important to also prepare procedures to support individuals and communities who have been targeted by hate speech. No one must tolerate harassment.

Questions to consider:

- Do you know how to act if you or your colleague encounter harassment?
- Does your organisation have support for a person who is a victim of hate speech? What do you do if your message offends someone?
- How to react if your message or communications offends

- Seek support, don't suffer alone.
- Save all messages immediately, as social media messages can be deleted or edited. Save all emails, text messages and other messages you receive – do not delete anything.
- Assess if there is a serious threat and if you are in danger.
- Report the inappropriate message to the organiser of the event or the administrator of the website or social media channel and ask them to delete it. You can also block the user.
- Do not respond to a message until you have assessed the situation. Try to be calm, do not respond if you are feeling very emotional. If you are going to answer use appropriate language.
- Show support to your colleague or community when needed.
- Sometimes accidents happen. If you notice or receive feedback that your message was hurtful, apologize and express regret. Learn from your mistakes and act differently next time.

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- [OECD \(2022\) Accessible and inclusive public communication Panorama of practices from OECD countries](#)
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- [WHO \(2017\) WHO Strategic Communications Framework for effective communications](#)

Guidelines for EU-projects

- [Bridging the Gap - Inclusive and accessible communication guidelines \(2018\)](#)
- [Inclusive Communication Manual A practical guide on how to communicate inclusively with international youth SIEM Social Inclusion & Engagement in Mobility \(2020\).](#)

Other tools and guidelines

- [ADCES \(2021\). Speaking the Language of Diabetes:Language Guidance for Diabetes-RelatedResearch, Education and Publications](#)
- [Creating accessible and inclusive communications | IncludeAbility](#)
- [Creating Accessible Social Media Content – GAAD Toolkit](#)
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JACARDI

Joint action
cardiovascular diseases
and diabetes

ANNEX IV: Methodological framework for country-level context analysis and review and identification of European best practices and other practices

JACARDI WP Task 5.1



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Glossary of Acronyms

Acronym	Description
CVDs	Cardiovascular Diseases
DG SANTE	European Commission's Directorate-General for Health and Food Safety
DM	Diabetes
EC	European Commission
EC Best Practice	EU Best Practice Portal
EU	European Union
GDPR	General Data Protection Regulation
ISS	Istituto Superiore di Sanità
JA	Joint Action
JACARDI	Joint Action on Cardiovascular Diseases and Diabetes
JANFP4Health	Joint Action of National Focal Points for Health
NCDs	Non-Communicable Diseases
NFP	National Focal Point
MS(s)	Member State(s)
WP	Work Package

Keywords

Context analysis, best practices, EU, cardiovascular diseases, diabetes

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Executive summary

The Methodological framework for country-level context analysis, and review and identification of European best practices and other practices provides essential guidance to support the Work packages (WPs) 6 to 11 in analyzing the context of cardiovascular diseases (CVDs) and diabetes across Europe. It helps identify the needs in current prevention and management practices and supports pilots to address them.

Additionally, the framework guides the WPs in selecting relevant evidence-based practices. This process not only strengthens the evidence-based rationale for pilots but also plays a vital role in team building by fostering a shared understanding of the objectives and activities. By learning from practices implemented in other settings, the core pilot teams can enhance the design and implementation of their own pilots.

In summary, this methodological framework is a foundational tool that ensures the JACARDI pilots are grounded in robust, context-specific evidence, thereby facilitating the successful implementation and sustainability of best practices in the prevention and management of CVDs and diabetes.

1. Introduction

1.1 Purpose and scope of the document

This document provides guidance for the activities planned in Task 5.1 of JACARDI. The objective of this task is to establish a methodological framework to support and facilitate the Work Packages (WPs) 6-11 in conducting context analyses and identifying best practices and other relevant practices related to cardiovascular diseases (CVDs) and diabetes, in alignment with the specific objectives of the WPs.

This methodological framework is divided into two parallel tasks:

- **Subtask 5.1.1** aims to perform a context analysis to assess the current state of the prevention and management of CVDs and diabetes at the European level. The topics covered in the context analysis align with the subjects of WPs 6-11. This assessment includes evaluating the availability of governance and financing, as well as the status of service delivery and capacity for the prevention and management of CVDs and diabetes, including aspects of intersectoral collaboration and equity. The overall aim of this subtask is to map the state of the art at both national and European levels, identifying specific needs.

In particular, through Task 5.1.1, the core pilot teams are able to determine whether their pilots are addressing the identified needs at the country level and how they are doing so. Since this information becomes available after they have already decided on their general objectives, specific objectives, and pilot implementation plans, the core pilot teams can still use this information during the intermediate reporting phase. At this stage, they have the opportunity to adjust their pilots. They also benefit from the results of this mapping in the development of the Final Implementation Report (Step XII) and the Sustainability Action Plan (Steps XIII to XV).

- **Subtask 5.1.2** aims to guide the WPs 6-11 in identifying best practices (from EU Best Practice Portal) and/or other pertinent and appropriate practices to design the implementation of pilots. This process is pivotal in providing a strong evidence-based rationale for the pilots and also serves as an important step in team building, aimed at understanding the pilots' objectives and activities.

In particular, through Task 5.1.2, the core pilot teams have the opportunity to scan the context in other settings where practices relevant to their pilot have already been implemented and to learn from them. This is done even if they are limited by the information made available by the EU Best Practice Portal and other publication sources.

1.2 Structure of the document

This document is structured as follows:

1. Introduction: Presents the scope and purpose, outlines the document's structure, and explains its connection to other project activities.
2. Development process: Details the process used to develop the country-level context analysis mapping and the selection of evidence-based practices for the pilot projects.
3. Methodological frameworks: Describes the methodological frameworks for the country-level context analysis and for the review and identification of best practices or other appropriate practices.
4. Conclusions and recommendations: Offers final insights and suggestions for future.

1.3 Relation to other work in the project

This document is directly connected to WPs 6-11. Specifically, in the context analysis activity, it integrates information on the equity lens promoted by Task 5.3.

2. Development process

2.1 Development process of the Methodological framework for country-level context analysis

2.1.1 Rationale

The rationale behind conducting a context analysis at the European and country levels arises from the necessity of considering the broader context when implementing a new intervention. To achieve this goal effectively, it is crucial to first describe the current state in terms of the strategic framework, policies, and service delivery and capacity for the prevention and management of CVDs and diabetes. Secondly, it is important to assess how closely this aligns with the ideal state, as defined by evidence from international/European guidelines, scientific literature, and expert knowledge.

By examining the deviations between the current state and the ideal state, we can establish the essential groundwork for identifying areas needing improvement. This assessment is crucial for identifying needs and understanding how the core pilot teams can address them through implementation, for example by remodulating their pilots and/or aligning their sustainability action plan.

In particular, this assessment serves multiple critical purposes:

- For WP6-11 leadership teams: It provides essential insights for developing roadmaps to scale up the results and outcomes of the pilots. It also helps identify the characteristics and factors that need to be considered when developing implementation strategies.
- As input into the JACARDI sustainability action plan: It supports the potential future impact of JACARDI as a Joint Action (JA), ensuring the sustainability and long-term benefits of the initiatives.
- For national (and regional) policymakers and other stakeholders: It informs the design of future policy responses to the burden of CVDs, diabetes, and other NCDs. This includes the incorporation of the results and outputs of JACARDI pilots into national and regional strategies.
- For European policymakers and other stakeholders: It aids in supporting EU policy development and initiatives to tackle the burden of CVDs and diabetes. This includes fostering collaboration and synergies among EU countries to create a unified and effective approach.

2.1.2 Objective

The objective of Task 5.1.1 was to identify and assess the status of existing measures for the prevention and management of CVDs and diabetes at the European and country level, and to evaluate their alignment with international recommendations (ideal state). Specifically, the assessment focused on six thematic areas: health literacy and awareness, data availability, quality and harmonization, screening of high-risk populations, integrated care pathways, and patients' self-management and labour participation. These areas align with the activities planned in the project's WPs 6–11. This comprehensive context analysis included evaluating governance and financing, as well as the status of service delivery and capacity, intersectoral collaboration, and equity. The overall aim was to map the current state at both national and European levels, identifying specific needs to inform future improvements.

2.1.3 Methods

To achieve the objective of Task 5.1.1, a questionnaire was implemented, specific to each thematic area and tailored for both CVDs and diabetes, to map the current state at the national level. The questionnaires were distributed to National Focal Points for Health through a collaboration with the JA of National Focal Points for Health (JANFP4Health) in 32 European countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Moldova, Netherlands, Norway, Poland, Portugal, Republic of Serbia, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine. Of these countries, 21 are included in JACARDI; the questionnaires were sent also to the 21 Competent Authorities participating in JACARDI to maximize synergies between the two JA and increase the response rate (for more details on distribution please see section 2.3.3 Questionnaire distribution).

2.2 Development process of the Methodological framework for the review and identification of best practices and other practices

2.2.1 Rationale

The rationale to identify successful practices and interventions, or single elements of these, that have been already implemented across Europe, lies on the idea that only relevant and appropriate practices should be implemented by pilot sites and that each pilot project should have a strong evidence-based rationale at its basis.

Through this, we aimed to ensure that the pilots to be implemented were effective and efficient, transferable, sustainable, and encompass participation and intersectoral collaboration as well as an equity approach following the core and qualifier criteria from DG Santé evaluation of Best Practices.

2.2.2 Objective

The specific objective of this methodological framework is to guide the technical WPs in identifying key elements of best practices from the EU Best Practice Portal (EC Best Practice) and other relevant and appropriate practices for potential adaptation and implementation within pilot sites, with a focus on the sustainability of their results. This process is pivotal in providing a rationale for the pilots and serves as an important step in team building, aimed at understanding the pilots' objectives and activities.

2.2.3 Methods

The identification of best practices and other practices was centered on internal discussion among WPs 6-11 and a review of the EU Best Practices Portal, scientific sources, evidence from other existing projects and initiatives, and grey literature.

3. Methodological frameworks

3.1 Methodological framework for context analysis at the European and country level

3.1.1 The country-level questionnaires

Following a common structure ([Appendix A: Questionnaire Framework](#)), 12 structured questionnaires were developed, tailored for six thematic areas:

1. Health literacy and awareness
2. Data availability, quality, accessibility and sharing
3. Screening high-risk populations and individuals
4. Integrated care pathways
5. Patients' self-management
6. Labour participation

Each was developed for both CVDs and diabetes separately.

The context analysis evaluated two main sections for each of the six thematic areas. These topics were derived and adapted from the [Scirocco maturity model](#) and [WHO building blocks](#):

i. Governance and Financing

This section, made of about 15 questions, assessed the state of legal framework, policies, strategies, action plans, and financing related to CVDs and diabetes prevention and management at national level. In particular, the section was subdivided in five topics:

- Legal framework
- Strategic framework
- Intersectional policies and practices
- Equity-oriented approach
- Fundings

The framework has been tailored to the specific characteristics of each WPs 6-11. The questions were developed by the Task 5.1 team, adapted to the specific characteristics of each thematic area, and subsequently refined in coordination with WP6-11 leadership teams.

In this section, the ideal state to strive for is the presence and implementation of the subject matter of the question itself (such as the presence of a regulatory framework for the prevention and management of CVDs and diabetes, the presence of a national plan for the prevention and management of CVDs and diabetes, etc.).

ii. Service Delivery and Capacity

This section assessed the current implementation of services to the population.

This section was developed individually by the WPs 6-11 teams, providing specific content tailored to the characteristics and objectives of each thematic area. This section provided the WP with the opportunity to map the current situation of services, and to highlight needs, challenges, and opportunities at the national and European level.

In particular, to populate the “Service Delivery and Capacity” section of the questionnaire, technical WP leaders were tasked to initially identify **the ideal state** pertaining to service delivery and capacity relevant to

their WP's topic (*Appendix C: Template for the identification of the Ideal State*). To identify the ideal state, WP6-11 leadership teams and teams relied on three levels of sources:

- i) The knowledge and expertise of WP6-11 leadership teams and partners, with references and bibliographies required as scientific evidence;
- ii) Relevant scientific literature, grey literature, international and national guidelines, and evidence from previous EU JA or projects;
- iii) Other pertinent data sources, such as experts and stakeholders in the field, specific databases, and web resources, deemed reliable and trustworthy.

Upon receiving all questions developed by each WPs 6-11, the Task 5.1 team proceeded with the harmonization and finalization of each questionnaire.

3.1.2 REDCap Tool

The REDCap online software was chosen for the distribution of the questionnaires, especially for its reliability and ease of use, as well as its compliance to the standards of the GDPR for data collection and privacy.

The questionnaires on REDCap were sent via 12 different links for the online completion. Submission of responses was possible only after all mandatory questions had been answered. The questionnaires could have been completed in multiple sessions, with the ability to save responses progressively. The completion process is entirely anonymous.

3.1.3 Questionnaire distribution

The surveys were distributed to National Focal Points for Health (NFPs) participating in the Joint Action National Focal Point for Health (JANFP4Health). The National Focal Point decided whether to respond directly or to forward specific questionnaires to national experts. Additionally, the Competent Authorities participating in JACARDI were involved and asked to support their respective NFP in selecting experts and/or completing the questionnaires.

Along with the 12 links for the online completion of the questionnaires, each NFP received a Guide to Completion, a Glossary, and the 12 questionnaires in PDF format for preliminary consultation regarding the content. Online completion was strongly encouraged.

3.1.4 Data analysis and reporting

The data collection period started on 2 April 2024 and ended on 7 June 2024, for a total of 67 days of data collection. The data analysis was performed by the Task 5.1 team between June and September 2024. The final report on the general results of the survey will be completed within the Deliverable 5.2 at Month 18 by the Task 5.1 team. Findings of the context analysis were summarized at WP and Country level. For each WP and for both CVDs and diabetes, a summary report was produced. Results were presented through a combination of figures and text boxes to return a concise yet comprehensive overview of the current status of the CVDs and diabetes prevention and management at European level. Each WP report was complemented with country profiles providing a snapshot of the governance, financing, service delivery and capacity situation in each country that responded to the survey. In addition, the collected data was shared

with the technical WPs (WP6-11) to serve as a source of information for achieving their respective milestones based on the available information from EU countries.

3.1.5 Timeline

On April 2, 2024, the questionnaires were sent to the NFPs and Competent Authorities of JACARDI, covering 32 European countries, including the 21 countries participating in JACARDI, with a response deadline of May 17, 2024. On May 17, 2024, an extension was granted until June 7, 2024.

Responses were collected by the Task 5.1 team through REDcap.

The raw data, divided by WP, was shared with the WP6-11 teams for further analysis on their specific topic to be incorporated in their respective milestones.

The analysis was conducted between June and September 2024 by the Task 5.1 team. The report with the results at both the European and national levels, divided by thematic area and disease, will be produced by October - November 2024 (Deliverable 5.2).

A first session to share the synergy between JACARDI and JANFP4Health, as well as the methodological process of mapping, took place during the “Synergies for Integrated Care” Showcase event, co-organized by HaDEA on October 28-29. A more in-depth workshop to present the results will be organized in January 2025.

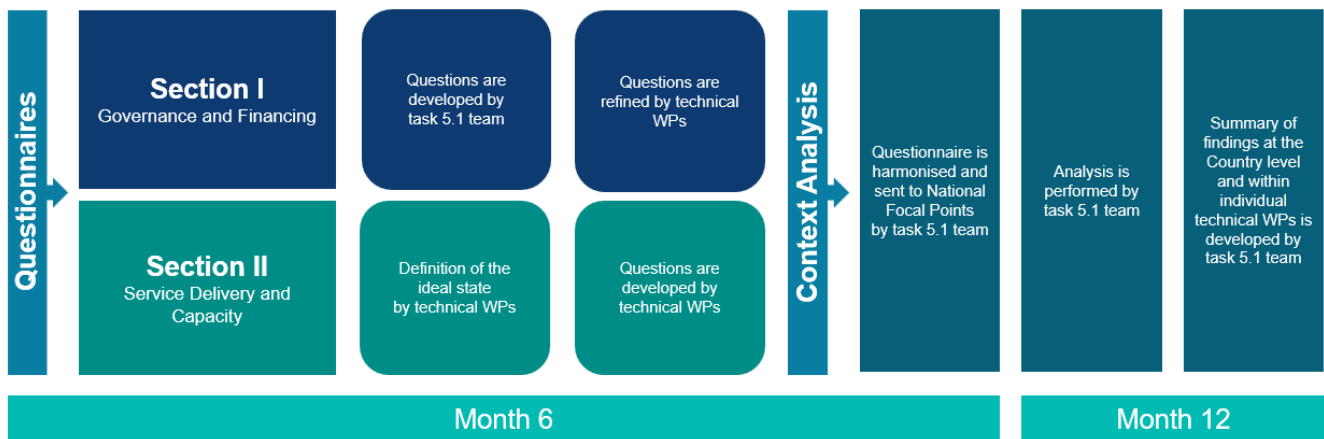


Figure 1. Visual of the Methodological framework for country-level context analysis

3.2 Methodological framework for the identification of best practices and other practices

3.2.1 The process of the identification of best and other practices

The process for the identification of relevant practices was conducted in **three operational phases (0, I, II)**, with an additional Phase III dedicated to the presentation and validation process.

Phase 0

Phase 0 was based on **internal discussions** within the WPs 6-11, where WP6-11 leadership teams and partners collaboratively reviewed the characteristics of the pilots they proposed for implementation. This assessment's aim was to strengthen team building and further strengthen the objectives and characteristics of the pilots, and identify whether they relied on EC Best Practices or other relevant practices from existing initiatives or projects.

Phase I

Phase I involved **reviewing the EU Best Practice Portal** by the core pilot teams to determine if there is a best practice that aligns with the activities and objectives of the proposed pilot. The European Commission defines the best practice as *a relevant policy or intervention implemented in a real life setting and which has been favorably assessed in terms of adequacy (ethics and evidence) and equity as well as effectiveness and efficiency related to processes and outcomes*. Other criteria considered important for the successful transferability of the practice beyond the scope of JACARDI included a clear definition of the context, sustainability, intersectionality, and active involvement of stakeholders.

If the core pilot team identified a Best Practice that could serve as the rationale for its pilot, it proceeded by completing Appendix D (Appendix D: Template for data extraction for Best-Practice (Phase I)) with the main information regarding the Best Practice.

The template for best practices (Appendix D) included:

- Title
- Origin
- Country
- Year of selection
- Pre-selected thematic areas where the best practice falls into
- The elements or single element to be implemented

If the core pilot team did not identify any best practice in the EU Best Practice Portal, it moved on to Phase II.

Phase II

Phase II involves the core pilot team **identifying appropriate practices from other resources**, such as scientific evidence, literature reviews, and other European projects and initiatives. **After identifying a practice that is appropriate and aligned with the objectives and activities of the pilot, the core pilot team completes Appendix E (Appendix E: Template for data extraction for other relevant practices (Phase II)), including relevant information about the selected practice.**

Since these practices have not been evaluated by the meticulous process as the ones shown at EU Best Practice Portal, after their identification, they were required to be validated by a delegation of

the Implementation Board through a formal presentation of the pilot project. The validation process was incorporated within the capacity building efforts of the respective WPs 6-11, where all core pilot teams had the opportunity to present, share, and discuss the explanations and arguments regarding why and how the respective practices may be relevant for the pilots.

Template for other practices (Appendix E) included:

- Platform or existing initiatives/projects where the practice has been retrieved
- Year of implementation
- Location and geographical extension
- Setting
- Target population
- Number of population reached
- Methodology
- Outcomes
- Pre-selected thematic areas where the practice falls into
- Alignment with the WP's aim (100 words)
- The elements or single element to be implemented
- At least one criteria (see below) identified, including the explanatory arguments, why and how the element(s) of the practice would be relevant for the respective pilot to achieve the stated criterion. This part is crucial for the Implementation Board validation.

The validation of these practices was completed by a delegation of the Implementation Board. The six criteria used by the European Commission "[Criteria to select Best Practices in Health Promotion and Disease Prevention and Management in Europe](#)" were considered. **The pilot team was asked to explain how the use of the identified practice would help achieve at least one of the following six criteria:**

- i) Effectiveness and efficiency of the intervention
- ii) Equity
- iii) Transferability
- iv) Sustainability
- v) Participation
- vi) Intersectoral collaboration

Phase III - Practice presentation and Validation

Once practices were identified by each pilot and Appendix D and Appendix E were completed, the WPs 6-11 and the Implementation Board delegation organized **presentation sessions for each WPs 6-11**; in preparation for these sessions WP6-11 leadership team provided the guidance to the core pilot teams.

Each core pilot team presented its objective and the identified practice (either best practice or other practice). This process was a crucial moment for the entire JACARDI initiative, as the core pilots team had the opportunity to present their arguments and engage with other similar pilots by theme or geographical area. WPs leadership teams gain deeper insights into their pilots, and the JACARDI coordination team, along with the WP5 team, obtain an overview of the pilots to provide optimal methodological support.

Pilots that identified an "other practice" during Phase II (Appendix E), were also required to present at least one of the six criteria (listed above) that they aimed to achieve by applying the experiences from the chosen

practice. The Implementation Board then assessed the relevance, rationale, and alignment of these practices, ultimately validating the selected practice, following an evaluation check-list (*Appendix F: JACARDI pilots presentation and “validation” of their scientific rationale – practice(s) identified (Checklist)*).

3.2.2 Timeline

The identification of practices (Phase 0, I, and II) began in December 2023 and concluded on April 30th 2024. The presentation of the pilots and the validation of the other practices (Phase III) by the Implementation Board took place in June 2024.

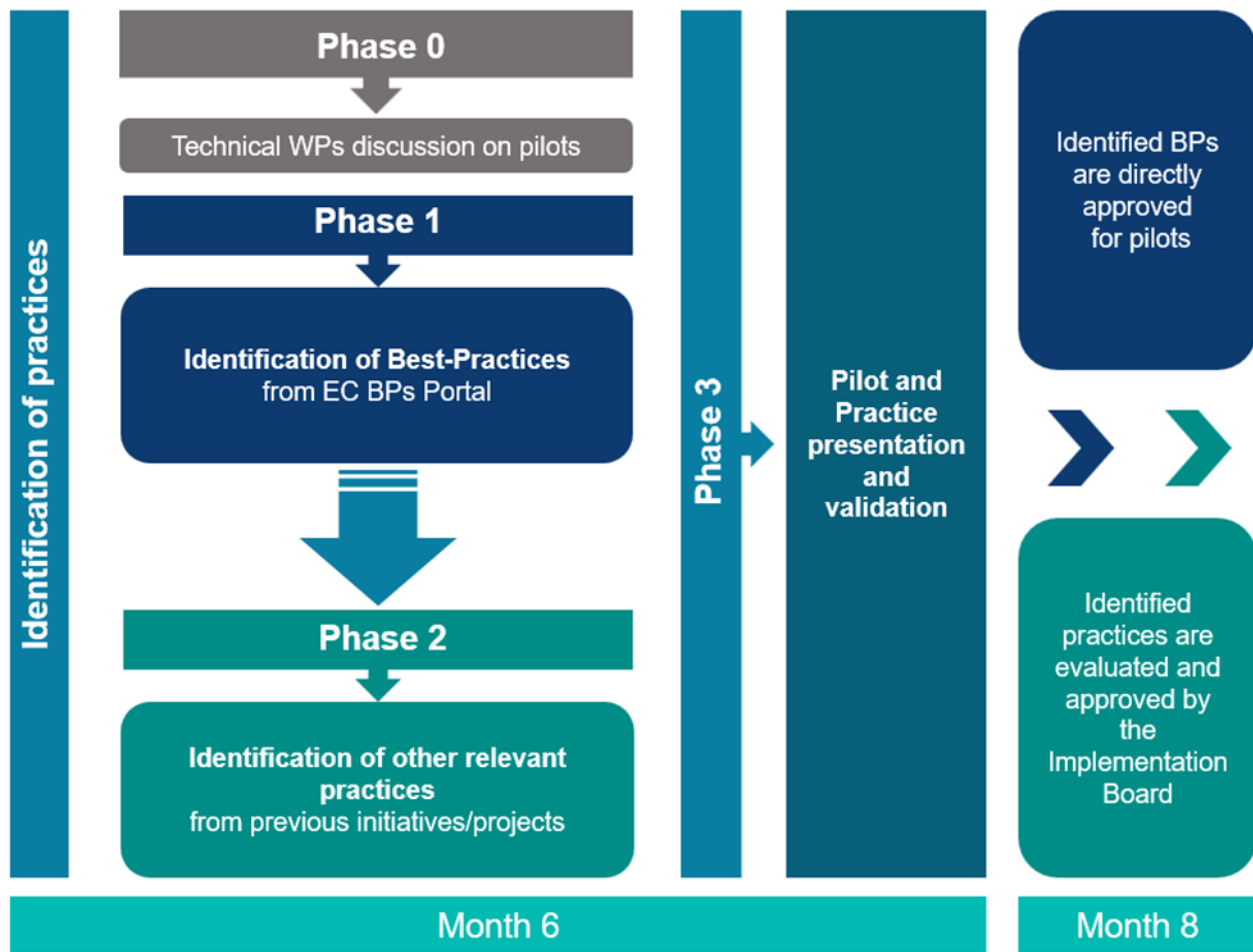


Figure 2. Visual of the Methodological framework for the identification of best practices or other appropriate practices

4. Conclusions and recommendations

The results from Tasks 5.1.1 and 5.1.2 populate the Deliverable 5.2. This deliverable includes an in-depth report on the findings from the country-level context analysis, presented as a valuable tool for mapping the state of the art in CVD and diabetes prevention and management strategies and services at both the European and topic-specific levels. This report will serve as a useful resource for healthcare professionals, researchers, and policymakers. Additionally, the deliverable will showcase the selection of evidence-based practices that form the rationale for the pilot projects to be implemented in JACARDI.

Appendices

Appendix A: Questionnaire Framework

Section I GOVERNANCE AND FINANCING
<p>Availability of: <i>(Tailoring of these sub-areas to match the specific focus of the WPs 6-11)</i></p> <ul style="list-style-type: none"> - Legal Framework The presence of binding agreements or legal provisions designed to ensure the practical implementation of relevant policies. - Strategic Framework The presence of political commitment and the existence of national policies, strategies, or action plans specifically addressing cardiovascular diseases (CVD) and diabetes as well as their associated risk factors. - Intersectoral Policies and Practices The level of coordination and collaboration among diverse governmental and non-governmental stakeholders in addressing CVD and diabetes. - Equity-Oriented Approach The presence of policies and action plans which take into consideration equity and curbing health inequalities. This evaluation will explore whether social and demographic characteristics, such as age, gender, sex, ethnic background, education, income, or housing conditions are explicitly acknowledged and addressed in each policy framework analyzed. - Funding The presence of dedicated financial resources allocated within the government budget to support activities, strategies, and programs related to CVD and diabetes.
Section II SERVICE DELIVERY AND CAPACITY
<p>Availability of: <i>(Tailoring of these sub-areas to match the specific focus of the WPs 6-11)</i></p> <ul style="list-style-type: none"> - Service Delivery and Capacity The presence of CVD and diabetes services, encompassing areas such as promotion, education, training, health information systems, and community engagement. - Tailoring of Specific WPs Contents The presence of the content within specific WPs thematic areas. This section has to take into consideration the following cross-cutting aspects: - Equity-Oriented Approach The presence of interventions which take into consideration equity and curbing health inequalities. This evaluation will explore whether social and demographic characteristics, such as age, gender, sex, ethnic background, education, income, or housing conditions are explicitly acknowledged and addressed. - Intersectoral Service delivery The level of the extent to which integration occurs across different sectors, encompassing health, labor, social, and third sector organizations.

Appendix B: Pre-selected thematic areas to be covered by the implementation

<p>WP6 - Health literacy and awareness of CVD and DM</p> <ul style="list-style-type: none"> ● Health literacy: <ul style="list-style-type: none"> ○ Community health literacy ○ Health literacy development ○ Health literacy of an individual ○ Health literacy responsiveness ○ Organisational health literacy ● Health promotion and awareness 	<p>WP9 - Integrated care pathways</p> <ul style="list-style-type: none"> ● Care delivery ● Decision support ● Information systems and technology ● Social/community resources
<p>WP7 - Data availability, quality, accessibility and sharing</p> <ul style="list-style-type: none"> ● Data availability ● Data quality and coverage of pre-existing registries and data sources on CVD or DM ● Data harmonisation, accessibility and sharing ● Value of data; epidemiology, quality of care, health equity and benchmarking 	<p>WP10 - Patients' self-management</p> <ul style="list-style-type: none"> ● Making lifestyle changes ● Self-monitoring and self-care (including medication management and/or adherence) ● Communicating with healthcare professionals (including shared decision-making) ● Coping with CVD or DM in daily life
<p>WP8 - Screening high-risk populations and individuals</p> <ul style="list-style-type: none"> ● Population screening <ul style="list-style-type: none"> ○ Population based survey ○ Clinical assessment ● Personal/individual level screening and risk assessment <ul style="list-style-type: none"> ○ Clinical setting ○ Nonclinical setting 	<p>WP11 - Labour participation of people living with NCDs, in particular with CVD and DM</p> <ul style="list-style-type: none"> ● Awareness on inclusiveness and work ability ● Inclusion, maintenance, return to work and participation of people with NCDs in the workplace ● Prevention of NCDs, correct management and integration in the labour settings ● Employment opportunities for young adults with CVD or DM

Appendix C: Template for the identification of the Ideal State

Work Package	Topic <i>(please refer to the specific question of the Section II of the questionnaire)</i>	Thematic area covered	Ideal state <i>(please include quantitative indicator or threshold if applicable)</i>	Reference

Appendix D: Template for data extraction for Best-Practice (Phase I)

Pilot Coding <i>WPX_Countryabbreviation_numberofpilotassignedbyWP</i> <i>i.e. WP6_FI_5</i> <i>i.e. WP11_IT_3</i>	
Pilot Title and Acronym (optional)	
Indicator/Key metrics	Practice Identified
Title	
Origin	
Country	
Year of selection	
Pre-selected thematic areas where the Best-Practice falls into (*Appendix B: Pre-selected thematic areas to be covered by the implementation)	
The elements or single element to be implemented	

Appendix E: Template for data extraction for other relevant practices (Phase II)

Pilot Coding <i>WPX_Countryabbreviation_numberofpilotassignedbyWP</i> i.e. <i>WP6_FL_5</i> i.e. <i>WP11_IT_3</i>	
Pilot Title and Acronym (optional)	
Indicator/Key metrics	Practice Identified
Title	
Platform or existing initiatives/projects where the practice has been retrieved	
Year of implementation	
Location and geographical extension	
Setting	
Target population	
Number of population reached	
Methodology	
Outcomes	
Pre-selected thematic areas where the practices fall into (*Appendix B: Pre-selected thematic areas to be covered by the implementation)	
Alignment with the WP's aim (100 words)	
The elements or single element to be implemented	
<p>Criteria ⁽¹⁾ to be evaluated by the IB to approve the practice for pilot implementation (At least one criteria identified, including the explanatory arguments, why and how the element(s) of the practice would be relevant for the respective pilot to achieve the stated criterion, written from the perspective of the pilot)</p>	

Explanation of Criteria to be evaluated by the Implementation Board

- Effectiveness and efficiency of the intervention:**
 This criterion defines the degree to which the intervention was successful in producing a desired result in an optimal way. It measures the extent to which the objectives of quantity, quality and time have been met under real conditions at the lowest possible cost.
- Equity:**
 This criterion considers that the practice should take into account the needs of the population when allocating the

¹ The criteria are: Effectiveness and efficiency of the intervention; Equity; Transferability; Sustainability; Participation; Intersectoral collaboration. For further details, please refer to [Criteria to select Best Practices in Health Promotion and Disease Prevention and Management in Europe](#).

resources and identify and reduce health inequalities. As the reduction of inequities is a major issue in Europe, a practice that includes elements that promote equity, should be ranked higher (for example, if considering a gender perspective).

- **Transferability:**

This criterion measures to which extent the implementation results are systematized and documented, making it possible to transfer it to other contexts/settings/countries or to scale it up to a broader target population/geographic context. It would be a plus if transfer of the practice would address EU added value elements

- **Sustainability:**

This criterion assesses the practice's ability to be maintained in the long-term with the available resources, adapting to social, economic and environmental requirements of the context in which it is developed. Please note, that this definition is narrower than the one used at JACARDI level, but is applicable for this specific use.

- **Intersectoral collaboration:**

This criterion assesses the ability of the practice to foster collaboration among the different sectors (e.g. health, social, education) involved in the domain of interest (e.g., health promotion, disease prevention and management, etc.).

- **Participation:**

This criterion assesses the inclusion of stakeholders throughout the whole life cycle of the process and the ability of the practice to foster collaboration among the different sectors involved.

Appendix F: JACARDI pilots presentation and “validation” of their scientific rationale – practice(s) identified (Checklist)

This checklist is intended for the representatives of the Implementation Board to monitor the process of pilots’ presentation of their objective and their scientific rationale meets the expected quality. The IB representatives will complete the checklist in order to:

- assess whether specific criteria are met;
- provide specific feedback or concerns to the pilots and WP leader, which can be addressed in a separate ad hoc meeting.

Pilot name - coding	
The Rationale of the pilot is scientifically robust (the explanation of rationale of pilot has strong scientific basis)	Yes No
The general objectives of pilots are clear	Yes No
The practice(s) presented are evidence based (for more in-depth details, please refer to the Appendix D : Template for data extraction for Best-Practice (Phase I) or Appendix E : Template for data extraction for other relevant practices (Phase II))	Yes No
The practice(s) presented are relevant for the pilot	Yes No
The pilot met at least one of the six criteria identified_	Yes No Not applicable (in the case the practice is a Best-Practice)
The criteria were presented with explanatory arguments	Yes No Not applicable (in the case the practice is a Best-Practice)
The pilot and the corresponding practices are validated	Without comments With minor comments With major comments/concerns
Additional comments (please, report here argumentation if you checked major comments/concerns, including potential risks overall or related to any of the specified criteria)	





JACARDI

Joint action
cardiovascular diseases
and diabetes

ANNEX V: Methodological framework for multidimensional pilot assessment

JACARDI WP 5 Task 5.6



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Keywords

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Executive summary

The Methodological framework for multidimensional assessment of pilots aims to guide pilot teams in assessing six key outcome dimensions (effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability - including scalability/transferability, and additional implementation and process outcomes) and determining the effects of pilots. The framework ensures a standardized assessment process from the start, promotes consistent criteria across pilots, and facilitates the collection of high-quality data for comprehensive assessments and reporting within and across countries. It also supports the design and analysis of studies, enabling in-depth assessment of selected pilots.

The development of the multidimensional pilot assessment framework involved three key phases:

- Firstly, key dimensions were identified and defined.
- Then, scientifically robust methods and tools to collect data and assess each dimension were selected and refined through discussions to meet the project's needs.
- Lastly, various study designs were presented to infer causality, including observational and experimental approaches.

The framework was iteratively refined, with the aim of offering pilot teams comprehensive guidance to help them define consistent and transparent multidimensional assessment plans.

The framework for the multidimensional assessment of pilots provides guidance on the following aspects: (1) definition of outcomes, that can be assessed within the pilot, in alignment to pilot's general and specific objectives; (2) definition of the appropriate design of the pilot and of the data collection; (3) definition of measures/indicators for the assessment and analytical methods to be used; (4) data collection and timing; (5) ethical and legal issues; (6) identification of possible barriers and enablers of data collection; and, (7) reporting.

Pilot implementation activities are supported by the multidimensional assessment framework at various steps of the implementation process, as follows:

- At Step VI, to develop multidimensional assessment plan. At this step Task 5.6 performs two types of activities with the work packages 6-11, a short presentation of the framework and a longer training session with the opportunity for pilots to start developing their assessment plans. Those sessions are organized together with the work package leadership teams.;
- At Step VIII, to deliver intermediary results No. 1, if found relevant within multidimensional assessment plan. At this step Task 5.6 provides continuous support to pilots as they go through the implementation stage and may require clarifications on how to better collect the required data.;
- At Step XI, to deliver intermediary results No. 2, if found relevant within multidimensional assessment plan. At this step Task 5.6 continues to support the pilots during their implementation stage as in Step VIII.;
- At Step XII, to deliver final results of the multidimensional assessment within Final implementation report. Task 5.6 provides the reporting template for multidimensional assessment that is integrated into the general reporting questionnaires for pilots.
- At Steps XIII and XIV, to provide inputs into Sustainability action plans.

Dedicated workshops and support to core pilot teams will be provided by the Task 5.6 team, starting from the design of the pilot implementation plan, to apply each aspect of the multidimensional assessment

framework. More specifically, these workshops will include presentation of the framework and of the assessment plan for a sample pilot by Task 5.6, followed by the individual and group work activities dedicated to developing an assessment plan by each of the pilots and discussing the results with other pilots. Task 5.6 will be present at the discussions to answer possible questions. Sample pilot assessment plans are created before the workshops together with one volunteer pilot from each technical work package, one representative assessment plan per each WP6 – 11. Capacity activities will be conducted jointly with the Implementation Board, having an expert in economic evaluation as a member. In addition, an expert in applying multidimensional assessment framework will be available to participate in all Learning sessions, if invited by discretion of WP6-11 leadership teams.

1. Introduction

1.1 Purpose and scope of the document

The methodological framework for multidimensional assessment of pilots (multidimensional assessment framework) serves as the principal instrument for guiding the core pilot teams in assessing six outcome dimensions (effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability - including scalability/transferability, and additional implementation and process outcomes) and determining the effect of the interventions under investigation. Pilot teams should refer to the framework from the very beginning of the planning of the implementation to ensure that all aspects are considered to allow future consistent assessment.

The main objectives are the following:

1. To provide guidance to pilot core team on (1) definition of key outcomes that can be assessed within the pilot, in alignment to pilot's general and specific objectives; (2) definition of appropriate measures/indicators, tools and timing for data collection; (3) definition of methods for data analysis; (4) definition of the appropriate study design that allows to estimate the effect of the intervention.
2. To provide a standardized assessment process to ensure that consistent criteria are applied across the different pilots and that the conclusions on the effect of the intervention are methodologically robust
3. To ensure the collection and reporting (in collaboration with Task 5.7) of complete high-quality quantitative and qualitative data to allow the multidimensional pilot assessment within and across countries.
4. To ensure that the data collected, in aggregate form (i.e., distributions of relevant variables) rather than individual-level data, can be used to perform an in-depth analysis of a chosen pilot for each WPs 6 – 11.

1.2 Structure of the document

Annex V is structured as follows:

1. Introduction: Outlines the scope and purpose, the structure of the document, and its relation to other work in the project.
2. Development process: Describes the process used to develop the methodological framework for multidimensional pilot assessment
3. Multidimensional assessment framework: Provides an overview of the methodological framework for multidimensional pilot assessment including guidance and templates for pilots
4. Conclusions and Recommendations: Provides final thoughts and suggestions for future actions.
5. Appendices:
 - Appendix A is a detailed description of methodological framework for multidimensional assessment of pilots (word file).
 - Appendix B is a brief description of methodological framework for multidimensional assessment of pilots (word file).
 - Appendix C is a detailed description of methodological framework for multidimensional assessment of pilots (PDF file).
 - Appendix D is a brief description of methodological framework for multidimensional assessment of pilots (PDF file).

The Appendix D (brief description) includes cross-reference links to the longer version in Appendix C. The links work only if the following documents (accessible in JACARDI Teams) are downloaded separately as three documents in the same folder:

- Appendix C. Methodological framework for multidimensional pilot assessment Long version PDF
- Appendix D. Methodological framework for multidimensional pilot assessment Brief version PDF
- JACARDI_Methodology_Long_version_September_19_2024 PDF document.

Box 1. How to use cross-reference links Appendix D-C

1.3 Relation to other work in the project

This document is directly related to other work packages (WPs), specifically WPs 6-11, which focus on providing detailed guidance on how to perform multidimensional assessment to the pilots. The results of the assessment will contribute to the development of the reporting documentation that is required by each pilot (Final implementation report, Sustainability action plan), by each WP6-11 leadership team (final deliverables of per each of WP6-11) and by WP5 (Tasks 5.6 and 5.7). It complements other elements of JACARDI Methodological framework in providing integrated methodology for design, implementation, monitoring and reporting from JACARDI pilots.

2. Development process of the Multidimensional assessment framework

The development of the **multidimensional assessment framework** followed a structured and iterative process, consisting of several key phases.

Phase 1: Selection and definition of assessment dimensions

The initial phase focused on identifying and defining the key dimensions to be evaluated. The dimensions initially identified— effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability - including scalability and/or transferability, and additional implementation and process outcomes —were chosen for their relevance to the project's overarching objectives. These dimensions were deemed critical for providing a comprehensive assessment of the impact and potential value of the pilot interventions.

The effectiveness dimension includes both health outcomes and patient-reported outcomes (PROs). Together with the assessment of economic efficiency, a full economic evaluation, such as a cost-effectiveness analysis, can determine whether the intervention offers good value for money. The results of economic evaluation can ultimately inform resource allocation decisions, including reimbursement and coverage. Measuring patient (or user) experience is vital for understanding the perceived value of healthcare services from the perspective of the end-user. This assessment is key to improving the quality of care and ensuring that interventions meet the needs and expectations of patients. Equity and diversity dimensions are central to JACARDI's goals of ensuring fair access to interventions and addressing health disparities. Given the pilot nature of the interventions, assessing their long-term sustainability and potential for scalability/transferability is essential. This includes evaluating the ability of interventions to maintain their impact over time and their capacity to be expanded or replicated in different settings or larger populations. Other dimensions and outcomes, such as implementation outcomes, were considered based on the heterogeneity of objectives across pilots. These were included to address specific aspects of the pilots that may not align directly with the main dimensions but are nonetheless critical for a comprehensive evaluation. The definitions for these dimensions were drawn from relevant scientific literature and were subsequently refined through discussions with representatives from other WPs to ensure consistency and homogeneity across the different components of the JACARDI project.

Even though every pilot is expected to assess each dimension, not all outcomes outlined above may be relevant for or applicable to every pilot. In this case, the pilot should provide justification why the dimension is not relevant.

Phase 2: Development of methods and tools for assessment

The second phase involved defining the methods and tools to assess each dimension, supplemented by practical examples. The methods and tools were carefully selected from the published literature, ensuring that they were scientifically robust and applicable to the specific needs of the JACARDI project. The examples provided were initially drafted from the literature and were then refined through multiple rounds of discussions with representatives from the WP6-11, ensuring they accurately reflected the diversity of pilot objectives. This phase aimed at providing pilots with a robust and appropriate approach to design first and evaluate later the interventions' impact.

Phase 3: Description of possible study designs

The third phase focused on presenting and classifying various study designs according to their ability to infer causality. Ideally, the assessment should investigate the causal effects of the interventions on all the proposed dimensions. However, recognizing the challenges in establishing causation, especially in real-world settings, the framework also includes study designs (e.g., observational studies) that allow for correlation analysis when experimental (e.g., RCTs) or quasi-experimental designs (e.g., Difference-in-Differences) are impractical or unfeasible.

The framework was refined iteratively, incorporating feedback from representatives of WP6-11 and other methodological WPs. This collaborative approach included discussions with the Implementation Board and representative pilots of WP6 – 11. It ensured that the framework was comprehensive, consistent, practical, and aligned with the diverse needs of the JACARDI project.

Based on the multidimensional assessment framework, a set of facilitatory questions was developed to help pilot core teams to plan and to report the results of multidisciplinary assessment, shown in the Main results section.

3. Multidimensional assessment framework

The main outcome of Task 5.6 is the development of a detailed document outlining the multidimensional assessment framework. This document aims at supporting several methodological choices of the pilot teams, to ensure that their data collection and analysis plans are scientifically sound. This, in turn, ensures that the conclusions regarding the effect of the intervention are sound and meaningful.

The second main outcome is a set of supporting material for core pilot team, aligned with the Steps I to XV that pilots follow in JACARDI.

The third main outcome is a set of Tables, that will be used for harmonized reporting of all assessment steps, that are integrated in the Final implementation report to allow for single-point reporting from all JACARDI pilots.

Multidimensional assessment framework flowchart

The framework proposes an assessment of six dimensions: effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability - including scalability and/or transferability, and additional implementation and process outcomes. The core pilot team makes choices on study design, type of data that is feasible to collect, and type of analysis. The framework provides examples of tools that can be used by core pilot teams when defining these three aspects. The sequence of steps or actions for the assessment of the cited dimensions are represented through a flowchart. The flowchart helps break down complex processes into simpler, understandable parts, providing a clear, step-by-step representation of how a process flows from start to end. The flowchart is presented in Appendix B and Appendix D. This structure has been verified by performing exemplary assessments for the representative pilots in WPs 6 – 11.

Supporting questions for core pilot teams

Based on experience in communication related to assessment, a set of facilitatory questions were developed. The questions cover study design, outcomes, and data collection pilot decisions. The purpose of these questions is to provide pilots with an easy-to-follow structure to make decisions on their assessment plans. Moreover, this structure allows pilots to provide necessary data for assessment plan reporting in all stages of the JACARDI project.

In Step VI, to develop multidimensional assessment plan, with an aim to assess the achievement of the general and, potentially, specific objectives of the pilot, and to assess the potential for sustainability and scalability/transferability, at the level of outcomes. Monitoring of the implementation at the level of each activity and each specific objective is more extensively described in Deliverable 5.1.

Approaches and/or measures to assess the pilot outcomes	
General questions	
Pilot code in JACARDI (e.g., WP9_BE_87)	
Describe the target group of the pilot (who is expected to directly benefit from the intervention):	
<ul style="list-style-type: none"> Age profile 	

<ul style="list-style-type: none"> • occupation (if any specific group is targeted, e.g., health professionals) • specific characteristics (e. g., patients with diabetes) 	
How many targeted individuals will be reached by the intervention? (If you have several target groups, specify the number for each of them)	
Where does the intervention take place? Please specify the type of setting that the intervention takes place in.	
How are the targeted individuals selected? (e.g. through hospital discharge lists/health practitioner lists/etc.)	
What are the inclusion criteria?	
What are the exclusion criteria?	
Questions about the study design for the assessment of the pilot.	
How is the treatment group of the pilot defined? What intervention will they receive?	
How is the counterfactual (control group) defined? What intervention will they receive?	
How are the treatment group participants selected? Please describe if this is done through randomization among all the potential participants or any other way.	
How are the control group participants selected? Please describe if this is done through randomization among all the potential participants or any other way.	
What is the timeline of the intervention and for its assessment?	
Questions about the assessment dimensions.	
What are the primary expected outcomes of the intervention that is planned to be piloted?	
What are the secondary outcomes, if any?	
How do you measure the primary outcomes (what outcome measures, what data collection approach, at what time points has the outcome been measured)? If there is more than one primary outcome, please provide this information for each outcome.	
How do you measure the secondary outcomes (what outcome measures, what data collection approach, at what time points has the outcome been measured)? If there is more than one	

secondary outcome, please, provide this information for each outcome.	
Will patient or individual experiences be assessed? If so, specify what measure(s) will be used, how the data will be collected, and at what time points.	
What costs of pilot implementation will it be possible to measure (e.g. equipment/tests performed/surveys/etc.) How do you plan to measure those costs? Will you be able to measure costs for the intervention and for the counterfactual separately?	
Will an economic evaluation be done? If so, please, describe the type of evaluation, what efficiency measure will be calculated, and what data will be used in the calculations.	
Which sociodemographic characteristics of the subjects will be measured during the pilot? (e.g. age, gender, income level, area of residence, migrant status, disability status, etc.)	
What measures will be used for sociodemographic characteristics, and how will the relevant data be collected?	
Will your assessment determine if the pilot intervention can continue after the end of JACARDI (sustainability), and can be extended to other sites and countries (scalability/transferability)? On what basis do you plan to reach that conclusion?	
Will you assess implementation outcomes in the pilot (e.g. acceptability, appropriateness, feasibility, adoption, fidelity, penetration)? If so, please, specify which measures you will use, how the data will be collected, and at what points in time.	

Table 1. Approaches and/or measures to assess the pilot outcomes

Reporting

Reporting requirements for multidimensional assessment are included in Final implementation report in Annex VII.

4. Conclusions and recommendations

The multidimensional pilot assessment framework has been developed to become a detailed and highly efficient tool to support all the steps of the data collection and analysis (identification of outcomes, data sources, study design, data collection, analysis) and to guide the pilot core teams in this process. The framework, in principle, should allow to establish causal relationships between the interventions considered and their effects. By standardizing the assessment process, the results of the pilot assessment can be compared among and within WPs 6 – 11. Moreover, these results contribute to the reporting stage of pilot development, aligning the framework with several steps of the pilot implementation process.

Appendices



Annex V Appendix A

Detailed description of methodological framework for multidimensional assessment of pilots

INTRODUCTION

The objective of this document is to define a framework to assess the outcomes of pilots undertaken in Work Packages (WPs) 6 to 11. This assessment framework applies to activities under Task 5.6.

The framework provides an objective basis for evaluating the outcomes of pilots. These assessments should determine the effects of the interventions under investigation in each pilot on the identified outcome dimensions.

All pilots will be assessed. For a subset of pilot projects, comprising at least one project from each of the technical WP6-11, the assessment will be undertaken by the core team for Task 5.6 (Bocconi University, Milan, Italy; Imperial College, London, UK), in collaboration with the relevant pilot teams, and will involve in-depth and long-term analyses.

The other pilots will be evaluated by the pilot teams themselves. All six dimensions of the framework should be assessed by each pilot except when any of the dimensions is either not relevant or not measurable. In this case, the pilot core team should explain why the assessment was not done. WP6-11 leaders may use the present framework as a reference to find detailed specifications on the pilots' assessment activities. WP6-11 leaders and pilots will be able to benefit from the methodological support and guidance of the 5.6 core team, that can assist the relevant partners in conducting independent analyses on multidimensional health and economic evaluations based on the collected data.

Assessment plans and procedures are reflected in JACARDI's Data Management Plan. In short, each partner implementing a pilot project has to act as an independent data controller. The personal data collected for each pilot action should be processed for the respective purposes within JACARDI at the local level. Each partner conducting a pilot project should share an aggregated, anonymized data set with the Coordination Team (WP1), WP5 members, and leaders and co-leaders of other WPs. Each partner acting as a data controller, pursuant to the GDPR, is fully responsible for the processing of personal data, from collection to storage and subsequent deletion.

Purpose

The definition of an assessment framework can help standardize the assessment process to ensure that consistent criteria are applied across the different pilots. This is crucial in assessment activities, where subjective judgments can introduce bias. Objective assessment criteria help ensure a more rigorous and reliable assessment. In case pilots are conducted to assess the feasibility of larger-scale projects, the assessment framework helps pilot teams

systematically evaluate the feasibility aspects, such as resource requirements, potential challenges, and scalability. The framework facilitates clear communication between pilot teams, stakeholders, and implementers (e.g., clinicians). Transparent criteria and assessment processes make it easier for others to understand how pilot study outcomes are assessed, fostering trust and accountability.

Finally, the framework will ensure the collection of complete high-quality quantitative and qualitative data to allow the multidimensional assessment of a wide range of pilot outcomes within and across countries.

In summary, the purpose of developing an assessment framework is to bring structure, objectivity, and consistency to the evaluation of pilots' outcomes, ultimately contributing to the improvement of activities/practices and the advancement of knowledge in a particular field.

Structure of the framework

The framework provides detailed guidance on several methodological aspects of the assessment of pilots, as outlined in the following sections:

- definition of outcomes: this section clarifies the conceptual definition of outcomes to be measured in the pilot studies. For each relevant outcome dimension, guidance is provided on the appropriate measures/indicators, tools and timing for data collection, along with related ethical considerations. Additionally, recommendations for data analysis are provided.
- pilot assessment design: this section outlines the possible study designs that can be used by pilots in order to assess the effect of the intervention. Additionally, it describes how to establish causation by using the counterfactual model.
- extended assessment of selected pilots: a number of selected pilots (at least one for each WP6 – 11) will work with Task 5.6 to develop an in-depth assessment. This activity is expected to be beneficial for pilots as they will have close support during the pilot implementation to define and execute data collection and assessment.

DEFINITION OF OUTCOMES

The performance of the pilots will be evaluated through a multidimensional assessment. The following outcomes should be considered:

- Effectiveness, which may include patient-reported outcomes: the extent to which the piloted intervention affects health outcomes and/or patient-reported outcomes as assessed with patient-reported outcome measures – PROMs.
- Patient experiences: the extent to which the pilot intervention influences patient and/or caregiver experiences as assessed with patient-reported experience measures – PREMs.
- Economic efficiency: whether the piloted intervention provides “value for money”, i.e. represents a good use of scarce health and social care resources, relative to other potential uses.
- Equity and diversity: the extent to which the piloted intervention generates a desirable, or aspirational, distribution of opportunities, resources, or outcomes among individuals and population groups (equity), and includes different characteristics or social dimensions within a group, organization, or community (diversity).
- Sustainability, including scalability/transferability: whether the piloted intervention can be continued over a longer period of time after the pilot phase (sustainability), and findings

from the interventions are being/have been transferred into changes in policies on local, regional, and national levels (scalability/transferability).

- Additional implementation outcomes and process indicators: the extent to which implementation of an intervention is being or has been successfully achieved (implementation outcomes); intervention's activities and outputs (process indicators).

Even though every pilot is expected to assess each dimension, not all outcomes outlined above may be relevant for or applicable to every pilot. In this case, the pilot should provide justification why the dimension is not relevant.

EFFECTIVENESS

The concept of effectiveness should be intended with a broad meaning, considering the possible effects of the pilot intervention on relevant health outcomes, including both clinical and patient-reported outcomes [Walton et al, 2015].

The first step is to clearly articulate the goals and objectives of the pilot and to specify the intended health outcomes, such as improved health status, improved functioning, reduced disease prevalence, or enhanced well-being.

The second step is to identify and define specific and measurable indicators that can be used to assess the intended health outcomes. These indicators should be quantifiable and aligned with the pilot objectives.

The third step is to implement a robust data collection strategy to gather information on the identified indicators. A combination of quantitative and qualitative methods, such as surveys, interviews, focus groups, and health metrics may be used. A baseline assessment before the pilot implementation to establish a starting point for the identified indicators is recommended to assess outcome changes over time.

The selection of appropriate effectiveness outcomes can be informed by the resources available on the COMET (Core Outcome Measures in Effectiveness Trials) Initiative website (<https://www.comet-initiative.org/>). This multi-stakeholder initiative aims to develop and continuously update agreed standardized sets of outcomes, known as core outcome sets (COS), for different health conditions. A COS represents the minimum that should be measured and reported in clinical trials of a specific condition, but each COS is intended to be suitable also for use in routine care, clinical audit, and research other than randomized trials.

The direct and indirect effects of the pilot on health outcomes should be assessed. While the measurement of direct effects on health outcomes may be straightforward (e.g., the occurrence of major cardiovascular events), the assessment of indirect effects may be more complex. Indirect effects encompass outcomes that still address the core question "Does the intervention work?" but involve a broader definition of Effectiveness. In instances where the specific nature of the pilot or the short timeframe of the JACARDI project precludes the direct measurement of health outcomes, the assessment of indirect effects is recommended to demonstrate the pilot's effectiveness. In such cases, pilots should provide evidence of a well-established relationship between the measured outcome (e.g., patient empowerment) and the final health outcome (e.g., occurrence of major cardiovascular events).

Pilots on cardiovascular diseases and diabetes can have indirect effects on health outcomes through various mechanisms. For example, pilots may involve the implementation of novel healthcare delivery models or interventions aimed at improving access to healthcare services for individuals at risk of or living with CVD/diabetes. By increasing access to

preventive care, early detection, and treatment, these interventions can lead to better management of CVD/diabetes and related health outcomes. Another example relates to pilots involving the education of participants about CVD/diabetes risk factors, prevention strategies, and lifestyle modifications. This increased awareness can lead to healthier behaviors and better management of risk factors such as smoking cessation, improved diet, and increased physical activity, ultimately contributing to improved health outcomes.

Additionally, some pilots may be interested in measuring the impact of an intervention on the health literacy of individuals, including patients and other relevant stakeholders (e.g., employers). Health literacy is a multidimensional concept that encompasses an individual's knowledge and confidence in accessing, understanding, appraising, and using information about health and healthcare. Over the years, several self-administered questionnaires have been developed to facilitate the measurement of this multidimensional concept, with some examples provided below:

- European Health Literacy Survey Questionnaire (HLS-EU-Q) (<https://doi.org/10.1186/1471-2458-13-948>)
- Health Literacy Questionnaire (HLQ) (<https://doi.org/10.1186/1471-2458-13-658>)

Some pilots may envisage interventions aimed at enhancing knowledge of and awareness about CVDs and diabetes, targeting both patients and the general population. To assess the impact of these interventions on public knowledge and awareness, data might be collected before and after the intervention through surveys, interviews, and/or focus groups. If the outcome of interest is disease knowledge, disease-specific questionnaires designed for self-administration might be used, such as:

- Revised Diabetes Knowledge Scale (<https://doi.org/10.1111/j.1464-5491.2010.03190.x>)
- Heart Disease Knowledge Questionnaire (<https://doi.org/10.1080/19325037.2011.10599175>)

Some pilots may aim to modify patients' health behaviors by enhancing their self-management skills. Some questionnaires may be used to assess changes in self-care activities and perceived self-efficacy, for example:

- Diabetes Self-Management Questionnaire (<https://doi.org/10.1186/1477-7525-11-138>)
- Diabetes Management Self-Efficacy Scale (<https://doi.org/10.1046/j.1365-2648.1999.01077.x>)
- European Heart Failure Self-care Behavior Scale ([https://doi.org/10.1016/S1388-9842\(02\)00253-2](https://doi.org/10.1016/S1388-9842(02)00253-2))
- Hypertension Self-Care Questionnaire (<https://doi.org/10.22122/arya.v15i5.1835>)

Patient-reported outcomes

Patient-reported outcomes (PROs) is a broad term that includes direct subjective assessment by the patient of elements of their health, including symptoms, health-related quality of life, and functional status [Rothman et al, 2007]. Patient-reported outcome measures (PROMs) are standardized questionnaires administered directly to patients that allow to collect information on PROs [Churruca et al, 2021].

Initially designed for research purposes, particularly in clinical trials evaluating treatment effectiveness, PROMs have evolved to encompass various applications. These include supporting decision-making in healthcare, prioritizing patients for surgical procedures, comparing outcomes across healthcare providers, fostering quality improvement, and evaluating the effectiveness of certain interventions and policies.

PROMs are categorized into two main types: condition-specific and generic. The latter focuses on health concepts that are relevant to a diverse range of patient groups, allowing for aggregation and comparisons across different conditions and settings. Generic PROMs allow to measure a broad spectrum of impacts (either intended or unintended) on patients' perceived health and quality of life, extending beyond the specific condition being studied (e.g., cardiovascular disease or diabetes). An illustration of a generic PROM is the EQ-5D-5L, developed by the EuroQol Group (<https://euroqol.org/information-and-support/euroqol-instruments/>). This instrument consists of five questions on the patient's health on a given day, covering aspects such as mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each aspect/dimension, it is possible to express the indication on 5 response levels. The second section includes a visual-analog scale graphically represented as a graduated thermometer from 0 (worst possible health status) to 100 (best possible health status) on which the patient indicates the perceived level of health. An algorithm allows the calculation of a final score (utility coefficient u , between 0 and 1) based on the attribution of weights for each questionnaire answer. The higher the score, the better the health.

Condition-specific PROMs capture elements of health relevant to a particular condition. For example, different PROMs may be used in the context of cardiovascular diseases (CVDs):

1. **Seattle Angina Questionnaire (SAQ)** (<https://pubmed.ncbi.nlm.nih.gov/7829785/>): this PROM assesses the impact of angina on patients' daily lives, including physical limitations, angina stability, and treatment satisfaction.
2. **Minnesota Living with Heart Failure Questionnaire (MLHFQ)** (<https://license.umn.edu/product/minnesota-living-with-heart-failure-questionnaire-mlhfq>): focused on heart failure, this PROM evaluates the impact of heart failure symptoms on a patient's quality of life, covering aspects like physical, emotional, and social well-being.
3. **Peripheral Artery Questionnaire (PAQ)** (<https://pubmed.ncbi.nlm.nih.gov/14760329/>): designed for patients with peripheral arterial disease, this PROM assesses the impact of leg symptoms on daily life and activities.

Or for patients with diabetes:

1. **Diabetes Impact Measurement Scales (DIMS)** (<https://eprovide.mapi-trust.org/instruments/diabetes-impact-measurement-scales>): designed to measure the impact of diabetes on various aspects of a patient's life, including physical health, psychological well-being, and social function.
2. **Audit of Diabetes-Dependent Quality of Life (ADDQoL)** (<https://healthpsychologyresearch.com/guidelines/addqol19-audit-diabetes-dependent-quality-life-0/>): specifically focused on diabetes, this PROM evaluates the impact of diabetes on a patient's quality of life, considering various domains such as living conditions, family life, and relationships.
3. **Diabetes Treatment Satisfaction Questionnaire (DTSQ)** (<https://healthpsychologyresearch.com/guidelines/dtsq-diabetes-treatment-satisfaction-questionnaire/>): this PROM assesses patient satisfaction with their diabetes treatment

regimen, including aspects like perceived hyperglycemia and hypoglycemia, the convenience of treatment, and flexibility in daily life.

These are just a few examples since there are many PROMs developed and used in the assessment of PROs in the context of CVDs and diabetes. The choice of a specific PROM depends on the research or health objectives, the population under consideration, and the aspects of health and well-being that researchers or healthcare providers aim to measure.

Condition-specific and generic PROMs are both important for understanding and improving patient care at multiple levels of the healthcare system. In general, generic measures are needed when evaluating the allocative efficiency of used resources in health care.

The International Consortium for Health Outcomes Measurement (ICHOM) has defined Standard Sets of outcome measures for various medical conditions and patient populations (<https://www.ichom.org/>). They typically include a core set of patient-reported outcomes, clinical outcomes, and other relevant measures that are agreed upon by international experts in the field. ICHOM collaborates with a wide range of stakeholders, including healthcare providers, patient advocacy groups, researchers, policymakers, and industry partners, to develop and implement Standard Sets in clinical practice. The organization also provides resources, tools, and support to healthcare organizations for the implementation of standard sets.

To ensure greater confidence in the value of PRO data, it is always advisable to choose a PROM that has undergone psychometric validation [Churruca et al, 2021] in the intended language of use. The necessary psychometric properties of a PROM include reliability (i.e., the extent to which an instrument yields the same number or score each time it is administered when the construct being measured has not changed), validity (extent to which an instrument measures what it was intended to measure), and responsiveness (instrument's ability to detect clinically meaningful change over time – or sensitivity to change: ability to detect any degree of change over time) [Frost et al, 2007].

PROMs are often measured at specific points in a patient's healthcare journey to assess the impact of a health condition or treatment from the patient's perspective. The timing of PROM measurements can vary based on the nature of the condition, treatment plan, and research objectives. In ICHOM standard sets collection time-points are proposed based on expert consensus. Here are common points when PROMs may be measured:

- At baseline: PROMs are often measured at the beginning of a patient's healthcare journey to establish a baseline understanding of their health status before initiating a treatment or intervention. Before the beginning of a new treatment, surgery, or therapeutic intervention, PROMs can be measured to capture the patient's health status and relevant outcomes. This baseline assessment helps in comparing pre- and post-treatment outcomes.
- Post-treatment or post-intervention or after significant events: Following the completion of a treatment or intervention, or after significant health events (such as a relapse, adverse reactions to medication, or the development of new symptoms) PROMs are often measured to provide insights into the patient's experience and guide adjustments to the care plan.
- At discharge or transition points: Measuring PROMs at the point of discharge from a hospital or during transitions of care helps evaluate the patient's health status and any challenges they may face post-discharge.

- At follow-up appointments: PROMs can be integrated into routine clinical visits to gather continuous feedback on the patient's experience and outcomes. This approach facilitates ongoing assessment and adjustment of the treatment plan. For chronic conditions or ongoing treatments, PROMs may be measured at regular intervals during treatment to monitor changes in symptoms, functioning, and overall well-being.

The specific timing of PROM measurements depends on the health context, treatment plan, and research goals. Incorporating PROMs at various points in the patient's healthcare journey provides a comprehensive understanding of the patient's experience and treatment outcomes.

PATIENT EXPERIENCES

Patients' or caregivers' experiences can be assessed with patient-reported experience measures (PREMs) [Jamieson Gilmore et al, 2023]. These are instruments designed to capture and assess patients' perceptions, experiences, and interactions with health and social care systems and services. Not all pilots will be designed to have an impact on patient journeys through the health care system and may lead to meaningful and measurable changes in patient experiences. However, the concept of measuring the subjective experience of those who are targeted by a pilot intervention can be extended to relevant populations, not necessarily involving patients.

PREMs are typically implemented in the form of surveys, questionnaires, or interviews. Patients are asked to provide feedback on specific aspects of their care. They differ from satisfaction surveys, although PREM surveys may incorporate one or more questions soliciting an overall opinion on a patient's experience. These inquiries explore specific aspects, such as whether particular types of information were conveyed during admission or discharge, rather than focusing solely on the patient's satisfaction with the information. This approach helps minimize the impact of patient expectations on survey responses. PREMs seek to record what occurred to patients, from their perspective, rather than their overall evaluation.

PREMs can be either relational or functional. Relational PREMs focus on the patient's experience of their relationships during treatment (for example, whether they perceived that the healthcare professionals fully understood their concerns). Functional PREMs examine more practical issues, such as patients' perceptions of the facilities available.

A varied range of surveys is currently available and actively utilized. Some are designed for application across various settings and demographics. In contrast, others are tailored for specific services, such as emergency departments or primary care, or specific aspects of care, like continuity.

To ensure reliability and validity, PREMs are often psychometrically validated. This means that the survey instruments undergo rigorous testing to ensure they measure what they intend to measure consistently. It is always advisable to use previously validated PREMs in the intended language of use.

The data collected through PREMs are valuable for healthcare providers, organizations, and policymakers. Insights gained from patient-reported experiences can inform quality improvement initiatives and enhance the overall delivery of healthcare services.

In the context of diabetes, two PREMs are mainly used (Martin-Delgado 2021):

- Swedish National Diabetes Register (SNDR) (Hallgren Elfgren 2016)
- National Diabetes Audit (NDA) - Patient Experience of Diabetes Services Survey (<https://www.bjd-abcd.com/index.php/bjd/article/view/229>)

In the context of CVDs, two examples of the assessment of PREMs in patients with chronic heart failure (CHF) are reported in the literature (Lagha 2012). When considering the rehabilitation setting, Nesbitt and colleagues (Nesbitt 2023) published a PREM for the evaluation of patient experience to improve attendance to a cardiac rehabilitation program.

The literature provides also some generic (i.e., not disease-specific) PREMs that can be used for assessing certain aspects of patients' experience:

- Consultation and Relational Empathy (CARE) questionnaire (<https://doi.org/10.1093/fampra/cmh621>; <https://caremeasure.stir.ac.uk/>): this questionnaire measures empathy in the context of the therapeutic relationship during a one-on-one consultation between a clinician and a patient
- 9-item Shared Decision-Making Questionnaire (SDM-Q-9) (<https://doi.org/10.1016/j.pec.2009.09.034>; http://www.patient-als-partner.de/index.php?article_id=20&clang=2/): this questionnaire measures the extent to which patients are involved in the process of decision-making from the perspective of the patient
- Questionnaire for Patients' Experiences Across Health Care Sectors (PEACS 1.0) (<https://doi.org/10.1093/intqhc/mzu044>): this questionnaire measures patients' experiences across healthcare sectors with a focus on quality improvement
- Person-Centred Coordinated Care Experiences Questionnaire (P3CEQ) (<https://doi.org/10.1093/intqhc/mzy212>; <http://p3c.org.uk/prom-detail/29>): this questionnaire addresses important aspects of chronic care.

A systematic review by Bull and colleagues (2019) offers a valuable overview of PREMs, albeit limited to evidence up to 2018. The review categorizes PREMs according to type of individual, condition, setting, and country-specific context, and provides an assessment of their validity and reliability.

PREMs are typically measured at various points throughout a patient's interaction with the health or social care system. The timing of PREM measurements can provide valuable insights into different aspects of the patient's journey. PREMs may be measured:

- During care provision: Patients can be asked to provide feedback on their experiences during or immediately after receiving healthcare services (e.g., doctor's visit, hospital stay or outpatient procedure, treatment). This real-time measurement captures their impressions while the care is still fresh in their minds.
- At the end of a treatment/intervention or after a significant event: Measuring PREMs at the conclusion of a treatment or episode of care provides a comprehensive assessment of the patients' journey. This can include their overall satisfaction, perceptions of the effectiveness of the care received, and suggestions for improvement.
- At discharge or transition points: PREMs can be measured at the point of discharge from a healthcare facility or during transitions of care. This allows for insights into the patient's overall experience and any challenges faced during the transition to a different phase of care.
- At follow-up appointments: During follow-up appointments, patients can be asked to provide feedback on their experiences since the last visit. This helps in tracking changes in their perceptions and identifying any ongoing issues. For patients undergoing long-term care, periodic measurements of PREMs at regular intervals provide a longitudinal

perspective. This approach can reveal changes in the patient's experience over time and assess the impact of ongoing treatments.

The specific timing of PREM measurements depends on the goals of the assessment, the nature of the healthcare services being provided, and the research or quality improvement objectives. Regular, systematic measurement at multiple points can provide a comprehensive understanding of the patient's journey through the healthcare system.

ECONOMIC EFFICIENCY

Measuring economic efficiency involves evaluating how well resources are allocated to produce (healthcare) services, aiming to achieve the maximum possible output with the least input. There are several methods and indicators to assess economic efficiency, and the choice of the approach often depends on the context. In general, both (health) outcomes (or any relevant intermediate proxy measures, when health outcomes cannot be observed in the pilot) and resource costs, are necessary to perform the assessment. Common analyses include cost-effectiveness, cost-utility, or cost-benefit analyses [Drummond 2015, Sanders 2016, Husereau 2022] (see following paragraphs). These approaches evaluate the relationship between costs and (health) outcomes by comparing the pilot intervention/program with the standard of care (e.g., no intervention). These evaluations can be approached from various perspectives, each offering a unique view on costs and benefits. The main perspectives used in economic evaluations include:

- **Healthcare Service perspective:** focuses on the costs and benefits relevant to the health care system or payer; in particular, it considers direct medical costs such as costs for hospitalizations, outpatient visits, medications, and medical devices.
- **Societal perspective:** this is the broadest perspective, considering all costs and benefits to society as a whole, regardless of who incurs the costs or receives the benefits.

The choice of perspective depends on the purpose of the evaluation and the stakeholders involved. The societal perspective is often preferred for comprehensive analyses, as it provides a complete picture of the economic impact. However, specific perspectives like the health care system/payer perspective may be more relevant for the scope of JACARDI as it provides information for decision-makers regarding budgetary impacts and cost-containment strategies. Each perspective offers distinct insights, and sometimes multiple perspectives are used to provide a more rounded analysis.

For the analysis, a time horizon should be defined. Some pilots may assess resource use during the trial period, while others may extend the analysis to post-trial follow-up periods to capture longer-term effects.

It is important to conduct **sensitivity analyses** to assess the impact of uncertainties or variations in resource utilization or cost estimates. Performing sensitivity analysis on a pilot involves examining the impact of variations in key parameters or assumptions on the study outcomes. This helps in understanding the robustness of the results to changes in key parameters. The following steps should be followed to conduct a sensitivity analysis:

- 1) Identify key parameters: determine the parameters or assumptions that are critical to the pilot outcomes. These could include variables such as sample size, effect size, dropout rates, compliance rates, or other factors that may influence the study results.
- 2) Define ranges: define plausible ranges for each key parameter. Consider both optimistic and pessimistic scenarios and determine the upper and lower bounds for

- each parameter based on available data, literature review, expert opinion, or prior experience.
- 3) Choose the methodology: select the appropriate methodology for conducting sensitivity analysis based on the nature of the study and the parameters involved. Common methods include one-way sensitivity analysis, scenario analysis, and probabilistic sensitivity analysis. The simplest way is to perform a one-way sensitivity analysis; this means that one key parameter is varied within its defined range while keeping all other parameters constant at their baseline values. This involves adjusting the chosen parameter to different values within its range and observing the resulting changes in the considered outcomes.
 - 4) Interpret the results: analyze the results of the sensitivity analysis to understand how variations in key parameters influence the pilot outcomes. Identify which parameters have the greatest impact on the results and assess the sensitivity of the findings to changes in these parameters.
 - 5) Communicate the findings: clearly communicate the findings of the sensitivity analysis, including any uncertainties or limitations identified. Discuss how variations in key parameters may affect the interpretation and generalizability of the study results.
 - 6) Consider implications: consider the implications of the sensitivity analysis findings for the interpretation of pilots' results and future directions. Determine whether adjustments to study design, sample size, or other parameters are warranted based on the sensitivity analysis findings.

Other aspects to be taken into consideration are monitoring and ethical issues. Monitoring and assessing participant compliance with the assigned programs, interventions, or treatments is of utmost importance since non-compliance can impact resource utilization and produce bias in the results.

The data collection on resource utilization must be aligned with ethical standards, including patient privacy and confidentiality. For pilots involving participants actively, obtaining informed consent from them regarding the use of their healthcare data for the scope of the pilots is a mandatory step.

By systematically measuring health and social care resource use during a pilot, pilot teams can gain insights into the economic implications of the intervention, inform healthcare policy decisions, and contribute valuable information to the broader field of health economics.

Measuring the use of health and social care resources

Measuring the use of healthcare resources during a pilot involves tracking and analyzing various aspects of resource utilization. This information is crucial for assessing the cost-effectiveness and economic impact of a new treatment or intervention.

The first step is to clearly define a list of the (healthcare) resources that will be considered in the study. This can include hospital admissions, outpatient visits, laboratory tests, medications, procedures, and any other relevant services. It is useful to specify the units of measurement for each resource (e.g., number of hospital days, number of outpatient visits, dosage of medications).

Healthcare resource use should be gathered at the patient or individual level. This may involve reviewing medical records, conducting interviews, or using patient diaries to capture healthcare encounters, treatments, and services. In general, medical records and administrative databases may provide data on specialist visits, examinations, hospitalizations, emergency room visits, and prescribed medications. Some pilots may also use time diaries to

measure the time that healthcare professionals need to provide the pilot. On the other side, patient-reported resource use through surveys or interviews may provide valuable information on over-the-counter medication use, non-prescription treatments, and other healthcare-related expenses.

If a pilot intervention is expected to have an impact on costs that is not limited to the third payer perspective (e.g., national health service, health insurance funds, etc.) but is spread over a variety of stakeholders (e.g., patients and their families, employers, society), data on the consumption of non-healthcare resources may also be collected. These resources may encompass for instance travel, accommodation, and formal and informal care. Furthermore, suppose the intervention is expected to have an impact on patients' productivity, either due to absenteeism or reduced efficiency (presenteeism) during paid or unpaid work. In that case, data on productivity losses may be gathered. To streamline data collection for productivity losses, a validated questionnaire developed by the institute for Medical Technology Assessment (iMTA) may be used (iMTA Productivity Cost Questionnaire, <https://www.imta.nl/questionnaires/ipcq/>).

Monetary quantification

This phase is related to the assignment of costs to each (healthcare) resource used during a pilot. This may involve obtaining cost information from (healthcare) providers, payer databases, or using standardized cost estimates. Costs can be applied to each unit of resource used. The costs should be assessed for the possible intervention/program itself proposed by the pilot and for the variations in healthcare resource use the intervention/program implies. In detail, monetary quantification should follow these steps:

1. Assign monetary values to each resource based on the gathered cost data and the defined units of measurement. This may involve multiplying the quantity of each resource by its corresponding unit cost to calculate the total monetary value. If the analysis is conducted from the Healthcare Service perspective, the interest is to evaluate the current tariffs that the Healthcare Service uses to compensate hospitals and other healthcare providers for both inpatient and outpatient services. For the inpatient care, the cost of hospital admissions may be estimated through DRG (Diagnosis Related Groups) tariffs (in the Countries where they are available), while for outpatient care, the costs of visits, exams, and other services are obtained from the formulary for outpatient services issued by the Healthcare Service. For Countries in which health insurance schemes are applied, health care services funded by these organizations should be taken into account (more specific documentation can be found at <https://www.ispor.org/heor-resources/more-heor-resources/pharmacoeconomic-guidelines>). For example, the cost of specialist visits may be calculated by multiplying the number of visits performed by the specific visit tariff, while the cost of drugs may be calculated by multiplying the quantity administered by the unit cost per dose. For example, if a pilot aims at implementing a screening through the use of a particular device, the cost of the device must be considered in the assessment.

In case the societal perspective is the one of interest, both costs from the healthcare service perspective and societal costs are considered. Societal costs involve, as described above, productivity losses for absenteeism, presenteeism, premature death, costs of informal care provided by caregivers, out-of-pocket (OOP) costs sustained by

- the patients for the purchase of healthcare services not covered by the national healthcare service, costs for formal (paid) care, etc.
2. Aggregate the monetary values of all healthcare resources to obtain the total cost of the implementation of the pilot for a given period, setting, or population. This may involve summing the costs of personnel, equipment, facilities, medications, and procedures across all departments, services, or interventions within a (healthcare) system.
 3. Analyze and interpret the results: analyze the results of the monetary quantification to understand the distribution of healthcare costs, identify cost drivers, assess cost-effectiveness, and inform decision-making. Interpretation may involve comparing costs across different healthcare settings or interventions, evaluating the affordability of healthcare services, and identifying opportunities for cost-saving or efficiency improvements.

The steps presented here need to be performed also for the assessment of the standard of care to allow comparisons.

Cost-Effectiveness Analysis (CEA)

In a cost-effectiveness analysis, the costs associated with the implementation of an intervention are compared to the outcomes or benefits it produces. These outcomes are typically measured in terms of a specific unit relevant to the intervention's objectives, such as life-years gained, quality-adjusted life years (QALYs), or units of disease prevented [Drummond 2015, Sanders 2016, Husereau 2022]. The more detailed analysis considers QALYs as the measure of health outcomes. If the assessment of QALYs is not possible, life expectancy or other proxies (intermediate outcomes) may be considered. It's important that these proxies are correlated to final outcomes like life expectancy or QALYs. For example, a decrease in blood pressure may be a relevant health outcome for a pilot if it can improve life expectancy and QALYs (the literature should state that).

A QALY is a measure used in healthcare to quantify both the quantity and quality of life lived. It combines the length of time a person lives with their health-related quality of life during that time. Essentially, it measures both the length and the quality of life gained from a program/intervention or health condition.

To calculate QALYs, the following steps should be followed:

1. Assess patient's health states: determine the health states experienced by an individual, which can range from perfect health to death. This assessment is usually carried out through the administration of an EQ-5D-5L questionnaire.
2. Assign utility values (u) to each health state on a scale from 0 to 1. These values represent the preference associated with each health state. Perfect health is typically assigned a value of 1, while death is assigned a value of 0. Other health states are assigned values between 0 and 1 based on perceived quality of life. The EuroQol Group provides many country-specific value sets (i.e., utility value estimates), which can be freely downloaded from its website (<https://euroqol.org/information-and-support/resources/value-sets/>). An example of how to assign utility value to a health state is provided below.
3. Calculate years lived in each health state: determine the number of years a person spends in each health state over a specific period.

4. Multiply utility by years lived: multiply the utility value of each health state by the number of years lived in that state.
5. Sum up: sum up the products obtained from the previous step across all health states to get the total QALYs gained.

This method allows for a standardized measure to compare the impact of different health interventions or conditions on quality of life, facilitating healthcare decision-making and resource allocation. A step-by-step guidance to calculate QALYs is reported in Appendix 1.

A CEA consists of estimating the incremental cost-effectiveness ratio (ICER) that is calculated with the formula:

$$\text{ICER} = \text{incremental cost} / \text{incremental effectiveness}$$

The incremental cost represents the difference in costs between the two interventions under investigation (or intervention vs. no intervention/standard of care); analogously, the incremental effectiveness represents the difference in effectiveness between the two interventions under investigation (or intervention vs. no intervention/standard of care). Effectiveness is generally expressed as life years (e.g., life expectancy). In case the effectiveness is expressed in QALYs, the analysis is called Cost-Utility Analysis (CUA).

The ICER represents the additional cost incurred to achieve an additional unit of outcome (e.g., additional year of life) with one intervention compared to the other. In general, a lower ICER indicates a better value for money, as it means that the intervention is achieving outcomes at a lower additional cost. The ICER is then compared to a threshold, which represents the willingness to pay for an additional unit of health outcome (or QALY) gained through an intervention. These thresholds are used to determine whether an intervention is considered cost-effective. However, the specific thresholds can vary depending on the context, country, and healthcare system. Here are some commonly cited ICER thresholds:

- World Health Organization (WHO) threshold: the WHO suggests a threshold of 1 to 3 times the Gross Domestic Product (GDP) per capita for a QALY
- Country-specific thresholds: many countries have developed their own ICER thresholds based on their healthcare budgets, priorities, and societal values. For example:
 - In the United States, the commonly cited threshold is around \$50,000 to \$150,000 per QALY gained
 - In the United Kingdom, the National Institute for Health and Care Excellence (NICE) has historically used a threshold range of £20,000 to £30,000 per QALY gained.
 - In Italy applied thresholds are in the range of 25,000-60,000€ [Messori 2004, Fattore 2009]

It's important to note that ICER thresholds can evolve over time based on changes in healthcare priorities, economic conditions, and societal values. Additionally, while ICER thresholds provide a useful framework for evaluating cost-effectiveness, they should be considered alongside other factors such as budget constraints, equity considerations, and the strength of the evidence supporting the intervention's effectiveness.

EQUITY AND DIVERSITY (WHO BENEFITS FROM THE INTERVENTION?)

In JACARDI, “equity” (see also glossary) refers to a desirable, or aspirational, distribution of opportunities, resources, or outcomes among individuals and population groups, according to a given set of values or principles. Conversely, “inequity” relates to a distribution

characterized by inequalities between individuals and population groups deemed unjust and avoidable. “Diversity” (see glossary) refers to the presence of different characteristics or social dimensions within a group, organization, or community, such as age, gender, race, ethnicity, sexual orientation, socioeconomic status, physical and cognitive abilities, religious beliefs, and cultural background.

This methodological framework for the assessment of pilot projects will remain neutral to different values and principles that may inform equity judgments. Therefore, the focus will be on identifying and measuring inequalities and diversity in those who are exposed to, and those who benefit from, the interventions deployed in each pilot. This will lead to an assessment of whether, and to what extent, the intervention is likely to mitigate, or exacerbate, existing inequalities in CVD and DM outcomes among individuals and relevant population groups.

The main steps in the equity and diversity dimension of the evaluation are as follows:

A. Identify potential equity dimensions. Relevant dimensions will include those along which significant inequalities already exist that the intervention may help redressing, or those along which the intervention might exacerbate existing inequalities. A non-exhaustive list of potentially relevant dimensions includes the following:

- a. Age (differences in exposure to the intervention, or benefit from the intervention, for individuals in different age groups);
- b. Gender and sexual identity;
- c. Socioeconomic position (SEP) (see glossary), a broad concept covering the factors that produce social stratification within society, such as income or education;
- d. Place of residence, especially when linked to degrees of social and economic deprivation in different geographical areas;
- e. Ethnic origin;
- f. Migrant status;
- g. Cultural identity;
- h. Disability status;
- i. Other vulnerability dimensions.

It would be advisable to also consider intersections of these groups, ex. aged persons with disabilities, ethnic minority pregnant women, low-income elderly people living in rural areas etc., or groups identified within the pilot through the situation analysis.

B. Determine whether relevant equity dimensions are measurable. Once relevant equity dimensions are identified, Pilots will have to assess whether the information needed to characterize those exposed to the intervention along the relevant dimensions can be collected (is it feasible? is it ethical? will individuals agree for those characteristics to be collected and reported?).

C. Identify appropriate exposure and outcome measures for the equity assessment. Not all of the exposure (participation) and outcome measures used in a Pilot would need to be assessed through an equity and diversity lens. Each Pilot will select one or more that are especially important. For exposure, Pilots may wish to use indicators of actual participation (did someone participate in the intervention?), or opportunity to participate (was someone offered to participate?). For outcomes, Pilots may select one or more measures among those identified under Section 1 of this framework.

D. Select and calculate appropriate inequality measures. The choice of method to assess impacts on inequalities depends on the specific context, the nature of the outcomes being measured, and the available data. A combination of quantitative and qualitative approaches often provides a more comprehensive understanding of impacts on

inequalities. As for quantitative measures, a first assessment can be based on descriptive statistics, such as proportions, means, or medians, to provide a snapshot of the distribution of the outcome(s) across the different subgroups. Going a step forward, we can distinguish relative and absolute measures of inequality. Relative measures include those based on ratios (e.g. rate ratio, prevalence ratio, hazard ratio, etc.), which represent the percent excess of an outcome in one group compared to the outcome in another group (taken as a reference). So, for example, the prevalence ratio (PR) of CVD among migrants is computed as the ratio of the prevalence of a disease among migrants (e.g., 7%) over the prevalence among non-migrants (e.g., 5%); we obtain $PR=1.4$, which suggests that migrants have a 40% higher prevalence of CVD compared to non-migrants within the studied population. Absolute measures are computed as differences (e.g., rate difference - RD, etc.) and represent the gap in the actual number of people with the outcome between the two groups. In the previous example, the difference in the prevalence rate would be $RD=0.02$, which implies that there are 2% more people with the disease among migrants. We would have obtained the same value if the two prevalence rates had been 50% and 48%, but in that case, the prevalence ratio would have indicated only nearly 4% higher rate in relative terms. Hence, both relative and absolute measures can be of interest in monitoring inequalities, but the overall level of the outcome must always be considered to give a correct interpretation of the results (Houweling 2007). A further important distinction can be made between inequality measures comparing two groups and those measuring the entire gradient, i.e. based on the complete ranking of the SEP indicator. The advantage of these measures is that they account for the distribution of the population across the different socioeconomic categories, although they are more complex to compute and are often based on regression models. Examples of this group of indicators are the concentration index and the index of inequality, both with their absolute and relative versions; a more complete examination of inequality measures can be found in the suggested readings [Schlotheuber et al, 2022].

SUSTAINABILITY

Sustainability in JACARDI is defined as the ability of JACARDI to ensure and sustain project impact after EU funding ends. Further exploitation of JACARDI results will be supported at three levels: i) high-level policy sustainability; ii) sustainable impacts within topics of health literacy, data availability, quality, accessibility and sharing, screening, integrated care pathways, self-management and labor participation (supported by roadmaps per each topic, summarizing the results of the pilots, identifying the characteristics and factors important for development of further programs and their implementation strategies, or scaling up); and iii) sustainability of JACARDI pilots' results and outcomes.

Different indicators may be used to assess sustainability. More general characteristics of the pilot such as community engagement and institutional support will be assessed with the tools developed by WP4; the multidimensional assessment framework allows pilots to evaluate the sustainability of resources and capabilities that refer to further exploitation of the pilot results after the end of JACARDI (third-level perspective of sustainability in JACARDI). This can be done using the results of the multidimensional assessment dimensions presented in the document above (budget, funding sources, cost-effectiveness) and the various strategic planning techniques, for example, SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis.

Assessing the sustainability of a pilot is best done at strategic points throughout its lifecycle, typically before, during, and after implementation. Here's when it's most appropriate to assess sustainability:

- **Planning Phase:** sustainability considerations should be integrated into the planning phase of the pilots (for example, when establishing implementation team and stakeholders' network, developing strategic objectives, performing situation analysis, and developing implementation plan).
- **During Implementation:** conducting a midpoint evaluation allows to assess how well the pilots are progressing and identify any emerging sustainability challenges or opportunities. This may involve revisiting opportunities for political and institutional support, addressing level of partner and community engagement, reviewing financial data, monitoring resource utilization, and soliciting feedback from stakeholders. Adjustments can be made to enhance sustainability based on mid-term findings.
- **Post-implementation evaluation and planning:** after the pilots conclude, a comprehensive evaluation should be conducted to assess their overall sustainability. This involves analyzing the long-term impact of the pilots, evaluating the continued relevance of their findings, and determining the feasibility of scaling up or replicating successful interventions. Lessons learned from the pilots can inform future sustainability planning efforts which should be included in the Sustainability Action Plan for the period after JACARDI ends.

By systematically addressing these factors, a comprehensive understanding of the pilots' sustainability may be performed and proactive steps may be taken to enhance their long-term impact.

Scalability/transferability

Assessing the scalability of a pilot involves evaluating its potential for expansion and replication to reach a larger population or be implemented in different settings, while the transferability refers to the extent to which the findings and outcomes of the pilot can be applied to other settings, populations, or contexts beyond the original study environment. The main steps for assessing the scalability/transferability of a pilot are the following:

- Clearly define the objectives of scalability/transferability. Determine whether the goal is to expand the program to serve a larger population, replicate it in different locations, or adapt it to diverse contexts.
- Evaluate the design and structure of the healthcare intervention to determine if it can be easily replicated. Consider whether the intervention components are modular, adaptable, and have a standardized framework that can be implemented in various settings. Standardization of protocols, procedures, and guidelines may ensure consistency in program implementation and facilitate easier replication and transferability.
- An evaluation of the resource requirements for the program implementation should be performed to determine whether the program can be implemented with available resources in new settings.
- The program should be adaptable to different cultural contexts. A scalable/transferable program should be culturally sensitive and able to engage diverse communities.

Other aspects may be considered in the assessment:

- The presence of training and capacity-building strategies embedded in the healthcare program may facilitate new implementations in different locations.
- Compatibility with existing systems facilitates smoother integration into existing healthcare systems or structures without requiring major overhauls.
- Scalable programs often leverage technology for data collection, monitoring, and communication, making it easier to manage and scale.
- The involvement of key stakeholders, including community members, healthcare providers, and policymakers, in the scaling process may provide inputs and enhance the likelihood of successful replication in new settings.

Assessing the scalability/transferability of a pilot is best done at strategic points throughout its lifecycle, typically before, during, and after implementation. Here's when it's most appropriate to assess scalability/transferability:

- **Planning Phase:** assessing scalability/transferability should begin during the planning phase of the pilots.
- **During Implementation:** conducting a midpoint evaluation allows to assess the feasibility of scaling up successful components of the pilots. This may involve identifying barriers to scalability/transferability, exploring expansion opportunities, and refining strategies to enhance scalability.
- **Post-implementation evaluation:** after the pilots conclude, a comprehensive evaluation should be conducted to assess their scalability/transferability potential. This involves analyzing the scalability of the intervention, evaluating the scalability/transferability of the implementation model, and identifying factors that may facilitate or hinder scaling up. Lessons learned from the pilots inform scalability/transferability planning for future expansion efforts.

Regularly reviewing and updating the scalability/transferability plan as the program evolves ensures that the scaling process remains dynamic and responsive to changing circumstances. A thorough assessment of these factors can guide the scalability/transferability potential of pilots.

ADDITIONAL IMPLEMENTATION OUTCOMES AND PROCESS INDICATORS

Implementation outcomes reflect the progress toward success of efforts to implement evidence-based interventions [Proctor et al, 2023]. In other words, implementation outcomes aim at measuring the success or failure of implementation.

Implementation outcomes might be classified into anticipated (i.e., forward-looking) and actual (i.e., backward-looking outcomes) outcomes, according to the timing of measurement [Damschroder et al, 2022]. Anticipated implementation outcomes reflect perceptions or assessments of the likelihood of future implementation success or failure. For instance, an anticipated outcome could be the projected probability that decision-makers will adopt or deliver the intervention in real-world settings before it has been implemented (e.g., the estimated number of clinical centers that may adopt the intervention). Actual implementation outcomes are based on perceptions or measures of current (or past) implementation success or failure. An example of actual implementation outcome is the extent to which decision-makers have adopted or delivered the intervention in real-world settings (e.g., the actual number of clinical centers that have adopted the intervention).

Both types of implementation outcomes can be assessed either quantitatively (e.g., through structured surveys or checklists, use of administrative records, extraction from the electronic health record) or qualitatively (e.g., through semi-structured interviews and focus groups).

The selection of implementation outcomes might be guided by existing frameworks, which propose a comprehensive taxonomy of those outcomes, offering a guide for their conceptualization and measurement. Moreover, these frameworks delve into the determinants that can either facilitate or hinder implementation outcomes (i.e., barriers and facilitators, including individual and setting-level factors). Well-established implementation frameworks in healthcare are the Consolidated Framework for Implementation Research (CFIR) [Damschroder et al, 2009] and its updated version [Damschroder et al, 2022], the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [Glasgow et al, 2019] or the Implementation Outcomes Framework (IOF) [Proctor et al, 2011].

Besides sustainability and scalability (see sections 5a and 5b), frequently measured implementation outcomes include:

- **Acceptability:** the extent to which an intervention is perceived as agreeable, palatable, or satisfactory. Acceptability implies an evaluation of how well the intervention aligns with personal criteria: different individuals might have different judgments of the acceptability of the same intervention if their needs, preferences, or expectations differ. The measurement of acceptability can be informed by existing frameworks, for example, the Theoretical Framework of Acceptability (TFA) [Sekhon et al, 2017].
- **Appropriateness:** perceived fit, relevance, or compatibility of an intervention for a given context, or its perceived fit to address a particular issue. Acceptability implies an evaluation of how well the intervention aligns with technical or social criteria: an intervention might be judged appropriate if it is seen as effective for achieving some objectives given existing conditions or seen as consistent with norms or values.
- **Feasibility:** the extent to which an implementation target can be successfully used or deployed within a given setting. Feasibility implies an evaluation of how well the intervention aligns with practical criteria: an intervention might be judged if it can be performed relatively easily or conveniently given existing resources and circumstances.
- **Adoption (or uptake):** intention, initial decision, or action to employ an intervention. Adoption can be measured at the setting level and/or at the staff/provider level in terms of the absolute number, proportion, and representativeness of settings and deliverers who are likely or have decided to deliver the intervention.
- **Fidelity:** the degree to which an intervention was implemented as prescribed or intended. Fidelity can be measured by collecting data on the adherence to the intervention, amount of intervention delivered, and quality of program delivery.
- **Penetration:** integration or saturation of an intervention within a service setting and its subsystem. Penetration can be measured by estimating the number of eligible persons who access the intervention, divided by the total number of persons eligible for that intervention.

The aforementioned implementation frameworks not only focus on conceptual definitions but also provide approaches to operationalizing implementation outcomes. Additionally, there are several available resources that can support researchers in selecting appropriate quantitative measures to evaluate the different implementation outcomes. First, the Implementation Outcome Repository (<https://implementationoutcomerepository.org/>) is an online resource that offers free access to a variety of quantitative instruments. For each quantitative instrument, the repository provides information on its psychometric quality (i.e.,

reliability and validity), methodological quality, and usability. Another valuable resource is the SIRC Instrument Repository (<https://societyforimplementationresearchcollaboration.org/measures-collection/>), which originated from a systematic review by Lewis and colleagues (2015). This repository is another online resource that provides a collection of quantitative instruments, guided by the CFIR and IOF frameworks. The website is constantly updated, however access to the repository requires membership. The RE-AIM website (<https://re-aim.org/resources-and-tools/measures-and-checklists/>) includes several measures and checklists to support the design of a quantitative evaluation based on the related implementation framework. Lastly, a publicly available website (<https://www.health-policy-measures.org/find-measures>) was recently developed based on a systematic review of health policy implementation measures [Allen et al, 2020].

Process indicators might be measured for interventions that are expected to have significant implications not only for the individuals they target but also at the organizational levels. Process indicators measure the intervention's activities and outputs (in other words, whether planned activities took place). Process indicators can be used to assess the quality of the activities performed, based on some established criteria, practice guidelines, or standards. Examples of process indicators are adherence to existing guidelines/recommendations and timeliness of intervention.

PILOT ASSESSMENT DESIGN

The evaluation of the outcomes of pilots should ideally be made in a causal inference framework. This refers to the process of determining whether an observed association reflects a cause-and-effect relationship. For each pilot, the assessment should investigate the effect of the intervention/program under investigation on the proposed outcomes (effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability – including scalability – and additional implementation and process outcomes).

Establishing causation can be a challenging task. **Randomized controlled trials (RCTs)** are generally viewed as the gold standard approach in assessing the effects of treatment, program, or exposure [Jacob 2016]. RCTs are characterized by the random assignment of study participants to intervention and control groups. When executed correctly, randomization is anticipated, on average, to equalize observed and unobserved participant characteristics across trial arms. This equilibrium facilitates attributing any divergence in outcomes across arms to the intervention and poses RCTs at the top of the pyramid of evidence of causality [Leroy 2022, Goldstein 2019].

Nevertheless, carrying out an RCT might be impractical for various reasons, such as lack of essential financial or time resources, or when dealing with an exposure or hypothesis that cannot be applied or altered for trial participants due to ethical concerns. Additionally, the sample of willing participants may not adequately represent the broader patient population, potentially compromising the meaningfulness of the results [Lyons 2022]. Moreover, RCTs have also received some criticism, as they may not represent the real clinical practice, therefore real-world evaluations, in addition to RCT, are getting more attention now. Furthermore, a 'controlled environment' like one of RCTs may 1) not always be feasible, but 2) also not help to assess the effectiveness of an intervention in day-to-day practice. As such, RCTs often overestimate the effectiveness that can be expected in a natural environment. On

the other hand, pragmatic trials, conducted in a real-world setting, apply less restrictive inclusion criteria for participants, which seems very relevant considering the high prevalence of multimorbidity in DM/CVD patients. Moreover, JACARDI will pilot mainly organizational (rather than clinical) interventions, which are usually complex/multi-component interventions that may not fit the strict requirements of an RCT.

When the experimental RCT design is not possible or practical or adequate, causal inference can still be achieved with an observational study design. In observational studies, researchers observe and analyze subjects in their natural settings without randomly assigning treatments, which are instead prescribed according to clinical practice. These studies are valuable when randomization is not feasible or ethical, providing insights into associations and correlations between exposures and outcomes in real-world scenarios. It's important to note that observational studies may have limitations, such as potential endogeneity and confounding, that can impact the ability to establish causation compared to RCTs. Nevertheless, endogeneity and confounding can be eliminated, or significantly reduced, through appropriate study designs relying on relevant quasi-experimental counterfactuals. Examples of such study designs include the following:

- **Difference-in-Differences (DiD) design:** this is a quasi-experimental research design commonly used in observational studies to estimate causal effects. While it does not provide the same level of control as RCTs, DiD analysis can contribute evidence toward establishing causal relationships under certain conditions. It compares changes in outcomes over time between a treatment group and a control group. By examining the difference in changes, this design attempts to account for both time-fixed and time-varying confounders [Callaway 2021]. Key factors influencing the ability of DiD analysis to assess causality include:
 - o Assumption of parallel trends: the validity of DiD analysis relies on the assumption that, in the absence of treatment, the treatment and control groups would have followed parallel trends over time. If this assumption holds, any deviation from parallel trends after the introduction of the treatment can be attributed to the causal effect.
 - o Accounting for confounding factors: DiD requires careful consideration and control for potential confounding factors that might independently influence the outcomes. Failing to adequately address confounding variables can compromise the ability to draw causal inferences.
 - o Correct specification of the model: the success of DiD analysis in assessing causality also depends on correctly specifying the statistical model. This involves selecting appropriate covariates, understanding potential sources of bias, and using statistical techniques to control for observed and unobserved factors.
 - o Data quality and measurement: the reliability and accuracy of data play a crucial role in the success of DiD analysis. Researchers need to ensure that the measurements are valid and that any measurement errors are minimized.

While Difference-in-Differences analysis can offer valuable insights into causal relationships, researchers should interpret the results cautiously and consider potential limitations. The ability to make causal claims with confidence depends on the robustness of the research design, the validity of assumptions, and the rigorous application of statistical methods. In situations where randomization is not feasible, DiD analysis remains a useful tool for estimating causal effects and understanding the impact of interventions or treatments over time.

- **Regression discontinuity design (RDD):** it is a quasi-experimental research design that can be used to assess causality. RDD is particularly effective in situations where intervention or treatment is assigned based on a threshold or cutoff point, and individuals just above or below this threshold are expected to be comparable. One key assumption of RDD is that individuals close to the cutoff are essentially similar, and any observed differences can be attributed to the treatment or intervention rather than pre-existing differences. RDD involves conducting a regression analysis to model the relationship between the outcome variable and the assignment variable (distance from the cutoff). The regression estimates the treatment effect by comparing outcomes for individuals just above and below the cutoff. Researchers typically examine whether there is a discontinuity in the outcomes at the cutoff point. If a significant jump or discontinuity is observed, it suggests that the treatment or intervention had a causal effect. To enhance the validity of causal inferences, researchers need to control for potential confounding variables that may influence the outcome. This involves including covariates in the regression model. This step helps minimize selection bias and allows for stronger causal inferences [Albers 2010]. The success of RDD in assessing causality depends on the correct identification and implementation of the cutoff point, the validity of assumptions, and the rigorous application of statistical methods. When applied appropriately, RDD offers a credible approach to estimating causal effects in situations where randomization may not be feasible.

- **Instrumental variables analysis:** it uses an instrumental variable - a variable that is correlated with the exposure but is not directly related to the outcome - to estimate causal effects. This method is often used when randomization is not feasible [Iwashyna 2013]. This approach is used to figure out cause-and-effect relationships between variables, especially when traditional methods might give misleading results. It works by finding a third variable, called “instrumental”, that affects the variable of interest but isn't affected by the same hidden factors that might skew the results. This helps to tease out the true relationships between variables, even when there are tricky issues like hidden biases or omitted factors in the data. Using instrumental variables analysis to understand cause-and-effect relationships between variables can be tricky. One main challenge is finding suitable instruments that truly affect the variable of interest but aren't influenced by hidden factors. Weak instruments that don't strongly relate to the variable can also cause problems, leading to unreliable results. Additionally, there's the risk of using too many instruments or assuming they're unrelated to the errors in the model, which can also distort findings. Lastly, ensuring that the instruments apply to all parts of the data and aren't influenced by selection biases presents another hurdle in IV analysis.

Other observational study designs may be applied if none of the above can be used, but generally, they do not guarantee a causal assessment. These are:

- **Pre-post design:** observations or measurements are taken on the outcome of interest on the same subjects before and after the implementation of an intervention, treatment, or exposure. The goal is to examine changes over time and determine whether there is a causal relationship between the intervention and the observed outcomes. If there is a significant and consistent change in the post-intervention measures, a causal relationship between the intervention and the observed outcomes may be highlighted. While pre-post designs are straightforward and can provide valuable information, they have limitations. One major challenge is the lack of a control group, making it difficult to rule out alternative

explanations for observed changes. Without a comparison group, it is challenging to attribute changes solely to the intervention, as other factors may contribute to the observed outcomes. An example of pre-post design is the **Interrupted Time Series (ITS) design**. It is used to assess causality by studying the effects of an intervention or treatment over time. In an interrupted time series analysis, repeated measurements are taken on a single group or population before and after the implementation of an intervention, and the goal is to determine whether the intervention had a causal impact on the observed outcomes. The intervention is introduced at a specific point in time, often referred to as the “interruption” point. This could be the implementation of a policy, the introduction of a treatment, or any other event that is expected to influence the outcome. Data is collected at multiple time points before and after the intervention. The analysis involves examining the trajectory of the outcome variable over time and assessing whether there is a significant change in the level or trend of the outcome after the intervention. Statistical models, such as regression models, are commonly used in interrupted time series analysis. These models allow researchers to estimate the immediate and sustained effects of the intervention on the outcome. The design assumes a linear relationship between time and the outcome variable, implying that changes occur gradually over time. Like any study design, interrupted time series designs have limitations. They may be affected by confounding factors, and the identification of the intervention effect relies on assumptions about the absence of other external influences at the time of the intervention [Hudson 2019].

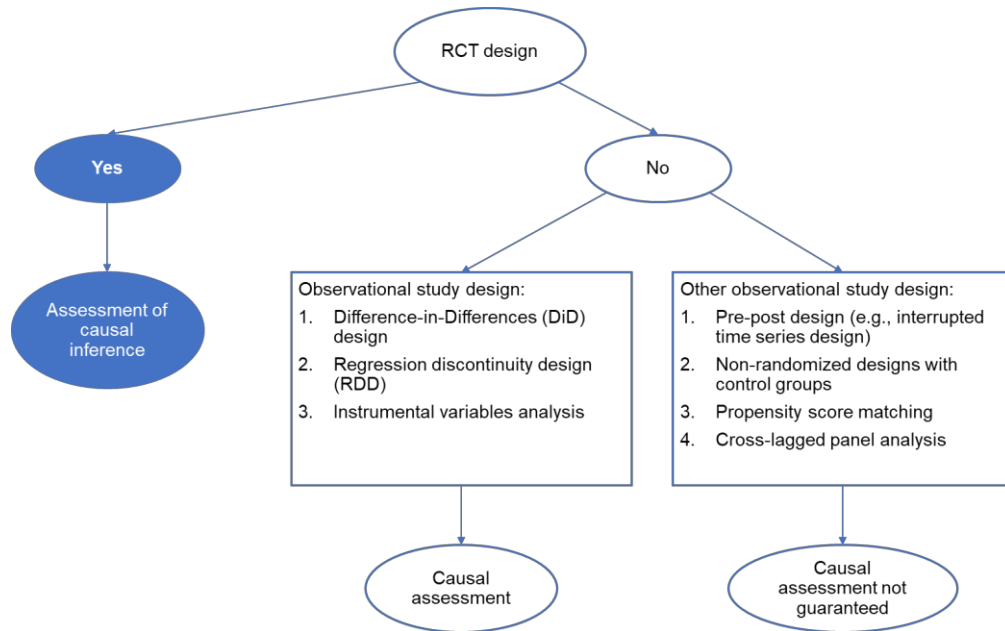
- **Non-randomized designs with control groups:** these designs include the study designs in which the control group cannot be selected in a way that prevents it from being systematically different from the intervention group. This means that the difference observed between the intervention and control groups cannot be assumed to be causal.

- **Propensity score matching:** it involves matching participants who received the treatment with those who did not based on their propensity scores, which estimate the likelihood of receiving the treatment. This helps control for observed confounders [Austin 2011] but not for unobserved ones.

- **Cross-lagged panel analysis:** commonly used in longitudinal studies, cross-lagged panel analysis examines the relationships between variables measured at multiple time points. This design helps infer causal relationships when temporal precedence is established [Reed 1988].

It's important to note that the strength of causal inference also depends on the quality of study implementation, control of confounding variables, and the validity of measurement methods. Researchers often use a combination of study designs and rigorous methodologies to build a compelling case for causality. Additionally, causal inference should be interpreted cautiously, recognizing that establishing causation is a complex and ongoing process, especially in implementation projects.

The following figure shows a summary of the different study designs and related assessments:



Assessment of causal effect

The counterfactual model is a conceptual framework used in the study of causal effects. The counterfactual represents what would have happened (the counterfactual outcome) to each participant if they had received an alternative treatment instead of the one they were assigned to (the observed outcome). The key idea is to create a hypothetical scenario where the individual or group in question did not experience the treatment, intervention, or exposure being studied in the specific pilot [Höfler 2005]. The essential components of the counterfactual model are the following:

- Counterfactual outcome (Y0): this represents the outcome that would have occurred in the absence of the intervention or exposure (e.g., in case of alternative treatment). It is a hypothetical scenario and is often denoted as Y0, where "0" signifies the absence of the treatment/intervention/program under investigation.
- Observed outcome (Y1): this is the actual outcome that occurred when the intervention or exposure was present. It is denoted as Y1, where "1" signifies the presence of the treatment/intervention/program.
- Causal effect (ΔY): the causal effect is the difference between the counterfactual outcome (Y0) and the observed outcome (Y1). Mathematically, $\Delta Y = Y1 - Y0$. This represents the impact or change in the outcome attributable to the treatment/intervention/program.
- Individual-level causal effect: at the individual level, the causal effect is the difference in outcomes for a specific individual with and without the intervention. It answers the question: What is the change in outcome for this individual because of the treatment?
- Average Causal Effect (ACE): the average causal effect is the average difference in outcomes across the entire population due to the intervention. It provides a measure of the average impact of the treatment on the outcome in the studied population.

The counterfactual model is crucial for establishing causation because it helps isolate the effect of an intervention (pilot) by comparing what actually happened with what would have happened in its absence. However, it is important to note that directly observing the counterfactual outcome for the same individual is often impossible. Statistical methods, study designs like randomized controlled trials, and sophisticated analytical techniques may be used to estimate and infer causal effects within the counterfactual framework. The counterfactual model can still be applied to estimate the causal effects of observational studies, where there is no control over the assignment of treatments or exposures to individuals. While observational studies may face challenges such as unmeasured confounding and selection bias, careful design and analysis can help mitigate these issues and provide valuable insights into causal relationships between variables.

In summary, the counterfactual model provides a structured way to conceptualize and analyze causal relationships, helping researchers navigate the complexities of attributing observed changes to specific interventions or exposures.

EXTENDED ASSESSMENT OF SELECTED PILOTS

The methodological framework for the multidimensional assessment of pilots offers an objective basis for evaluating the outcomes of all pilots. For a subset of pilots (at least one from each work package, WPs 6 to 11), an in-depth evaluation will be conducted by the central team for Task 5.6. This assessment will be based on the same framework but will extend the analysis to consider scaled-up scenarios. Pilots are typically conducted on a small scale to test the feasibility, effectiveness, and challenges of a new intervention, treatment, or healthcare practice. Scaling up refers to expanding these pilots to a broader context or larger scale, often across different settings (e.g., multiple hospitals, regions, or populations), to evaluate their effectiveness in real-world conditions.

To support this, a microsimulation model will be developed to project health outcomes and costs, providing multiple cross-sectional representations of the population over time, even beyond the data collection period. The goal is to capture the key dynamics and interactions between health parameters or risk factors and their impact on both health outcomes and costs.

At the start of the simulation, data from various sources will be integrated, and statistical methods will be used to create plausible equations that reflect population heterogeneity, including factors such as gender, socioeconomic status, and behaviors. Using these equations, the model generates a large sample of synthetic individuals representing the target population, each characterized by a unique health profile. As the simulation progresses, life-course events - such as adopting new behaviors, developing diseases, or death - are simulated, with events competing to occur based on probabilities calculated from individual attributes. This stochastic approach accounts for the inherent unpredictability of life events, allowing for a wide range of possible outcomes.

At the end of the simulation, the model will calculate various metrics that reflect the projected evolution of health outcomes and costs within the population. By modifying the equations, parameters, or initial distributions of individual characteristics, the model allows for testing of different interventions and alternative scenarios.

In the development of the microsimulation tool, the emphasis has been placed on the following attributes:

- **Generic:** it must be possible to use the same framework to test any combination of risk factors, provided that suitable risk factor data exists.
- **Flexible:** starting from the same data, a user must be able to test alternative hypotheses in terms of the causal links between variables.
- **Transparent:** the model displays all the inputs, equations, parameters that are used in the simulation. A user is, therefore, able to check and confirm every step of the simulation.
- **Efficient:** the aim is to minimize the time, processing power and memory needed to run the simulation, once the model code is fully developed and optimized, and a suitable user interface is available.
- **Accessible:** the model's user interface must be intuitive and user-friendly for most users, and at the same time it must offer advanced research users the option of updating and developing the source code in a way that would allow them to address new research questions.

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Appendix 1 Example of QALYs calculation

Suppose to have collected a completed EQ-5D-5L questionnaire from a certain respondent, wherein they have indicated their perceived health state across all dimensions.

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY	
I have no problems in walking about	<input checked="" type="checkbox"/>
I have slight problems in walking about	<input type="checkbox"/>
I have moderate problems in walking about	<input type="checkbox"/>
I have severe problems in walking about	<input type="checkbox"/>
I am unable to walk about	<input type="checkbox"/>
SELF-CARE	
I have no problems washing or dressing myself	<input type="checkbox"/>
I have slight problems washing or dressing myself	<input type="checkbox"/>
I have moderate problems washing or dressing myself	<input checked="" type="checkbox"/>
I have severe problems washing or dressing myself	<input type="checkbox"/>
I am unable to wash or dress myself	<input type="checkbox"/>
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	<input type="checkbox"/>
I have slight problems doing my usual activities	<input checked="" type="checkbox"/>
I have moderate problems doing my usual activities	<input type="checkbox"/>
I have severe problems doing my usual activities	<input type="checkbox"/>
I am unable to do my usual activities	<input type="checkbox"/>
PAIN / DISCOMFORT	
I have no pain or discomfort	<input type="checkbox"/>
I have slight pain or discomfort	<input type="checkbox"/>
I have moderate pain or discomfort	<input type="checkbox"/>
I have severe pain or discomfort	<input type="checkbox"/>
I have extreme pain or discomfort	<input checked="" type="checkbox"/>
ANXIETY / DEPRESSION	
I am not anxious or depressed	<input type="checkbox"/>
I am slightly anxious or depressed	<input type="checkbox"/>
I am moderately anxious or depressed	<input type="checkbox"/>
I am severely anxious or depressed	<input checked="" type="checkbox"/>
I am extremely anxious or depressed	<input type="checkbox"/>

Responses then need to be coded as single-digit numbers expressing the severity level selected in each dimension (from 1=no problems to 5=extreme problems):

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY	
I have no problems in walking about	<input checked="" type="checkbox"/> → 1
I have slight problems in walking about	<input type="checkbox"/>
I have moderate problems in walking about	<input type="checkbox"/>
I have severe problems in walking about	<input type="checkbox"/>
I am unable to walk about	<input type="checkbox"/>
SELF-CARE	
I have no problems washing or dressing myself	<input type="checkbox"/>
I have slight problems washing or dressing myself	<input type="checkbox"/>
I have moderate problems washing or dressing myself	<input checked="" type="checkbox"/> → 3
I have severe problems washing or dressing myself	<input type="checkbox"/>
I am unable to wash or dress myself	<input type="checkbox"/>
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	<input type="checkbox"/>
I have slight problems doing my usual activities	<input checked="" type="checkbox"/> → 2
I have moderate problems doing my usual activities	<input type="checkbox"/>
I have severe problems doing my usual activities	<input type="checkbox"/>
I am unable to do my usual activities	<input type="checkbox"/>
PAIN / DISCOMFORT	
I have no pain or discomfort	<input type="checkbox"/>
I have slight pain or discomfort	<input type="checkbox"/>
I have moderate pain or discomfort	<input type="checkbox"/>
I have severe pain or discomfort	<input type="checkbox"/>
I have extreme pain or discomfort	<input checked="" type="checkbox"/> → 5
ANXIETY / DEPRESSION	
I am not anxious or depressed	<input type="checkbox"/>
I am slightly anxious or depressed	<input type="checkbox"/>
I am moderately anxious or depressed	<input type="checkbox"/>
I am severely anxious or depressed	<input checked="" type="checkbox"/> → 4
I am extremely anxious or depressed	<input type="checkbox"/>

The digits for the five dimensions then need to be combined in a 5-digit code that describes the respondent's health state. In the example above, the health state of the respondent is: 13254.

To obtain the utility value for the overall health state, utility values (weights) need to be attached to each of the levels in each dimension. The index is calculated by deducting the appropriate weights from 1, the value for full health (i.e. state 11111). An example is provided below using utility values for Italy:

Health state: 13254

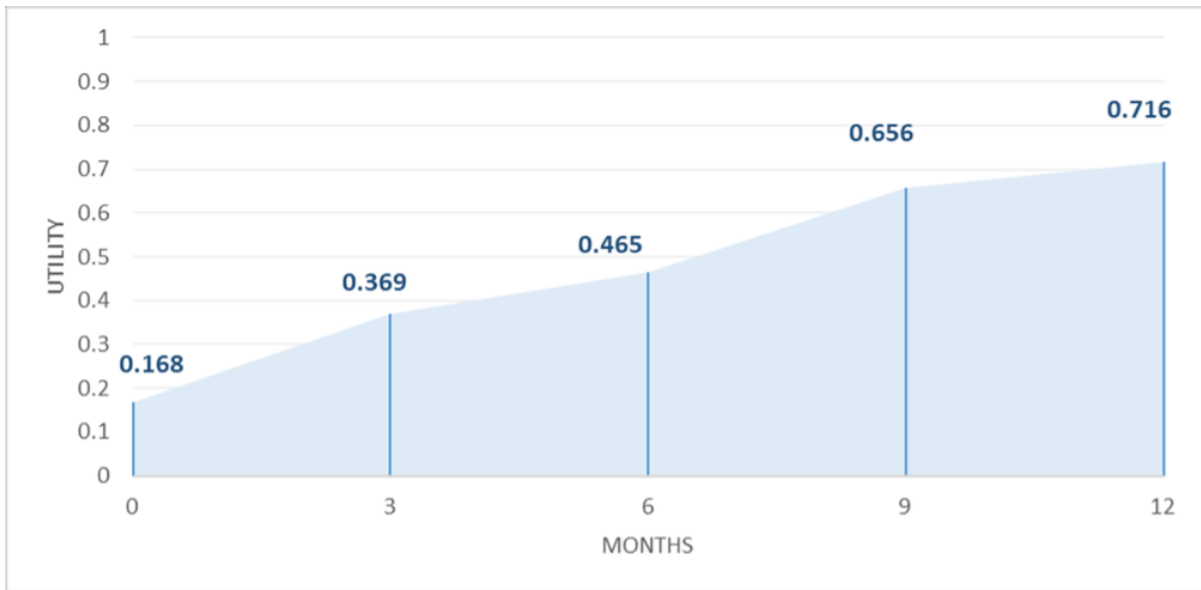
	Disutility due to mobility	Disutility due to self-care	Disutility due to usual activities	Disutility due to pain/discomfort	Disutility due to anxiety/depression
1	0	0	0	0	0
2	0.051	0.046	0.050	0.047	0.044
3	0.064	0.056	0.064	0.088	0.109
4	0.244	0.216	0.225	0.353	0.318
5	0.329	0.257	0.255	0.408	0.322

$$\text{Utility} = 1 - 0 - 0.056 - 0.050 - 0.408 - 0.318 = 0.168$$

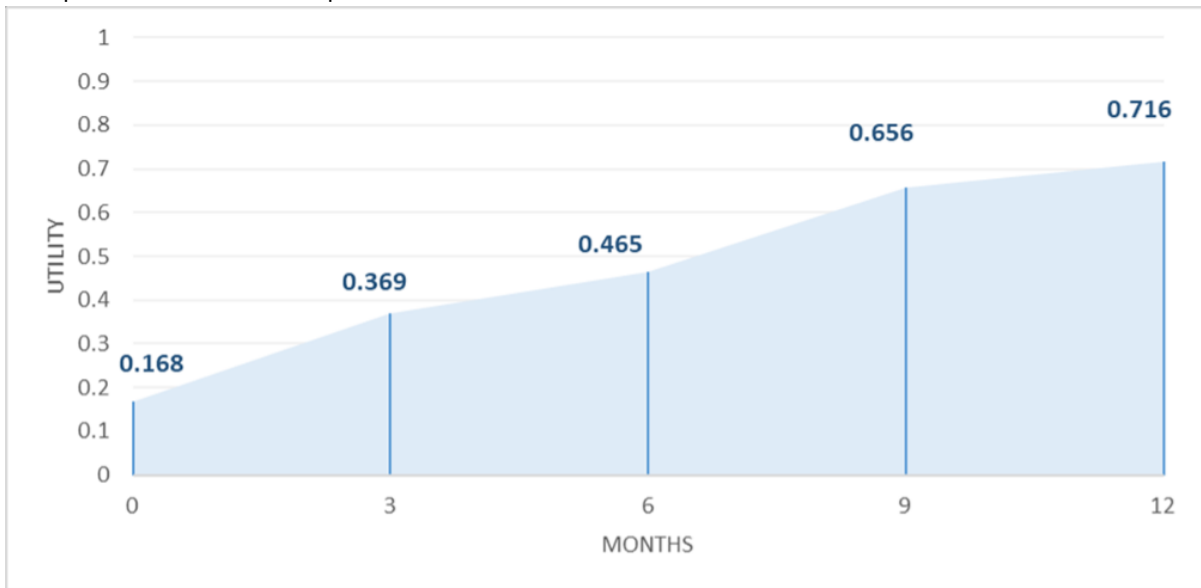
Now suppose that the EQ-5D-5L questionnaire was administered to the same respondent at different time points, for example, every 3 months from baseline to 1 year. Following the steps outlined above, it is possible to estimate the utility associated with each health state at all time points, for example:

Timepoint	Utility values
Baseline	0.168
3 months	0.369
6 months	0.465
9 months	0.656
12 months	0.716

Let's imagine representing the estimated quality of life on a graph, by reporting time on the x-axis and utility values on the y-axis:



By looking at the graph, total QALYs can be calculated by summing the areas of the trapezoids. If the time unit is different from the year, it should be converted to the year (for example, 3 months are equal to 0.25 years). An example of area calculation is provided below:



The total QALYs are therefore computed as follows:

$$\begin{aligned}
 \text{Total QALYS} &= \frac{(0.168+0.369)*0.25 \text{ years}}{2} + \frac{(0.369+0.465)*0.25 \text{ years}}{2} \\
 &+ \frac{(0.465+0.656)*0.25 \text{ years}}{2} + \frac{(0.656+0.716)*0.25 \text{ years}}{2} \\
 &= 0.483 \text{ QALYS}
 \end{aligned}$$

Annex V Appendix B

Brief description of methodological framework for multidimensional assessment of pilots

INTRODUCTION

The objective of this document is to define a framework to assess the outcomes of pilots undertaken in Work Packages (WP) 6 to 11. This is a brief version of the Detailed description of methodological framework for multidimensional assessment of pilots.

The framework provides an objective basis for evaluating the outcomes of pilots. These assessments should determine the effects of the interventions under investigation in each pilot on the identified outcome dimensions. The flowchart below presents the roadmap to perform the assessment.

All pilots will be assessed. For a subset of pilot projects, comprising at least one project from each of the technical WP6-11, the assessment will be undertaken by the core team for Task 5.6 (Bocconi University, Milan, Italy; Imperial College, London, UK), in collaboration with the relevant pilot teams, and will involve in-depth and long-term analyses. The other pilots will be evaluated by the pilot teams themselves. All six dimensions of the framework should be assessed by each pilot except when any of the dimensions is either not relevant or not measurable. In this case, the pilot core team should explain why the assessment was not done. WP6-11 leaders may use the present framework as a reference to find detailed specifications on the pilots' assessment activities. WP6-11 leaders and pilots will be able to benefit from the methodological support and guidance of the 5.6 core team, that can assist the relevant partners in conducting independent analyses on multidimensional health and economic evaluations based on the collected data.

More detailed guidance on each step of the flowchart is available further in this document.

ASSESSMENT OF EFFECTS OF THE INTERVENTIONS

The counterfactual model is a conceptual framework used in the study of causal effects. The counterfactual represents what would have happened (the counterfactual outcome) to each participant if they had received the alternative treatment instead of the one they were assigned to (the observed outcome). The key idea is to create a hypothetical scenario where the individual or group in question did not experience the treatment, intervention, or exposure being studied in the specific pilot. The essential components of the counterfactual model are the following:

- Counterfactual outcome (Y0): this represents the outcome that would have occurred in the absence of the intervention or exposure (e.g., in case of alternative treatment).

- Observed outcome (Y1): this is the actual outcome that occurred when the intervention or exposure was present.

- Causal effect (ΔY): the causal effect is the difference between the counterfactual outcome (Y0) and the observed outcome (Y1). Mathematically, $\Delta Y = Y1 - Y0$. It can be individual-level and Average Causal Effect (ACE).

The assessment of the outcomes of pilots should ideally be made in a causal inference framework. This refers to the process of determining whether an observed association truly indicates a cause-and-effect relationship. For each pilot, the assessment should evaluate the causal effect of the intervention/program under investigation on at least one of the proposed outcomes (effectiveness - including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability - including scalability/transferability, and additional implementation and process outcomes).

The counterfactual model is crucial for establishing causation because it helps isolate the effect of an intervention (pilot) by comparing what actually happened with what would have happened in its absence. However, it is important to note that directly observing the counterfactual outcome for the same individual is often impossible. Statistical methods, study designs like randomized controlled trials, and sophisticated analytical techniques may be used to estimate and infer causal effects within the counterfactual framework.

PILOT DESIGNS

A pilot design refers to the framework or plan that researchers use to conduct the investigation. It outlines the structure, methods, and procedures that will be employed to collect and analyze data in order to answer the research-specific question. Several study designs are commonly used to assess causality. Each study design has its strengths and limitations, and the choice should depend on factors such as the research question, available resources, and ethical considerations.

The assessment of the outcomes of pilots should ideally be made in a causal inference framework. This refers to the process of determining whether an observed association reflects a cause-and-effect relationship. For each pilot, the assessment should investigate the effect of the intervention/program under investigation on the proposed outcomes (effectiveness - including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability - including scalability - and additional implementation and process outcomes).

Randomized controlled trials (RCTs) are generally viewed as the gold standard approach in assessing the effects of treatment, program, or exposure [Jacob 2016]. Nevertheless, carrying out an RCT might be impractical for various reasons, such as lack of essential financial or time resources, or when dealing with an exposure or hypothesis that cannot be applied or altered for trial participants due to ethical concerns. When the experimental RCT design is not possible or practical or adequate, causal inference can still be achieved with an observational study design. It's important to note that observational studies may have limitations, such as potential endogeneity and confounding, that can impact the ability to establish causation compared to RCTs.

Randomized controlled trials (RCTs)

Randomized controlled trials (RCTs) are characterized by the random assignment of study participants to intervention and control groups. Organizational (rather than clinical)

interventions, that are piloted by JACARDI, may not fit the strict requirements of an RCT. More details can be found in the full version of the methodology document (page 17).

Observational studies

When the experimental RCT design is not possible or practical or adequate, causal inference can still be achieved with an observational study design. In observational studies, researchers observe and analyze subjects in their natural settings without randomly assigning treatments, which are instead prescribed according to clinical practice. It's important to note that observational studies may have limitations, such as potential endogeneity and confounding, that can impact the ability to establish causation compared to RCTs. Examples of such study designs include:

- Difference-in-Differences (DiD) design. More details can be found in the full version of the methodology document (page 17).
- Regression discontinuity design (RDD). More details can be found in the full version of the methodology document (page 18).
- Instrumental variables analysis. More details can be found in the full version of the methodology document (page 18).

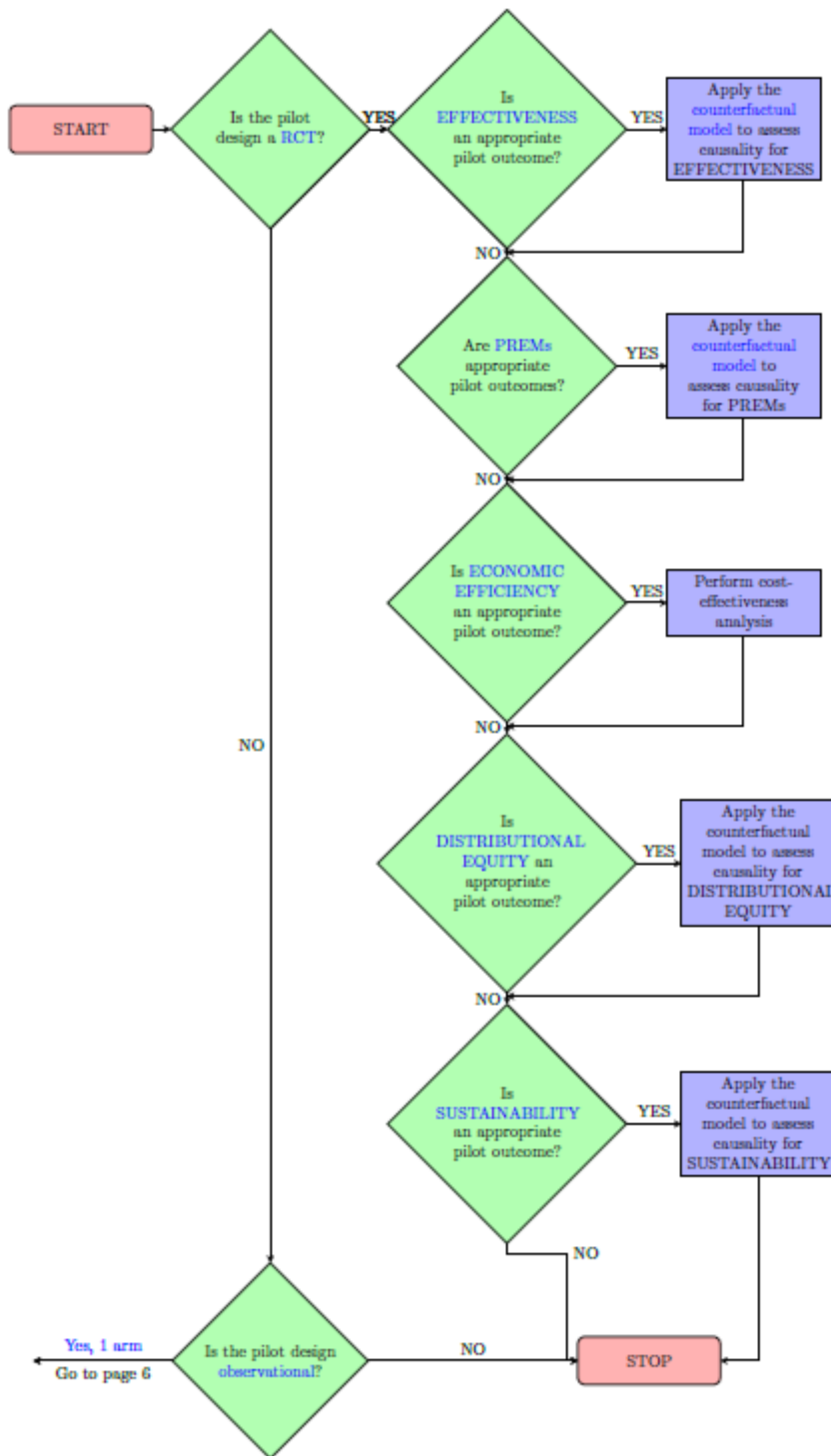
Note: the outcomes collected during a one-arm study should be compared to outcomes of standard of care (ideally standard of care data should be retrieved from administrative data or registries but may also be retrieved from published studies). Then the evaluation is the same as for a two-arms study.

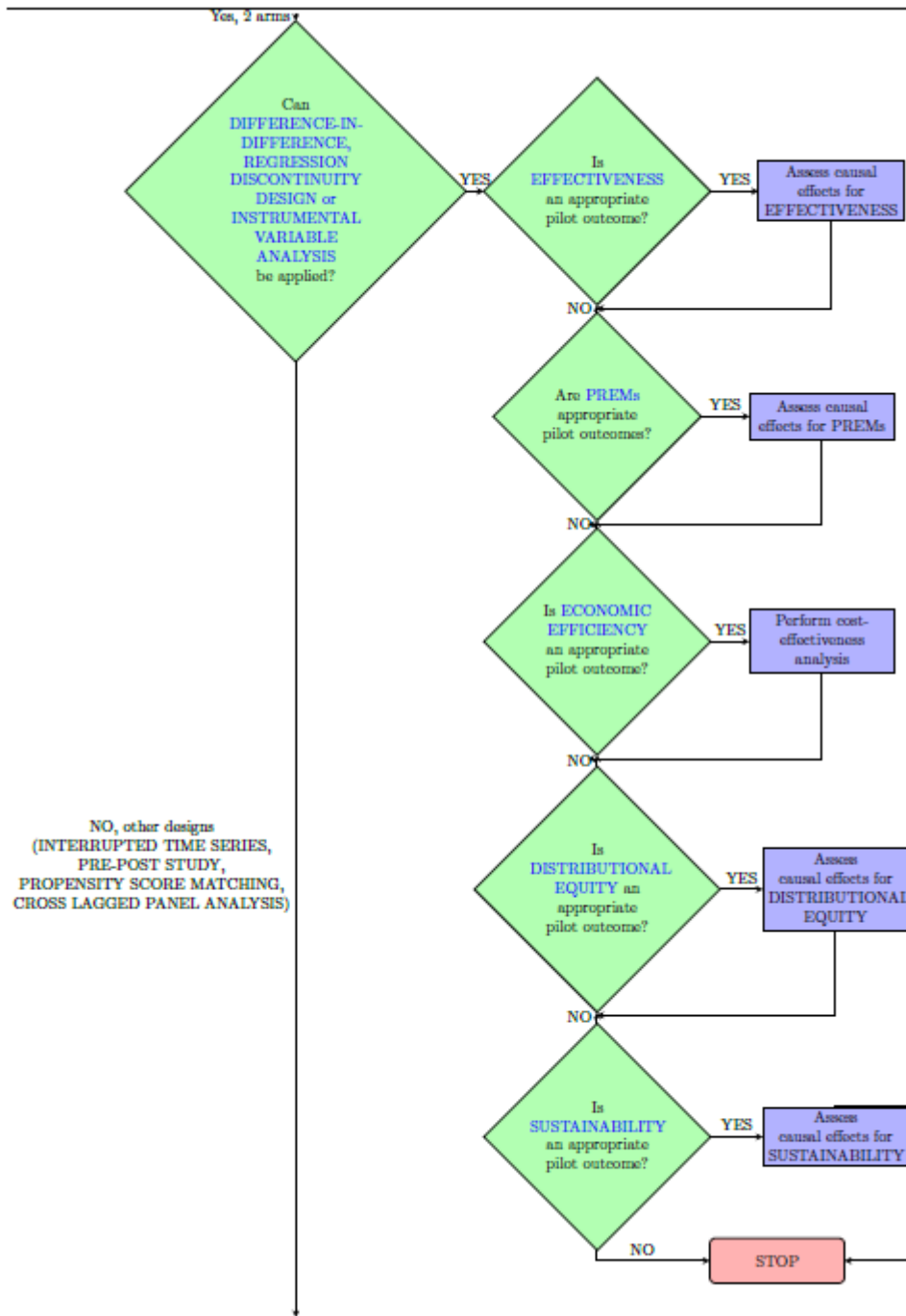
Other observational study designs

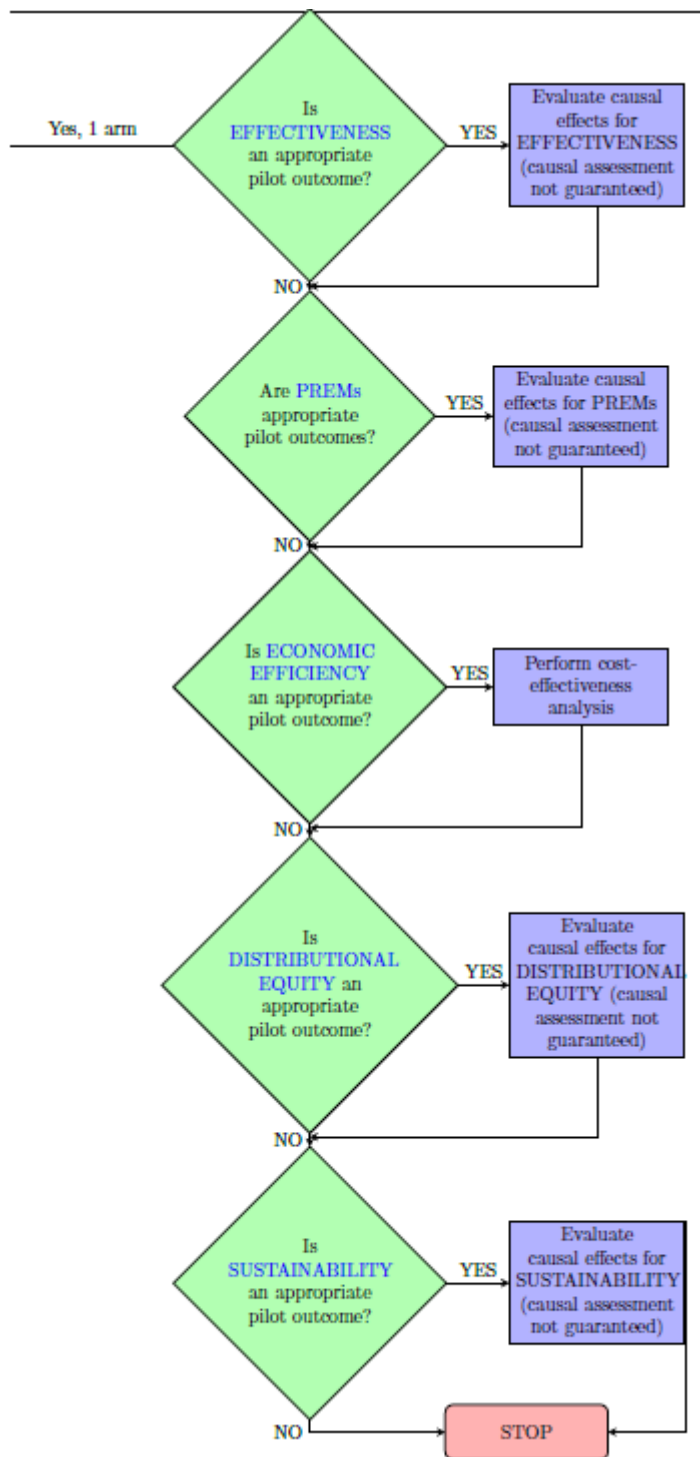
Other observational study designs may be applied if none of the above can be used, but generally, they do not guarantee a causal assessment. These are:

- Pre-post design (including Interrupted time series (ITS) design). More details can be found in the full version of the methodology document (page 18).
- Non-randomized designs with control groups. More details can be found in the full version of the methodology document (page 19).
- Propensity score matching. More details can be found in the full version of the methodology document (page 19).
- Cross-lagged panel analysis. More details can be found in the full version of the methodology document (page 19).

FLOWCHART







DEFINITION OF OUTCOMES

The performance of the pilots will be evaluated through a multi-dimensional health and economic assessment. The following outcomes should be considered:

EFFECTIVENESS

Effectiveness should be intended with a broad meaning, considering the possible effects of the pilot intervention on relevant health outcomes, including both clinical and patient-reported outcomes.

The first step is to clearly articulate the goals and objectives of the pilot and to specify the intended health outcomes, such as improved health status, improved functioning, reduced disease prevalence, or enhanced well-being.

The second step is to identify and define specific and measurable indicators that can be used to assess the intended health outcomes. These indicators should be quantifiable and aligned with the pilot objectives.

The third step is to implement a robust data collection strategy to gather information on the identified indicators. A combination of quantitative and qualitative methods, such as surveys, interviews, focus groups, and health metrics may be used.

More details can be found in the full version of the methodology document (page 3).

Patient-reported outcomes

Patient-reported outcomes (PROs) is a broad term that includes direct subjective assessment by the patient of elements of their health, including symptoms, health-related quality of life, and functional status. Patient-reported outcome measures (PROMs) are standardized questionnaires administered directly to patients that allow to collect information on PROs. To ensure greater confidence in the value of PRO data, it is always advisable to choose a PROM that has undergone psychometric validation in the intended language of use.

PROMs are categorized into two main types: condition-specific and generic. The latter focuses on health concepts applicable to a diverse range of patient groups, allowing for aggregation and comparisons across different conditions and settings. Condition-specific and generic PROMs are both important for understanding and improving patient care at multiple levels of the healthcare system. Several examples of PROMs can be found in the full version of the methodology document (page 4).

PROMs are often measured at specific points in a patient's healthcare journey to assess the impact of a health condition or treatment from the patient's perspective. The timing of PROM measurements can vary based on the nature of the condition, treatment plan, and research objectives. The common points when PROMs may be measured are at baseline, post-treatment/post-intervention, at discharge/transition points, and at follow-up appointments.

More details can be found in the full version of the methodology document (page 6).

PATIENT EXPERIENCES

Patients' or caregivers' experiences can be assessed with patient-reported experience measures (PREMs). Patient experiences - the extent to which the pilot intervention will influence patient and/or caregiver experiences and/or caregiver experiences as assessed with patient-reported experience measures (PREMs). These are instruments designed to capture and assess patients' perceptions, experiences, and interactions with health and social care systems and services. Not all pilots will be designed to have an impact on patient journeys through the health care system and may lead to meaningful and measurable changes in patient experiences. However, the concept of measuring the subjective experience of those who are targeted by a pilot intervention can be extended to relevant populations, not necessarily involving patients. PREMs are typically implemented in the form of surveys, questionnaires, or interviews.

PREMs can be either relational or functional. Relational PREMs focus on the patient's experience of their relationships during treatment (for example, whether they perceived that the healthcare professionals fully understood their concerns). Functional PREMs examine more practical issues, such as patients' perceptions of the facilities available.

PREMs are typically measured at various points throughout a patient's interaction with the health or social care system. They can be measured during care provision, at the end of a treatment/intervention or after a significant event, at discharge or transition points, and at follow-up appointments.

More details can be found in the full version of the methodology document (page 6).

ECONOMIC EFFICIENCY

Measuring economic efficiency involves evaluating how well resources are allocated to produce (healthcare) services, aiming to achieve the maximum possible output with the least input.

In general, both (health) outcomes (or any relevant intermediate proxy measures, when health outcomes cannot be observed in the pilot) and resource costs, are necessary to perform the assessment. Common analyses include cost-effectiveness, cost-utility, or cost-benefit analyses.

The data collection on resource utilization must be aligned with ethical standards, including patient privacy and confidentiality. For pilots involving participants actively, obtaining informed consent from them regarding the use of their healthcare data for the scope of the pilots is a mandatory step.

More details can be found in the full version of the methodology document (page 8).

Measuring the use of health and social care resources

Measuring the use of healthcare resources during a pilot involves tracking and analyzing various aspects of resource utilization. This information is crucial for assessing the cost-effectiveness and economic impact of a new treatment or intervention.

The first step is to clearly define a list of the (healthcare) resources that will be considered in the study. This can include hospital admissions, outpatient visits, laboratory tests, medications, procedures, and any other relevant services.

Healthcare resource use should be gathered at the patient or individual level. This may involve reviewing medical records, conducting interviews, or using patient diaries to capture healthcare encounters, treatments, and services.

If a pilot intervention is expected to have an impact on costs that is not limited to the third payer perspective (e.g., national health service, health insurance funds, etc.) but is spread over a variety of stakeholders (e.g., patients and their families, employers, society), data on the consumption of non-healthcare resources may also be collected. These resources may encompass for instance travel, accommodation, and formal and informal care.

More details can be found in the full version of the methodology document (page 9).

Monetary quantification

This phase is related to the assignment of costs to each (healthcare) resource used during a pilot. This may involve obtaining cost information from (healthcare) providers, payer databases, or using standardized cost estimates.

More details can be found in the full version of the methodology document (page 10).

Cost-Effectiveness Analysis (CEA)

In a cost-effectiveness analysis, the costs associated with the implementation of an intervention are compared to the outcomes or benefits it produces. These outcomes are typically measured in terms of a specific unit relevant to the intervention's objectives, such as life-years gained, quality-adjusted life years (QALYs), or units of disease prevented.

More details can be found in the full version of the methodology document (page 10).

EQUITY AND DIVERSITY (WHO BENEFITS FROM THE INTERVENTION?)

Equity refers to a desirable, or aspirational, distribution of opportunities, resources, or outcomes among individuals and population groups, according to a given set of values or principles. "Diversity" refers to the presence of different characteristics or social dimensions within a group, organization, or community, such as age, gender, race, ethnicity, sexual orientation, socioeconomic status, physical and cognitive abilities, religious beliefs, and cultural background.

The focus will be on identifying and measuring inequalities and diversity in those who are exposed to, and those who benefit from, the interventions deployed in each pilot. This will lead to an assessment of whether, and to what extent, the intervention is likely to mitigate, or exacerbate, existing inequalities in CVD and DM outcomes among individuals and relevant population groups.

The focus of this methodological framework will be on identifying and measuring inequalities and diversity in those who are exposed to, and those who benefit from, the interventions deployed in each pilot. This will lead to an assessment of whether, and to what extent, the intervention is likely to mitigate, or exacerbate, existing inequalities in CVD and DM outcomes among individuals and relevant population groups.

More details can be found in the full version of the methodology document (page 12).

SUSTAINABILITY

Sustainability in JACARDI is defined as the ability of JACARDI to ensure and sustain project impact after EU funding ends. The multidimensional assessment framework allows pilots to evaluate the sustainability of resources and capabilities that refer to further exploitation of the pilot results after the end of JACARDI.

This can be done using the results of the multidimensional assessment dimensions presented in the document before (budget, funding sources, cost-effectiveness) and the various strategic planning techniques, for example, SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis.

More details can be found in the full version of the methodology document (page 13).

Scalability/transferability

Assessing the scalability of a pilot involves evaluating its potential for expansion and replication to reach a larger population or be implemented in different settings. Guidance on how to assess the scalability of the pilot project can be found in the full version of the document.

Assessing the scalability of a pilot is best done at strategic points throughout its lifecycle, typically before, during, and after implementation.

More details can be found in the full version of the methodology document (page 14).

ADDITIONAL IMPLEMENTATION OUTCOMES AND PROCESS INDICATORS

Implementation outcomes aim at measuring the success or failure of implementation.

Process indicators might be measured for interventions that are expected to have significant implications not only for the individuals they target but also at the organizational levels.

More details can be found in the full version of the methodology document (page 15).

EXTENDED ASSESSMENT OF SELECTED PILOTS

The methodological framework for the multidimensional assessment of pilots offers an objective basis for evaluating the outcomes of all pilots. For a subset of pilots (at least one from each work package, WPs 6 to 11), an in-depth evaluation will be conducted by the central team for Task 5.6. This assessment will be based on the same framework but will extend the analysis to consider scaled-up scenarios.

To support this, a microsimulation model will be developed to project health outcomes and costs, providing multiple cross-sectional representations of the population over time, even beyond the data collection period. The goal is to capture the key dynamics and interactions between health parameters or risk factors and their impact on both health outcomes and costs. More details can be found in the full version of the methodology document (page 24, “EXTENDED ASSESSMENT OF SELECTED PILOTS”).

Annex V Appendix C

Detailed description of methodological framework for multidimensional assessment of pilots

Introduction

The objective of this document is to define a framework to assess the outcomes of pilots undertaken in Work Packages (WP) 6 to 11. This assessment framework applies to activities under Task 5.6.

The framework provides an objective basis for evaluating the outcomes of pilots. These assessments should determine the effects of the interventions under investigation in each pilot on the identified outcome dimensions.

All pilots will be assessed. For a subset of pilot projects, comprising at least one project from each of the technical WP6-11, the assessment will be undertaken by the core team for Task 5.6 (Bocconi University, Milan, Italy; Imperial College, London, UK), in collaboration with the relevant pilot teams, and will involve in-depth and long-term analyses.

The other pilots will be evaluated by the pilot teams themselves. All six dimensions of the framework should be assessed by each pilot except when any of the dimensions is either not relevant or not measurable. In this case, the pilot core team should explain why the assessment was not done. WP6-11 leaders may use the present framework as a reference to find detailed specifications on the pilots' assessment activities. WP6-11 leaders and pilots will be able to benefit from the methodological support and guidance of the 5.6 core team, that can assist the relevant partners in conducting independent analyses on multidimensional health and economic evaluations based on the collected data.

Assessment plans and procedures are reflected in JACARDI's Data Management Plan. In short, each partner implementing a pilot project has to act as an independent data controller. The personal data collected for each pilot action should be processed for the respective purposes within JACARDI at the local level. Each partner conducting a pilot project should share an aggregated, anonymized data set with the Coordination Team (WP1), WP5 members, and leaders and co-leaders of other WPs. Each partner acting as a data controller, pursuant to the GDPR, is fully responsible for the processing of personal data, from collection to storage and subsequent deletion.

Purpose

The definition of an assessment framework can help standardize the assessment process to ensure that consistent criteria are applied across the different pilots. This is crucial in assessment activities, where subjective judgments can introduce bias. Objective evaluation criteria help ensure a more rigorous and reliable assessment. In case pilots are conducted to assess the feasibility of larger-scale projects, the assessment framework helps pilot teams systematically evaluate the feasibility aspects, such as resource requirements, potential challenges, and scalability. The framework facilitates clear communication between pilot teams, stakeholders, and implementers (e.g., clinicians). Transparent

criteria and evaluation processes make it easier for others to understand how pilot study outcomes are assessed, fostering trust and accountability.

Finally, the framework will ensure the collection of complete high-quality quantitative and qualitative data to allow the multidimensional assessment of a wide range of pilot outcomes within and across countries.

In summary, the purpose of developing an assessment framework is to bring structure, objectivity, and consistency to the evaluation of pilots' outcomes, ultimately contributing to the improvement of activities/practices and the advancement of knowledge in a particular field.

Structure of the framework

The framework provides detailed guidance on several methodological aspects of the assessment of pilots, as outlined in the following sections:

- definition of outcomes: this section clarifies the conceptual definition of outcomes to be measured in the pilot studies. For each relevant outcome dimension, guidance is provided on the appropriate measures/indicators, tools and timing for data collection, along with related ethical considerations. Additionally, recommendations for data analysis are provided.
- pilot assessment design: this section outlines the possible study designs that can be used by pilots in order to assess the effect of the intervention. Additionally, it describes how to establish causation by using the counterfactual model.
- extended assessment of selected pilots: a number of selected pilots (at least one for each WP6 – 11) will work with Task 5.6 to develop an in-depth assessment. This activity is expected to be beneficial for pilots as they will have close support during the pilot implementation to define and execute data collection and assessment.

Definition of outcomes

The performance of the pilots will be evaluated through a multidimensional assessment. The following outcomes should be considered:

- o Effectiveness, which may include patient-reported outcomes: the extent to which the piloted intervention affects health outcomes and/or patient-reported outcomes as assessed with patient-reported outcome measures – PROMs.
- o Patient experiences: the extent to which the pilot intervention influences patient and/or caregiver experiences as assessed with patient-reported experience measures – PREMs.
- o Economic efficiency: whether the piloted intervention provides “value for money”, i.e. represents a good use of scarce health and social care resources, relative to other potential uses.
- o Equity and diversity: the extent to which the piloted intervention generates a desirable, or aspirational, distribution of opportunities, resources, or outcomes among individuals and population groups (equity), and includes different characteristics or social dimensions within a group, organization, or community (diversity).
- o Sustainability, including scalability: whether the piloted intervention can be continued over a longer period of time after the pilot phase (sustainability), and findings from the interventions are being/have been transferred into changes in policies on local, regional, and national levels (scalability).
- o Additional implementation outcomes and process indicators: the extent to which implementation of an intervention is being or has been successfully achieved (implementation outcomes); intervention's activities and outputs (process indicators).

Even though every pilot is expected to assess each dimension, not all outcomes outlined above may be relevant for or applicable to every pilot. In this case, the pilot should provide justification why the dimension is not relevant.

EFFECTIVENESS

The concept of effectiveness should be intended with a broad meaning, considering the possible effects of the pilot intervention on relevant health outcomes, including both clinical and patient-reported outcomes [Walton et al, 2015].

The first step is to clearly articulate the goals and objectives of the pilot and to specify the intended health outcomes, such as improved health status, improved functioning, reduced disease prevalence, or enhanced well-being.

The second step is to identify and define specific and measurable indicators that can be used to assess the intended health outcomes. These indicators should be quantifiable and aligned with the pilot objectives.

The third step is to implement a robust data collection strategy to gather information on the identified indicators. A combination of quantitative and qualitative methods, such as surveys, interviews, focus groups, and health metrics may be used. A baseline assessment before the pilot implementation to establish a starting point for the identified indicators is recommended to assess outcome changes over time.

The selection of appropriate effectiveness outcomes can be informed by the resources available on the COMET (Core Outcome Measures in Effectiveness Trials) Initiative website (<https://www.comet-initiative.org/>). This multi-stakeholder initiative aims to develop and continuously update agreed standardized sets of outcomes, known as core outcome sets (COS), for different health conditions. A COS represents the minimum that should be measured and reported in clinical trials of a specific condition, but each COS is intended to be suitable also for use in routine care, clinical audit, and research other than randomized trials.

The direct and indirect effects of the pilot on health outcomes should be assessed. While the measurement of direct effects on health outcomes may be straightforward (e.g., the occurrence of major cardiovascular events), the assessment of indirect effects may be more complex. Indirect effects encompass outcomes that still address the core question “Does the intervention work?” but involve a broader definition of Effectiveness. In instances where the specific nature of the pilot or the short timeframe of the JACARDI project precludes the direct measurement of health outcomes, the assessment of indirect effects is recommended to demonstrate the pilot’s effectiveness. In such cases, pilots should provide evidence of a well-established relationship between the measured outcome (e.g., patient empowerment) and the final health outcome (e.g., occurrence of major cardiovascular events).

Pilots on cardiovascular diseases and diabetes can have indirect effects on health outcomes through various mechanisms. For example, pilots may involve the implementation of novel healthcare delivery models or interventions aimed at improving access to healthcare services for individuals at risk of or living with CVD/diabetes. By increasing access to preventive care, early detection, and treatment, these interventions can lead to better management of CVD/diabetes and related health outcomes. Another example relates to pilots involving the education of participants about CVD/diabetes risk factors, prevention strategies, and lifestyle modifications. This increased awareness can lead to healthier behaviors and better management of risk factors such as smoking cessation, improved diet, and increased physical activity, ultimately contributing to improved health outcomes.

Additionally, some pilots may be interested in measuring the impact of an intervention on the health literacy of individuals, including patients and other relevant stakeholders (e.g., employers). Health literacy is a multidimensional concept that encompasses an individual’s knowledge and confidence in accessing, understanding, appraising, and using information about health and healthcare. Over the years, several self-administered questionnaires have been developed to facilitate the measurement of this multidimensional concept, with some examples provided below:

- European Health Literacy Survey Questionnaire (HLS-EU-Q)

(<https://doi.org/10.1186/1471-2458-13-948>)

- Health Literacy Questionnaire (HLQ) (<https://doi.org/10.1186/1471-2458-13-658>)

Some pilots may envisage interventions aimed at enhancing knowledge of and awareness about CVDs and diabetes, targeting both patients and the general population. To assess the impact of these interventions on public knowledge and awareness, data might be collected before and after the intervention through surveys, interviews, and/or focus groups. If the outcome of interest is disease knowledge, disease-specific questionnaires designed for self-administration might be used, such as:

- Revised Diabetes Knowledge Scale (<https://doi.org/10.1111/j.1464-5491.2010.03190.x>)
- Heart Disease Knowledge Questionnaire (<https://doi.org/10.1080/19325037.2011.10599175>)

Some pilots may aim to modify patients' health behaviors by enhancing their self-management skills. Some questionnaires may be used to assess changes in self-care activities and perceived self-efficacy, for example:

- Diabetes Self-Management Questionnaire (<https://doi.org/10.1186/1477-7525-11-138>)
- Diabetes Management Self-Efficacy Scale (<https://doi.org/10.1046/j.1365-2648.1999.01077.x>)
- European Heart Failure Self-care Behavior Scale ([https://doi.org/10.1016/S1388-9842\(02\)00253-2](https://doi.org/10.1016/S1388-9842(02)00253-2))
- Hypertension Self-Care Questionnaire (<https://doi.org/10.22122/arya.v15i5.1835>)

Patient-reported outcomes

Patient-reported outcomes (PROs) is a broad term that includes direct subjective assessment by the patient of elements of their health, including symptoms, health-related quality of life, and functional status [Rothman et al, 2007]. Patient-reported outcome measures (PROMs) are standardized questionnaires administered directly to patients that allow to collect information on PROs [Churruca et al, 2021].

Initially designed for research purposes, particularly in clinical trials evaluating treatment effectiveness, PROMs have evolved to encompass various applications. These include supporting decision-making in healthcare, prioritizing patients for surgical procedures, comparing outcomes across healthcare providers, fostering quality improvement, and evaluating the effectiveness of certain interventions and policies.

PROMs are categorized into two main types: condition-specific and generic. The latter focuses on health concepts applicable to a diverse range of patient groups, allowing for aggregation and comparisons across different conditions and settings. Generic PROMs allow to measure a broad spectrum of impacts (either intended or unintended) on patients' perceived health and quality of life, extending beyond the specific condition being studied (e.g., cardiovascular disease or diabetes). An illustration of a generic PROM is the EQ-5D-5L, developed by the EuroQol Group (<https://euroqol.org/information-and-support/euroqol-instruments/>). This instrument consists of five questions on the patient's health on a given day, covering aspects such as mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each aspect/dimension, it is possible to express the indication on 5 response levels. The second section includes a visual-analog scale graphically represented as a graduated thermometer from 0 (worst possible health status) to 100 (best possible health status) on which the patient indicates the perceived level of health. An algorithm allows the calculation of a final score (utility coefficient u , between 0 and 1) based on the attribution of weights for each questionnaire answer. The higher the score, the better the health.

Condition-specific PROMs capture elements of health relevant to a particular condition. For example, different PROMs may be used in the context of Cardiovascular Diseases (CVDs):

1. Seattle Angina Questionnaire (SAQ) (<https://pubmed.ncbi.nlm.nih.gov/7829785/>): this PROM assesses the impact of angina on patients' daily lives, including physical limitations, angina stability, and treatment satisfaction. this PROM assesses the impact of angina on patients' daily lives, including physical limitations, angina stability, and treatment satisfaction.
2. Minnesota Living with Heart Failure Questionnaire (MLHFQ) (<https://license.umn.edu/product/minnesota-living-with-heart-failure-questionnaire-mlhfq>): focused on heart failure, this PROM evaluates the impact of heart failure symptoms on a patient's quality of life, covering aspects like physical, emotional, and social well-being.
3. Peripheral Artery Questionnaire (PAQ) (<https://pubmed.ncbi.nlm.nih.gov/14760329/>): designed for patients with peripheral arterial disease, this PROM assesses the impact of leg symptoms on daily life and activities.

Or for patients with diabetes:

1. Diabetes Impact Measurement Scales (DIMS) (<https://eprovide.mapi-trust.org/instruments/diabetes-impact-measurement-scales>): designed to measure the impact of diabetes on various aspects of a patient's life, including physical health, psychological well-being, and social function.
2. Audit of Diabetes-Dependent Quality of Life (ADDQoL) (<https://healthpsychologyresearch.com/guidelines/addqol19-audit-diabetes-dependent-quality-life-0/>): specifically focused on diabetes, this PROM evaluates the impact of diabetes on a patient's quality of life, considering various domains such as living conditions, family life, and relationships.
3. Diabetes Treatment Satisfaction Questionnaire (DTSQ) (<https://healthpsychologyresearch.com/guidelines/dtsq-diabetes-treatment-satisfaction-questionnaire/>): this PROM assesses patient satisfaction with their diabetes treatment regimen, including aspects like perceived hyperglycemia and hypoglycemia, the convenience of treatment, and flexibility in daily life.

These are just a few examples since there are many PROMs developed and used in the assessment of PROs in the context of CVDs and diabetes. The choice of a specific PROM depends on the research or health objectives, the population under consideration, and the aspects of health and well-being that researchers or healthcare providers aim to measure.

Condition-specific and generic PROMs are both important for understanding and improving patient care at multiple levels of the healthcare system. In general, generic measures are needed when evaluating the allocative efficiency of used resources in health care.

The International Consortium for Health Outcomes Measurement (ICHOM) has defined Standard Sets of outcome measures for various medical conditions and patient populations (<https://www.ichom.org/>). They typically include a core set of patient-reported outcomes, clinical outcomes, and other relevant measures that are agreed upon by international experts in the field. ICHOM collaborates with a wide range of stakeholders, including healthcare providers, patient advocacy groups, researchers, policymakers, and industry partners, to develop and implement Standard Sets in clinical practice. The organization also provides resources, tools, and support to healthcare organizations for the implementation of standard sets.

To ensure greater confidence in the value of PRO data, it is always advisable to choose a PROM that has undergone psychometric validation [Churruca et al, 2021] in the intended language of use. The necessary psychometric properties of a PROM include reliability (i.e., the extent to which an instrument yields the same number or score each time it is administered when the construct being measured has not changed), validity (extent to which an instrument measures what it was intended to measure), and responsiveness (instrument's ability to detect clinically meaningful change over time – or sensitivity to change: ability to detect any degree of change over time) [Frost et al, 2007].

PROMs are often measured at specific points in a patient's healthcare journey to assess the

impact of a health condition or treatment from the patient's perspective. The timing of PROM measurements can vary based on the nature of the condition, treatment plan, and research objectives. In ICHOM standard sets collection time-points are proposed based on expert consensus. Here are common points when PROMs may be measured:

- At baseline: PROMs are often measured at the beginning of a patient's healthcare journey to establish a baseline understanding of their health status before initiating a treatment or intervention. Before the beginning of a new treatment, surgery, or therapeutic intervention, PROMs can be measured to capture the patient's health status and relevant outcomes. This baseline assessment helps in comparing pre- and post-treatment outcomes.
- Post-treatment or post-intervention or after significant events: Following the completion of a treatment or intervention, or after significant health events (such as a relapse, adverse reactions to medication, or the development of new symptoms) PROMs are often measured to provide insights into the patient's experience and guide adjustments to the care plan.
- At discharge or transition points: Measuring PROMs at the point of discharge from a hospital or during transitions of care helps evaluate the patient's health status and any challenges they may face post-discharge.
- At follow-up appointments: PROMs can be integrated into routine clinical visits to gather continuous feedback on the patient's experience and outcomes. This approach facilitates ongoing assessment and adjustment of the treatment plan. For chronic conditions or ongoing treatments, PROMs may be measured at regular intervals during treatment to monitor changes in symptoms, functioning, and overall well-being.

The specific timing of PROM measurements depends on the health context, treatment plan, and research goals. Incorporating PROMs at various points in the patient's healthcare journey provides a comprehensive understanding of the patient's experience and treatment outcomes.

PATIENT EXPERIENCES

Patients' or caregivers' experiences can be assessed with patient-reported experience measures (PREMs) [Jamieson Gilmore et al, 2023]. These are instruments designed to capture and assess patients' perceptions, experiences, and interactions with health and social care systems and services. Not all pilots will be designed to have an impact on patient journeys through the health care system and may lead to meaningful and measurable changes in patient experiences. However, the concept of measuring the subjective experience of those who are targeted by a pilot intervention can be extended to relevant populations, not necessarily involving patients.

PREMs are typically implemented in the form of surveys, questionnaires, or interviews. Patients are asked to provide feedback on specific aspects of their care. They differ from satisfaction surveys, although PREM surveys may incorporate one or more questions soliciting an overall opinion on a patient's experience. These inquiries explore specific aspects, such as whether particular types of information were conveyed during admission or discharge, rather than focusing solely on the patient's satisfaction with the information. This approach helps minimize the impact of patient expectations on survey responses. PREMs seek to record what occurred to patients, from their perspective, rather than their overall evaluation.

PREMs can be either relational or functional. Relational PREMs focus on the patient's experience of their relationships during treatment (for example, whether they perceived that the healthcare professionals fully understood their concerns). Functional PREMs examine more practical issues, such as patients' perceptions of the facilities available.

A varied range of surveys is currently available and actively utilized. Some are designed for application across various settings and demographics. In contrast, others are tailored for specific services, such as emergency departments or primary care, or specific aspects of care, like continuity.

To ensure reliability and validity, PREMs are often psychometrically validated. This means that the survey instruments undergo rigorous testing to ensure they measure what they intend to measure consistently. It is always advisable to use previously validated PREMs in the intended language of use.

The data collected through PREMs are valuable for healthcare providers, organizations, and policymakers. Insights gained from patient-reported experiences can inform quality improvement initiatives and enhance the overall delivery of healthcare services.

In the context of diabetes, two PREMs are mainly used (Martin-Delgado 2021):

- Swedish National Diabetes Register (SNDR) (Hallgren Elfgren 2016)
- National Diabetes Audit (NDA) - Patient Experience of Diabetes Services Survey (<https://www.bjd-abcd.com/index.php/bjd/article/view/229>)

In the context of CVDs, two examples of the assessment of PREMs in patients with chronic heart failure (CHF) are reported in the literature (Lagha 2012). When considering the rehabilitation setting, Nesbitt and colleagues (Nesbitt 2023) published a PREM for the evaluation of patient experience to improve attendance to a cardiac rehabilitation program.

The literature provides also some generic (i.e., not disease-specific) PREMs that can be used for assessing certain aspects of patients' experience:

- Consultation and Relational Empathy (CARE) questionnaire (<https://doi.org/10.1093/fampra/cmh621>; <https://caremeasure.stir.ac.uk/>): this questionnaire measures empathy in the context of the therapeutic relationship during a one-on-one consultation between a clinician and a patient.
- 9-item Shared Decision-Making Questionnaire (SDM-Q-9) (<https://doi.org/10.1016/j.pec.2009.09.034>; http://www.patient-als-partner.de/index.php?article_id=20&clang=2/): this questionnaire measures the extent to which patients are involved in the process of decision-making from the perspective of the patient.
- Questionnaire for Patients' Experiences Across Health Care Sectors (PEACS 1.0) (<https://doi.org/10.1093/intqhc/mzu044>): this questionnaire measures patients' experiences across healthcare sectors with a focus on quality improvement.
- Person-Centred Coordinated Care Experiences Questionnaire (P3CEQ) (<https://doi.org/10.1093/intqhc/mzy212>; <http://p3c.org.uk/prom-detail/29>): this questionnaire addresses important aspects of chronic care.

A systematic review by Bull and colleagues (2019) offers a valuable overview of PREMs, albeit limited to evidence up to 2018. The review categorizes PREMs according to type of individual, condition, setting, and country-specific context, and provides an assessment of their validity and reliability.

PREMs are typically measured at various points throughout a patient's interaction with the health or social care system. The timing of PREM measurements can provide valuable insights into different aspects of the patient's journey. PREMs may be measured:

- During care provision: Patients can be asked to provide feedback on their experiences during or immediately after receiving healthcare services (e.g., doctor's visit, hospital stay or outpatient procedure, treatment). This real-time measurement captures their impressions while the care is still fresh in their minds.
- At the end of a treatment/intervention or after a significant event: Measuring PREMs at the conclusion of a treatment or episode of care provides a comprehensive assessment of the patients' journey. This can include their overall satisfaction, perceptions of the effectiveness of the care received, and suggestions for improvement.
- At discharge or transition points: PREMs can be measured at the point of discharge from a healthcare facility or during transitions of care. This allows for insights into the patient's overall

experience and any challenges faced during the transition to a different phase of care.

- At follow-up appointments: During follow-up appointments, patients can be asked to provide feedback on their experiences since the last visit. This helps in tracking changes in their perceptions and identifying any ongoing issues. For patients undergoing long-term care, periodic measurements of PREMs at regular intervals provide a longitudinal perspective. This approach can reveal changes in the patient's experience over time and assess the impact of ongoing treatments.

The specific timing of PREM measurements depends on the goals of the assessment, the nature of the healthcare services being provided, and the research or quality improvement objectives. Regular, systematic measurement at multiple points can provide a comprehensive understanding of the patient's journey through the healthcare system.

ECONOMIC EFFICIENCY

Measuring economic efficiency involves evaluating how well resources are allocated to produce (healthcare) services, aiming to achieve the maximum possible output with the least input. There are several methods and indicators to assess economic efficiency, and the choice of the approach often depends on the context. In general, both (health) outcomes (or any relevant intermediate proxy measures, when health outcomes cannot be observed in the pilot) and resource costs, are necessary to perform the assessment. Common analyses include cost-effectiveness, cost-utility, or cost-benefit analyses [Drummond 2015, Sanders 2016, Husereau 2022] (see following paragraphs). These approaches evaluate the relationship between costs and (health) outcomes by comparing the pilot intervention/program with the standard of care (e.g., no intervention). These evaluations can be approached from various perspectives, each offering a unique view on costs and benefits. The main perspectives used in economic evaluations include:

- **Healthcare Service perspective:** focuses on the costs and benefits relevant to the health care system or payer; in particular, it considers direct medical costs such as costs for hospitalizations, outpatient visits, medications, and medical devices.
- **Societal perspective:** this is the broadest perspective, considering all costs and benefits to society as a whole, regardless of who incurs the costs or receives the benefits.

The choice of perspective depends on the purpose of the evaluation and the stakeholders involved. The societal perspective is often preferred for comprehensive analyses, as it provides a complete picture of the economic impact. However, specific perspectives like the health care system/payer perspective may be more relevant for the scope of JACARDI as it provides information for decision-makers regarding budgetary impacts and cost-containment strategies. Each perspective offers distinct insights, and sometimes multiple perspectives are used to provide a more rounded analysis.

For the analysis, a time horizon should be defined. Some pilots may assess resource use during the trial period, while others may extend the analysis to post-trial follow-up periods to capture longer-term effects.

It is important to conduct **sensitivity analyses** to assess the impact of uncertainties or variations in resource utilization or cost estimates. Performing sensitivity analysis on a pilot involves examining the impact of variations in key parameters or assumptions on the study outcomes. This helps in understanding the robustness of the results to changes in key parameters. The following steps should be followed to conduct a sensitivity analysis:

1. Identify key parameters: determine the parameters or assumptions that are critical to the pilot outcomes. These could include variables such as sample size, effect size, dropout rates, compliance rates, or other factors that may influence the study results.
2. Define ranges: define plausible ranges for each key parameter. Consider both optimistic and pessimistic scenarios and determine the upper and lower bounds for each parameter based on available data, literature review, expert opinion, or prior experience.

3. Choose the methodology: select the appropriate methodology for conducting sensitivity analysis based on the nature of the study and the parameters involved. Common methods include one-way sensitivity analysis, scenario analysis, and probabilistic sensitivity analysis. The simplest way is to perform a one-way sensitivity analysis; this means that one key parameter is varied within its defined range while keeping all other parameters constant at their baseline values. This involves adjusting the chosen parameter to different values within its range and observing the resulting changes in the considered outcomes.
4. Interpret the results: analyze the results of the sensitivity analysis to understand how variations in key parameters influence the pilot outcomes. Identify which parameters have the greatest impact on the results and assess the sensitivity of the findings to changes in these parameters.
5. Communicate the findings: clearly communicate the findings of the sensitivity analysis, including any uncertainties or limitations identified. Discuss how variations in key parameters may affect the interpretation and generalizability of the study results.
6. Consider implications: consider the implications of the sensitivity analysis findings for the interpretation of pilots' results and future directions. Determine whether adjustments to study design, sample size, or other parameters are warranted based on the sensitivity analysis findings.

Other aspects to be taken into consideration are monitoring and ethical issues. Monitoring and assessing participant compliance with the assigned programs, interventions, or treatments is of utmost importance since non-compliance can impact resource utilization and produce bias in the results.

The data collection on resource utilization must be aligned with ethical standards, including patient privacy and confidentiality. For pilots involving participants actively, obtaining informed consent from them regarding the use of their healthcare data for the scope of the pilots is a mandatory step.

By systematically measuring health and social care resource use during a pilot, pilot teams can gain insights into the economic implications of the intervention, inform healthcare policy decisions, and contribute valuable information to the broader field of health economics.

Measuring the use of health and social care resources

Measuring the use of healthcare resources during a pilot involves tracking and analyzing various aspects of resource utilization. This information is crucial for assessing the cost-effectiveness and economic impact of a new treatment or intervention.

The first step is to clearly define a list of the (healthcare) resources that will be considered in the study. This can include hospital admissions, outpatient visits, laboratory tests, medications, procedures, and any other relevant services. It is useful to specify the units of measurement for each resource (e.g., number of hospital days, number of outpatient visits, dosage of medications).

Healthcare resource use should be gathered at the patient or individual level. This may involve reviewing medical records, conducting interviews, or using patient diaries to capture healthcare encounters, treatments, and services. In general, medical records and administrative databases may provide data on specialist visits, examinations, hospitalizations, emergency room visits, and prescribed medications. Some pilots may also use time diaries to measure the time that healthcare professionals need to provide the pilot. On the other side, patient-reported resource use through surveys or interviews may provide valuable information on over-the-counter medication use, non-prescription treatments, and other healthcare-related expenses.

If a pilot intervention is expected to have an impact on costs that is not limited to the third payer perspective (e.g., national health service, health insurance funds, etc.) but is spread over a variety of stakeholders (e.g., patients and their families, employers, society), data on the consumption of non-healthcare resources may also be collected. These resources may encompass for instance travel, accommodation, and formal and informal care. Furthermore, suppose the intervention is expected to have an impact on patients' productivity, either due to absenteeism or reduced efficiency (presenteeism) during paid or unpaid work. In that case, data on productivity losses may be gathered. To streamline data collection for productivity losses, a validated questionnaire developed by the institute for Medical

Technology Assessment (iMTA) may be used (iMTA Productivity Cost Questionnaire, <https://www.imta.nl/questionnaires/ipcq/>).

Monetary quantification

This phase is related to the assignment of costs to each (healthcare) resource used during a pilot. This may involve obtaining cost information from (healthcare) providers, payer databases, or using standardized cost estimates. Costs can be applied to each unit of resource used. The costs should be assessed for the possible intervention/program itself proposed by the pilot and for the variations in healthcare resource use the intervention/program implies. In detail, monetary quantification should follow these steps:

1. Assign monetary values to each resource based on the gathered cost data and the defined units of measurement. This may involve multiplying the quantity of each resource by its corresponding unit cost to calculate the total monetary value. If the analysis is conducted from the Healthcare Service perspective, the interest is to evaluate the current tariffs that the Healthcare Service uses to compensate hospitals and other healthcare providers for both inpatient and outpatient services. For the inpatient care, the cost of hospital admissions may be estimated through DRG (Diagnosis Related Groups) tariffs (in the Countries where they are available), while for outpatient care, the costs of visits, exams, and other services are obtained from the formulary for outpatient services issued by the Healthcare Service. For Countries in which health insurance schemes are applied, health care services funded by these organizations should be taken into account (more specific documentation can be found at <https://www.ispor.org/heor-resources/more-heor-resources/pharmacoeconomic-guidelines>). For example, the cost of specialist visits may be calculated by multiplying the number of visits performed by the specific visit tariff, while the cost of drugs may be calculated by multiplying the quantity administered by the unit cost per dose. For example, if a pilot aims at implementing a screening through the use of a particular device, the cost of the device must be considered in the assessment.

In case the societal perspective is the one of interest, both costs from the healthcare service perspective and societal costs are considered. Societal costs involve, as described above, productivity losses for absenteeism, presenteeism, premature death, costs of informal care provided by caregivers, out-of-pocket (OOP) costs sustained by the patients for the purchase of healthcare services not covered by the national healthcare service, costs for formal (paid) care, etc.

2. Aggregate the monetary values of all healthcare resources to obtain the total cost of the implementation of the pilot for a given period, setting, or population. This may involve summing the costs of personnel, equipment, facilities, medications, and procedures across all departments, services, or interventions within a (healthcare) system.
3. Analyze and interpret the results: analyze the results of the monetary quantification to understand the distribution of healthcare costs, identify cost drivers, assess cost-effectiveness, and inform decision-making. Interpretation may involve comparing costs across different healthcare settings or interventions, evaluating the affordability of healthcare services, and identifying opportunities for cost-saving or efficiency improvements.

The steps presented here need to be performed also for the assessment of the standard of care to allow comparisons.

Cost-Effectiveness Analysis (CEA)

In a cost-effectiveness analysis, the costs associated with the implementation of an intervention are compared to the outcomes or benefits it produces. These outcomes are typically measured in terms of a specific unit relevant to the intervention's objectives, such as life-years gained, quality-adjusted life years (QALYs), or units of disease prevented [Drummond 2015, Sanders 2016, Husereau 2022]. The more detailed analysis considers QALYs as the measure of health outcomes, anyway if the assessment of QALYs is not possible, life expectancy or other proxies (intermediate outcomes) may be considered. It's important that these proxies are correlated to final outcomes like life expectancy or QALYs. For example, a decrease in blood pressure may be a relevant health outcome for a pilot if it can improve life expectancy and QALYs (the literature should state that).

A QALY is a measure used in healthcare to quantify both the quantity and quality of life lived. It combines the length of time a person lives with their health-related quality of life during that time. Essentially, it measures both the length and the quality of life gained from a program/intervention or health condition.

To calculate QALYs, the following steps should be followed:

1. Assess patient's health states: determine the health states experienced by an individual, which can range from perfect health to death. This assessment is usually carried out through the administration of an EQ-5D-5L questionnaire.
2. Assign utility values (u) to each health state on a scale from 0 to 1. These values represent the preference associated with each health state. Perfect health is typically assigned a value of 1, while death is assigned a value of 0. Other health states are assigned values between 0 and 1 based on perceived quality of life. The EuroQol Group provides many country-specific value sets (i.e., utility value estimates), which can be freely downloaded from its website (<https://euroqol.org/information-and-support/resources/value-sets/>). An example of how to assign utility value to a health state is provided below.
3. Calculate years lived in each health state: determine the number of years a person spends in each health state over a specific period.
4. Multiply utility by years lived: multiply the utility value of each health state by the number of years lived in that state.
5. Sum up: sum up the products obtained from the previous step across all health states to get the total QALYs gained.

This method allows for a standardized measure to compare the impact of different health interventions or conditions on quality of life, facilitating healthcare decision-making and resource allocation. A step-by-step guidance to calculate QALYs is reported in Appendix 1.

A CEA consists of estimating the incremental cost-effectiveness ratio (ICER) that is calculated with the formula:

$$\text{ICER} = \text{incremental cost} / \text{incremental effectiveness}$$

The incremental cost represents the difference in costs between the two interventions under investigation (or intervention vs. no intervention); analogously, the incremental effectiveness represents the difference in effectiveness between the two interventions under investigation (or intervention vs. no intervention/standard of care). Effectiveness is generally expressed as life years (e.g., life expectancy). In case the effectiveness is expressed in QALYs, the analysis is called Cost-Utility Analysis (CUA).

The ICER represents the additional cost incurred to achieve an additional unit of outcome (e.g., additional year of life) with one intervention compared to the other. In general, a lower ICER indicates a better value for money, as it means that the intervention is achieving outcomes at a lower additional cost. The ICER is then compared to a threshold, which represents the willingness to pay for an additional unit of health outcome (or QALY) gained through an intervention. These thresholds are used to determine whether an intervention is considered cost-effective. However, the specific thresholds can vary depending on the context, country, and healthcare system. Here are some commonly cited ICER thresholds:

- o World Health Organization (WHO) threshold: the WHO suggests a threshold of 1 to 3 times the Gross Domestic Product (GDP) per capita for a QALY
- o Country-specific thresholds: many countries have developed their own ICER thresholds based on their healthcare budgets, priorities, and societal values. For example:
 - In the United States, the commonly cited threshold is around 50,000 to 150,000 per QALY gained
 - In the United Kingdom, the National Institute for Health and Care Excellence (NICE) has

historically used a threshold range of £20,000 to £30,000 per QALY gained.

- In Italy applied thresholds are in the range of 25,000-60,000€ [Messori 2004, Fattore 2009]

It's important to note that ICER thresholds can evolve over time based on changes in healthcare priorities, economic conditions, and societal values. Additionally, while ICER thresholds provide a useful framework for evaluating cost-effectiveness, they should be considered alongside other factors such as budget constraints, equity considerations, and the strength of the evidence supporting the intervention's effectiveness.

EQUITY AND DIVERSITY (WHO BENEFITS FROM THE INTERVENTION?)

In JACARDI, “equity” (see also glossary) refers to a desirable, or aspirational, distribution of opportunities, resources, or outcomes among individuals and population groups, according to a given set of values or principles. Conversely, “inequity” relates to a distribution characterized by inequalities between individuals and population groups deemed unjust and avoidable. “Diversity” (see glossary) refers to the presence of different characteristics or social dimensions within a group, organization, or community, such as age, gender, race, ethnicity, sexual orientation, socioeconomic status, physical and cognitive abilities, religious beliefs, and cultural background.

This methodological framework for the assessment of pilot projects will remain neutral to different values and principles that may inform equity judgments. Therefore, the focus will be on identifying and measuring inequalities and diversity in those who are exposed to, and those who benefit from, the interventions deployed in each pilot. This will lead to an assessment of whether, and to what extent, the intervention is likely to mitigate, or exacerbate, existing inequalities in CVD and DM outcomes among individuals and relevant population groups.

The main steps in the equity and diversity dimension of the evaluation are as follows:

- A. **Identify potential equity dimensions.** Relevant dimensions will include those along which significant inequalities already exist that the intervention may help redressing, or those along which the intervention might exacerbate existing inequalities. A non-exhaustive list of potentially relevant dimensions includes the following:
 - a. Age (differences in exposure to the intervention, or benefit from the intervention, for individuals in different age groups);
 - b. Gender and sexual identity;
 - c. Socioeconomic position (SEP) (see glossary), a broad concept covering the factors that produce social stratification within society, such as income or education;
 - d. Place of residence, especially when linked to degrees of social and economic deprivation in different geographical areas;
 - e. Ethnic origin;
 - f. Migrant status;
 - g. Cultural identity;
 - h. Disability status;
 - i. Other vulnerability dimensions.

It would be advisable to also consider intersections of these groups, ex. aged persons with disabilities, ethnic minority pregnant women, low-income elderly people living in rural areas etc., or groups identified within the pilot through the situation analysis.

- B. Determine whether relevant equity dimensions are measurable.** Once relevant equity dimensions are identified, Pilots will have to assess whether the information needed to characterize those exposed to the intervention along the relevant dimensions can be collected (is it feasible? is it ethical? will individuals agree for those characteristics to be collected and reported?).
- C. Identify appropriate exposure and outcome measures for the equity assessment.** Not all of the exposure (participation) and outcome measures used in a Pilot would need to be assessed through an equity and diversity lens. Each Pilot will select one or more that are especially important. For exposure, Pilots may wish to use indicators of actual participation (did someone participate in the intervention?), or opportunity to participate (was someone offered to participate?). For outcomes, Pilots may select one or more measures among those identified under Section 1 of this framework.
- D. Select and calculate appropriate inequality measures.** The choice of method to assess impacts on inequalities depends on the specific context, the nature of the outcomes being measured, and the available data. A combination of quantitative and qualitative approaches often provides a more comprehensive understanding of impacts on inequalities. As for quantitative measures, a first assessment can be based on descriptive statistics, such as proportions, means, or medians, to provide a snapshot of the distribution of the outcome(s) across the different subgroups. Going a step forward, we can distinguish relative and absolute measures of inequality. Relative measures include those based on ratios (e.g. rate ratio, prevalence ratio, hazard ratio, etc.), which represent the percent excess of an outcome in one group compared to the outcome in another group (taken as a reference). So, for example, the prevalence ratio (PR) of CVD among migrants is computed as the ratio of the prevalence of a disease among migrants (e.g., 7%) over the prevalence among non-migrants (e.g., 5%); we obtain $PR=1.4$, which suggests that migrants have a 40% higher prevalence of CVD compared to non-migrants within the studied population. Absolute measures are computed as differences (e.g., rate difference - RD, etc.) and represent the gap in the actual number of people with the outcome between the two groups. In the previous example, the difference in the prevalence rate would be $RD=0.02$, which implies that there are 2% more people with the disease among migrants. We would have obtained the same value if the two prevalence rates had been 50% and 48%, but in that case, the prevalence ratio would have indicated only nearly 4% higher rate in relative terms. Hence, both relative and absolute measures can be of interest in monitoring inequalities, but the overall level of the outcome must always be considered to give a correct interpretation of the results (Houweling 2007). A further important distinction can be made between inequality measures comparing two groups and those measuring the entire gradient, i.e. based on the complete ranking of the SEP indicator. The advantage of these measures is that they account for the distribution of the population across the different socioeconomic categories, although they are more complex to compute and are often based on regression models. Examples of this group of indicators are the concentration index and the index of inequality, both with their absolute and relative versions; a more complete examination of inequality measures can be found in the suggested readings (Schlotheuber 2022).

SUSTAINABILITY

Sustainability in JACARDI is defined as the ability of JACARDI to ensure and sustain project impact after EU funding ends. Further exploitation of JACARDI results will be supported at three levels: i) high-level policy sustainability; ii) sustainable impacts within topics of health literacy, data availability, quality, accessibility and sharing, screening, integrated care pathways, self-management and labor participation (supported by roadmaps per each topic, summarizing the results of the pilots, identifying the characteristics and factors important for development of further programs and their implementation strategies, or scaling up); and iii) sustainability of JACARDI pilots' results and outcomes.

Different indicators may be used to assess sustainability. More general characteristics of the pilot such as community engagement and institutional support will be assessed with the tools developed by Working Package 4; the multidimensional assessment framework allows pilots to evaluate the sustainability of resources and capabilities that refer to further exploitation of the pilot results after the end of JACARDI (third-level perspective of sustainability in JACARDI). This can be done using the results

of the multidimensional assessment dimensions presented in the document before (budget, funding sources, cost-effectiveness) and the various strategic planning techniques, for example, SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis.

Assessing the sustainability of a pilot is best done at strategic points throughout its lifecycle, typically before, during, and after implementation. Here's when it's most appropriate to assess sustainability:

- Planning Phase: sustainability considerations should be integrated into the planning phase of the pilots (for example, when establishing the implementation team and stakeholders' network, developing strategic objectives, performing situation analysis, and developing an implementation plan).
- During Implementation: conducting a midpoint evaluation allows to assess how well the pilots are progressing and identify any emerging sustainability challenges or opportunities. This may involve revisiting opportunities for political and institutional support, addressing the level of partner and community engagement, reviewing financial data, monitoring resource utilization, and soliciting feedback from stakeholders. Adjustments can be made to enhance sustainability based on mid-term findings.
- Post-implementation evaluation and planning: after the pilots conclude, a comprehensive evaluation should be conducted to assess their overall sustainability. This involves analyzing the long-term impact of the pilots, evaluating the continued relevance of their findings, and determining the feasibility of scaling up or replicating successful interventions. Lessons learned from the pilots can inform future sustainability planning efforts which should be included in the Sustainability Action Plan for the period after JACARDI ends.

By systematically addressing these factors, a comprehensive understanding of the pilots' sustainability may be performed and proactive steps may be taken to enhance their long-term impact.

Scalability/transferability

Assessing the scalability of a pilot involves evaluating its potential for expansion and replication to reach a larger population or be implemented in different settings. The main steps for assessing the scalability of a pilot are the following:

- Clearly define the objectives of scalability. Determine whether the goal is to expand the program to serve a larger population, replicate it in different locations, or adapt it to diverse contexts.
- Evaluate the design and structure of the healthcare intervention to determine if it can be easily replicated. Consider whether the intervention components are modular, adaptable, and have a standardized framework that can be implemented in various settings. Standardization of protocols, procedures, and guidelines may ensure consistency in program implementation and facilitate easier replication and transferability.
- An evaluation of the resource requirements for the program implementation should be performed to determine whether the program can be implemented with available resources in new settings.
- The program should be adaptable to different cultural contexts. A scalable program should be culturally sensitive and able to engage diverse communities.

Other aspects may be considered in the assessment:

- The presence of training and capacity-building strategies embedded in the healthcare program may facilitate new implementations in different locations.
- Compatibility with existing systems facilitates smoother integration into existing healthcare systems or structures without requiring major overhauls.

- Scalable programs often leverage technology for data collection, monitoring, and communication, making it easier to manage and scale.
- The involvement of key stakeholders, including community members, healthcare providers, and policymakers, in the scaling process may provide inputs and enhance the likelihood of successful replication in new settings.

Assessing the scalability of a pilot is best done at strategic points throughout its lifecycle, typically before, during, and after implementation. Here's when it's most appropriate to assess scalability:

- o Planning Phase: assessing scalability should begin during the planning phase of the pilots.
- o During Implementation: conducting a midpoint evaluation allows to assess the feasibility of scaling up successful components of the pilots. This may involve identifying barriers to scalability, exploring expansion opportunities, and refining strategies to enhance scalability.
- o Post-implementation evaluation: after the pilots conclude, a comprehensive evaluation should be conducted to assess their scalability potential. This involves analyzing the scalability of the intervention, evaluating the scalability of the implementation model, and identifying factors that may facilitate or hinder scaling up. Lessons learned from the pilots inform scalability planning for future expansion efforts.

Regularly reviewing and updating the scalability plan as the program evolves ensures that the scaling process remains dynamic and responsive to changing circumstances. A thorough assessment of these factors can guide the scalability potential of pilots.

ADDITIONAL IMPLEMENTATION OUTCOMES AND PROCESS INDICATORS

Implementation outcomes reflect the progress toward success of efforts to implement evidence-based interventions [Proctor et al, 2023]. In other words, implementation outcomes aim at measuring the success or failure of implementation.

Implementation outcomes might be classified into anticipated (i.e., forward-looking) and actual (i.e., backward-looking outcomes) outcomes, according to the timing of measurement [Damschroder et al, 2022]. Anticipated implementation outcomes reflect perceptions or assessments of the likelihood of future implementation success or failure. For instance, an anticipated outcome could be the projected probability that decision-makers will adopt or deliver the intervention in real-world settings before it has been implemented (e.g., the estimated number of clinical centers that may adopt the intervention). Actual implementation outcomes are based on perceptions or measures of current (or past) implementation success or failure. An example of actual implementation outcome is the extent to which decision-makers have adopted or delivered the intervention in real-world settings (e.g., the actual number of clinical centers that have adopted the intervention).

Both types of implementation outcomes can be assessed either quantitatively (e.g., through structured surveys or checklists, use of administrative records, extraction from the electronic health record) or qualitatively (e.g., through semi-structured interviews and focus groups).

The selection of implementation outcomes might be guided by existing frameworks, which propose a comprehensive taxonomy of those outcomes, offering a guide for their conceptualization and measurement. Moreover, these frameworks delve into the determinants that can either facilitate or hinder implementation outcomes (i.e., barriers and facilitators, including individual and setting-level factors). Well-established implementation frameworks in healthcare are the Consolidated Framework for Implementation Research (CFIR) [Damschroder et al, 2009] and its updated version [Damschroder et al, 2022], the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [Glasgow et al, 2019] or the Implementation Outcomes Framework (IOF) [Proctor et al, 2011].

Besides sustainability and scalability (see sections 5a and 5b), frequently measured implementation outcomes include:

- Acceptability: the extent to which an intervention is perceived as agreeable, palatable, or satisfactory. Acceptability implies an evaluation of how well the intervention aligns with personal criteria: different individuals might have different judgments of the acceptability of the same intervention if their needs, preferences, or expectations differ. The measurement of acceptability can be informed by existing frameworks, for example, the Theoretical Framework of Acceptability (TFA) [Sekhon et al, 2017].
- Appropriateness: perceived fit, relevance, or compatibility of an intervention for a given context, or its perceived fit to address a particular issue. Acceptability implies an evaluation of how well the intervention aligns with technical or social criteria: an intervention might be judged appropriate if it is seen as effective for achieving some objectives given existing conditions or seen as consistent with norms or values.
- Feasibility: the extent to which an implementation target can be successfully used or deployed within a given setting. Feasibility implies an evaluation of how well the intervention aligns with practical criteria: an intervention might be judged if it can be performed relatively easily or conveniently given existing resources and circumstances.
- Adoption (or uptake): intention, initial decision, or action to employ an intervention. Adoption can be measured at the setting level and/or at the staff/provider level in terms of the absolute number, proportion, and representativeness of settings and deliverers who are likely or have decided to deliver the intervention.
- Fidelity: the degree to which an intervention was implemented as prescribed or intended. Fidelity can be measured by collecting data on the adherence to the intervention, amount of intervention delivered, and quality of program delivery.
- Penetration: integration or saturation of an intervention within a service setting and its subsystem. Penetration can be measured by estimating the number of eligible persons who access the intervention, divided by the total number of persons eligible for that intervention.

The aforementioned implementation frameworks not only focus on conceptual definitions but also provide approaches to operationalizing implementation outcomes. Additionally, there are several available resources that can support researchers in selecting appropriate quantitative measures to evaluate the different implementation outcomes. First, the Implementation Outcome Repository (<https://implementationoutcomerepository.org/>) is an online resource that offers free access to a variety of quantitative instruments. For each quantitative instrument, the repository provides information on its psychometric quality (i.e., reliability and validity), methodological quality, and usability. Another valuable resource is the SIRC Instrument Repository (<https://societyforimplementationresearchcollaboration.org/measures-collection/>), which originated from a systematic review by Lewis and colleagues (2015). This repository is another online resource that provides a collection of quantitative instruments, guided by the CFIR and IOF frameworks. The website is constantly updated, however access to the repository requires membership. The RE-AIM website (<https://re-aim.org/resources-and-tools/measures-and-checklists/>) includes several measures and checklists to support the design of a quantitative evaluation based on the related implementation framework. Lastly, a publicly available website (<https://www.health-policy-measures.org/find-measures>) was recently developed based on a systematic review of health policy implementation measures [Allen et al, 2020].

Process indicators might be measured for interventions that are expected to have significant implications not only for the individuals they target but also at the organizational levels. Process indicators measure the intervention's activities and outputs (in other words, whether planned activities took place). Process indicators can be used to assess the quality of the activities performed, based on some established criteria, practice guidelines, or standards. Examples of process indicators are adherence to existing guidelines/recommendations and timeliness of intervention.

Pilot Assessment Design

The evaluation of the outcomes of pilots should ideally be made in a causal inference framework. This refers to the process of determining whether an observed association reflects a cause-and-effect relationship. For each pilot, the assessment should investigate the effect of the intervention/program under investigation on the proposed outcomes (effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability – including scalability – and additional implementation and process outcomes).

Establishing causation can be a challenging task. **Randomized controlled trials (RCTs)** are generally viewed as the gold standard approach in assessing the effects of treatment, program, or exposure [Jacob 2016]. RCTs are characterized by the random assignment of study participants to intervention and control groups. When executed correctly, randomization is anticipated, on average, to equalize observed and unobserved participant characteristics across trial arms. This equilibrium facilitates attributing any divergence in outcomes across arms to the intervention and poses RCTs at the top of the pyramid of evidence of causality [Leroy 2022, Goldstein 2019].

Nevertheless, carrying out an RCT might be impractical for various reasons, such as lack of essential financial or time resources, or when dealing with an exposure or hypothesis that cannot be applied or altered for trial participants due to ethical concerns. Additionally, the sample of willing participants may not adequately represent the broader patient population, potentially compromising the meaningfulness of the results [Lyons 2022]. Moreover, RCTs have also received some criticism, as they may not represent the real clinical practice, therefore real-world evaluations, in addition to RCT, are getting more attention now. Furthermore, a 'controlled environment' like one of RCTs may 1) not always be feasible, but 2) also not help to assess the effectiveness of an intervention in day-to-day practice. As such, RCTs often overestimate the effectiveness that can be expected in a natural environment. On the other hand, pragmatic trials, conducted in a real-world setting, apply less restrictive inclusion criteria for participants, which seems very relevant considering the high prevalence of multimorbidity in DM/CVD patients. Moreover, JACARDI will pilot mainly organizational (rather than clinical) interventions, which are usually complex/multi-component interventions that may not fit the strict requirements of an RCT.

When the experimental RCT design is not possible or practical or adequate, causal inference can still be achieved with an observational study design. In observational studies, researchers observe and analyze subjects in their natural settings without randomly assigning treatments, which are instead prescribed according to clinical practice. These studies are valuable when randomization is not feasible or ethical, providing insights into associations and correlations between exposures and outcomes in real-world scenarios. It's important to note that observational studies may have limitations, such as potential endogeneity and confounding, that can impact the ability to establish causation compared to RCTs. Nevertheless, endogeneity and confounding can be eliminated, or significantly reduced, through appropriate study designs relying on relevant quasi-experimental counterfactuals. Examples of such study designs include the following:

- **Difference-in-Differences (DiD) design:** this is a quasi-experimental research design commonly used in observational studies to estimate causal effects. While it does not provide the same level of control as RCTs, DiD analysis can contribute evidence toward establishing causal relationships under certain conditions. It compares changes in outcomes over time between a treatment group and a control group. By examining the difference in changes, this design attempts to account for both time-fixed and time-varying confounders [Callaway 2021]. Key factors influencing the ability of DiD analysis to assess causality include:
 - o Assumption of parallel trends: the validity of DiD analysis relies on the assumption that, in the absence of treatment, the treatment and control groups would have followed parallel trends over time. If this assumption holds, any deviation from parallel trends after the introduction of the treatment can be attributed to the causal effect.
 - o Accounting for confounding factors: DiD requires careful consideration and control for potential confounding factors that might independently influence the outcomes. Failing to adequately address confounding variables can compromise the ability to draw causal inferences.

- Correct specification of the model: the success of DiD analysis in assessing causality also depends on correctly specifying the statistical model. This involves selecting appropriate covariates, understanding potential sources of bias, and using statistical techniques to control for observed and unobserved factors.
- Data quality and measurement: the reliability and accuracy of data play a crucial role in the success of DiD analysis. Researchers need to ensure that the measurements are valid and that any measurement errors are minimized.

While Difference-in-Differences analysis can offer valuable insights into causal relationships, researchers should interpret the results cautiously and consider potential limitations. The ability to make causal claims with confidence depends on the robustness of the research design, the validity of assumptions, and the rigorous application of statistical methods. In situations where randomization is not feasible, DiD analysis remains a useful tool for estimating causal effects and understanding the impact of interventions or treatments over time.

- **Regression discontinuity design (RDD)**: it is a quasi-experimental research design that can be used to assess causality. RDD is particularly effective in situations where intervention or treatment is assigned based on a threshold or cutoff point, and individuals just above or below this threshold are expected to be comparable. One key assumption of RDD is that individuals close to the cutoff are essentially similar, and any observed differences can be attributed to the treatment or intervention rather than pre-existing differences. RDD involves conducting a regression analysis to model the relationship between the outcome variable and the assignment variable (distance from the cutoff). The regression estimates the treatment effect by comparing outcomes for individuals just above and below the cutoff. Researchers typically examine whether there is a discontinuity in the outcomes at the cutoff point. If a significant jump or discontinuity is observed, it suggests that the treatment or intervention had a causal effect. To enhance the validity of causal inferences, researchers need to control for potential confounding variables that may influence the outcome. This involves including covariates in the regression model. This step helps minimize selection bias and allows for stronger causal inferences [Albers 2010]. The success of RDD in assessing causality depends on the correct identification and implementation of the cutoff point, the validity of assumptions, and the rigorous application of statistical methods. When applied appropriately, RDD offers a credible approach to estimating causal effects in situations where randomization may not be feasible.
- **Instrumental variables analysis**: it uses an instrumental variable - a variable that is correlated with the exposure but is not directly related to the outcome - to estimate causal effects. This method is often used when randomization is not feasible [Iwashyna 2013]. This approach is used to figure out cause-and-effect relationships between variables, especially when traditional methods might give misleading results. It works by finding a third variable, called “instrumental”, that affects the variable of interest but isn’t affected by the same hidden factors that might skew the results. This helps to tease out the true relationships between variables, even when there are tricky issues like hidden biases or omitted factors in the data. Using instrumental variables analysis to understand cause-and-effect relationships between variables can be tricky. One main challenge is finding suitable instruments that truly affect the variable of interest but aren’t influenced by hidden factors. Weak instruments that don’t strongly relate to the variable can also cause problems, leading to unreliable results. Additionally, there’s the risk of using too many instruments or assuming they’re unrelated to the errors in the model, which can also distort findings. Lastly, ensuring that the instruments apply to all parts of the data and aren’t influenced by selection biases presents another hurdle in IV analysis.

Other observational study designs may be applied if none of the above can be used, but generally, they do not guarantee a causal assessment. These are:

- **Pre-post design**: observations or measurements are taken on the outcome of interest on the same subjects before and after the implementation of an intervention, treatment, or exposure. The goal is to examine changes over time and determine whether there is a causal relationship between the intervention and the observed outcomes. If there is a significant and consistent change in the post-intervention measures, a causal relationship between the intervention and the observed

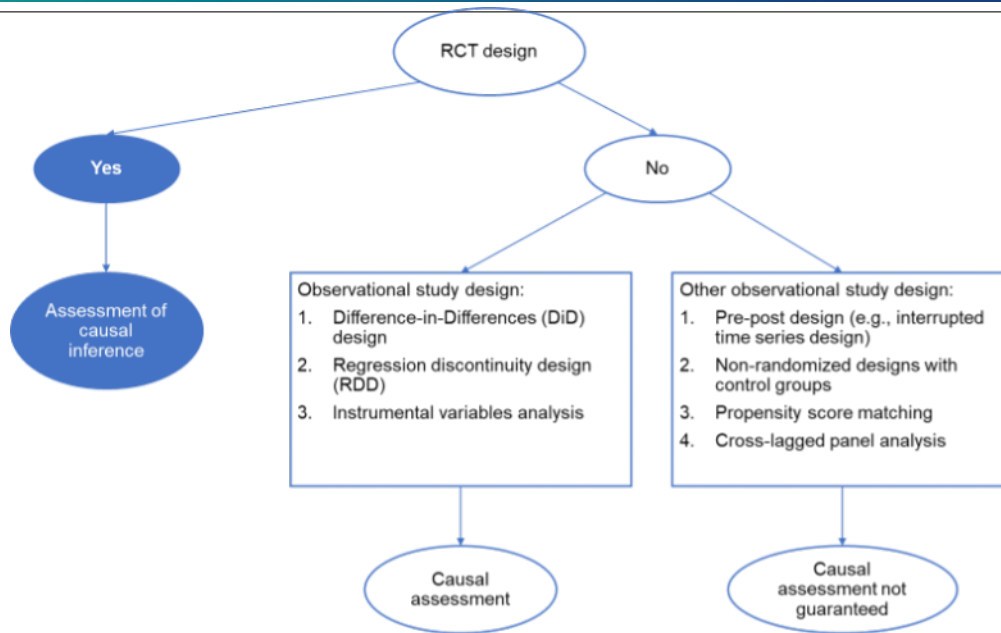
outcomes may be highlighted. While pre-post designs are straightforward and can provide valuable information, they have limitations. One major challenge is the lack of a control group, making it difficult to rule out alternative explanations for observed changes. Without a comparison group, it is challenging to attribute changes solely to the intervention, as other factors may contribute to the observed outcomes.

An example of pre-post design is the **Interrupted Time Series (ITS) design**. It is used to assess causality by studying the effects of an intervention or treatment over time. In an interrupted time series analysis, repeated measurements are taken on a single group or population before and after the implementation of an intervention, and the goal is to determine whether the intervention had a causal impact on the observed outcomes. The intervention is introduced at a specific point in time, often referred to as the “interruption” point. This could be the implementation of a policy, the introduction of a treatment, or any other event that is expected to influence the outcome. Data is collected at multiple time points before and after the intervention. The analysis involves examining the trajectory of the outcome variable over time and assessing whether there is a significant change in the level or trend of the outcome after the intervention. Statistical models, such as regression models, are commonly used in interrupted time series analysis. These models allow researchers to estimate the immediate and sustained effects of the intervention on the outcome. The design assumes a linear relationship between time and the outcome variable, implying that changes occur gradually over time. Like any study design, interrupted time series designs have limitations. They may be affected by confounding factors, and the identification of the intervention effect relies on assumptions about the absence of other external influences at the time of the intervention [Hudson 2019].

- **Non-randomized designs with control groups:** these designs include the study designs in which the control group cannot be selected in a way that prevents it from being systematically different from the intervention group. This means that the difference observed between the intervention and control groups cannot be assumed to be causal.
- **Propensity score matching:** it involves matching participants who received the treatment with those who did not based on their propensity scores, which estimate the likelihood of receiving the treatment. This helps control for observed confounders [Austin 2011] but not for unobserved ones.
- **Cross-lagged panel analysis:** commonly used in longitudinal studies, cross-lagged panel analysis examines the relationships between variables measured at multiple time points. This design helps infer causal relationships when temporal precedence is established [Reed 1988].

It’s important to note that the strength of causal inference also depends on the quality of study implementation, control of confounding variables, and the validity of measurement methods. Researchers often use a combination of study designs and rigorous methodologies to build a compelling case for causality. Additionally, causal inference should be interpreted cautiously, recognizing that establishing causation is a complex and ongoing process, especially in implementation projects.

The following figure shows a summary of the different study designs and related assessments:



Assessment of causal effect

The counterfactual model is a conceptual framework used in the study of causal effects. The counterfactual represents what would have happened (the counterfactual outcome) to each participant if they had received the alternative treatment instead of the one they were assigned to (the observed outcome). The key idea is to create a hypothetical scenario where the individual or group in question did not experience the treatment, intervention, or exposure being studied in the specific pilot [Höfler 2005]. The essential components of the counterfactual model are the following:

- Counterfactual outcome (Y0): this represents the outcome that would have occurred in the absence of the intervention or exposure (e.g., in case of alternative treatment). It is a hypothetical scenario and is often denoted as Y0, where "0" signifies the absence of the treatment/intervention/program under investigation.
- Observed outcome (Y1): this is the actual outcome that occurred when the intervention or exposure was present. It is denoted as Y1, where "1" signifies the presence of the treatment/intervention/program.
- Causal effect (Y): the causal effect is the difference between the counterfactual outcome (Y0) and the observed outcome (Y1). Mathematically, $Y = Y1 - Y0$. This represents the impact or change in the outcome attributable to the treatment/intervention/program.
- Individual-level causal effect: at the individual level, the causal effect is the difference in outcomes for a specific individual with and without the intervention. It answers the question: What is the change in outcome for this individual because of the treatment?
- Average Causal Effect (ACE): the average causal effect is the average difference in outcomes across the entire population due to the intervention. It provides a measure of the average impact of the treatment on the outcome in the studied population.

The counterfactual model is crucial for establishing causation because it helps isolate the effect of an intervention (pilot) by comparing what actually happened with what would have happened in its absence. However, it is important to note that directly observing the counterfactual outcome for the same individual is often impossible. Statistical methods, study designs like randomized controlled trials, and sophisticated analytical techniques may be used to estimate and infer causal effects within the counterfactual framework. The counterfactual model can still be applied to estimate the causal effects of observational studies, where there is no control over the assignment of treatments or exposures to individuals. While observational studies may face challenges such as unmeasured confounding and

selection bias, careful design and analysis can help mitigate these issues and provide valuable insights into causal relationships between variables.

In summary, the counterfactual model provides a structured way to conceptualize and analyze causal relationships, helping researchers navigate the complexities of attributing observed changes to specific interventions or exposures.

Extended assessment of selected pilots

The methodological framework for the multidimensional assessment of pilots offers an objective basis for evaluating the outcomes of all pilots. For a subset of pilots (at least one from each work package, WPs 6 to 11), an in-depth evaluation will be conducted by the central team for Task 5.6. This assessment will be based on the same framework but will extend the analysis to consider scaled-up scenarios. Pilots are typically conducted on a small scale to test the feasibility, effectiveness, and challenges of a new intervention, treatment, or healthcare practice. Scaling up refers to expanding these pilots to a broader context or larger scale, often across different settings (e.g., multiple hospitals, regions, or populations), to evaluate their effectiveness in real-world conditions.

To support this, a microsimulation model will be developed to project health outcomes and costs, providing multiple cross-sectional representations of the population over time, even beyond the data collection period. The goal is to capture the key dynamics and interactions between health parameters or risk factors and their impact on both health outcomes and costs.

At the start of the simulation, data from various sources will be integrated, and statistical methods will be used to create plausible equations that reflect population heterogeneity, including factors such as gender, socioeconomic status, and behaviors. Using these equations, the model generates a large sample of synthetic individuals representing the target population, each characterized by a unique health profile. As the simulation progresses, life-course events - such as adopting new behaviors, developing diseases, or death - are simulated, with events competing to occur based on probabilities calculated from individual attributes. This stochastic approach accounts for the inherent unpredictability of life events, allowing for a wide range of possible outcomes.

At the end of the simulation, the model will calculate various metrics that reflect the projected evolution of health outcomes and costs within the population. By modifying the equations, parameters, or initial distributions of individual characteristics, the model allows for testing of different interventions and alternative scenarios.

In the development of the microsimulation tool, the emphasis has been placed on the following attributes:

- **Generic:** it must be possible to use the same framework to test any combination of risk factors, provided that suitable risk factor data exist.
- **Flexible:** starting from the same data, a user must be able to test alternative hypotheses in terms of the causal links between variables.
- **Transparent:** the model displays all the inputs, equations, parameters that are used in the simulation. A user is, therefore, able to check and confirm every step of the simulation.
- **Efficient:** the aim is to minimize the time, processing power and memory needed to run the simulation, once the model code is fully developed and optimized, and a suitable user interface is available.
- **Accessible:** the model's user interface must be intuitive and user-friendly for most users, and at the same time it must offer advanced research users the option of updating and developing the source code in a way that would allow them to address new research questions.

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Appendix 1 Example of QALYs calculation

Suppose to have collected a completed EQ-5D-5L questionnaire from a certain respondent, wherein they have indicated their perceived health state across all dimensions.

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY	
I have no problems in walking about	<input checked="" type="checkbox"/>
I have slight problems in walking about	<input type="checkbox"/>
I have moderate problems in walking about	<input type="checkbox"/>
I have severe problems in walking about	<input type="checkbox"/>
I am unable to walk about	<input type="checkbox"/>
SELF-CARE	
I have no problems washing or dressing myself	<input type="checkbox"/>
I have slight problems washing or dressing myself	<input type="checkbox"/>
I have moderate problems washing or dressing myself	<input checked="" type="checkbox"/>
I have severe problems washing or dressing myself	<input type="checkbox"/>
I am unable to wash or dress myself	<input type="checkbox"/>
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	<input type="checkbox"/>
I have slight problems doing my usual activities	<input checked="" type="checkbox"/>
I have moderate problems doing my usual activities	<input type="checkbox"/>
I have severe problems doing my usual activities	<input type="checkbox"/>
I am unable to do my usual activities	<input type="checkbox"/>
PAIN / DISCOMFORT	
I have no pain or discomfort	<input type="checkbox"/>
I have slight pain or discomfort	<input type="checkbox"/>
I have moderate pain or discomfort	<input type="checkbox"/>
I have severe pain or discomfort	<input type="checkbox"/>
I have extreme pain or discomfort	<input checked="" type="checkbox"/>
ANXIETY / DEPRESSION	
I am not anxious or depressed	<input type="checkbox"/>
I am slightly anxious or depressed	<input type="checkbox"/>
I am moderately anxious or depressed	<input type="checkbox"/>
I am severely anxious or depressed	<input checked="" type="checkbox"/>
I am extremely anxious or depressed	<input type="checkbox"/>

Responses then need to be coded as single-digit numbers expressing the severity level selected in each dimension (from 1=no problems to 5=extreme problems):

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about → 1

I have slight problems in walking about

I have moderate problems in walking about

I have severe problems in walking about

I am unable to walk about

SELF-CARE

I have no problems washing or dressing myself

I have slight problems washing or dressing myself

I have moderate problems washing or dressing myself → 3

I have severe problems washing or dressing myself

I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities

I have slight problems doing my usual activities → 2

I have moderate problems doing my usual activities

I have severe problems doing my usual activities

I am unable to do my usual activities

PAIN / DISCOMFORT

I have no pain or discomfort

I have slight pain or discomfort

I have moderate pain or discomfort

I have severe pain or discomfort

I have extreme pain or discomfort → 5

ANXIETY / DEPRESSION

I am not anxious or depressed

I am slightly anxious or depressed

I am moderately anxious or depressed

I am severely anxious or depressed → 4

I am extremely anxious or depressed

The digits for the five dimensions then need to be combined in a 5-digit code that describes the respondent's health state. In the example above, the health state of the respondent is: 13254.

To obtain the utility value for the overall health state, utility values (weights) need to be attached to each of the levels in each dimension. The index is calculated by deducting the appropriate weights from 1, the value for full health (i.e. state 11111). An example is provided below using utility values for Italy:

Health state: 13254

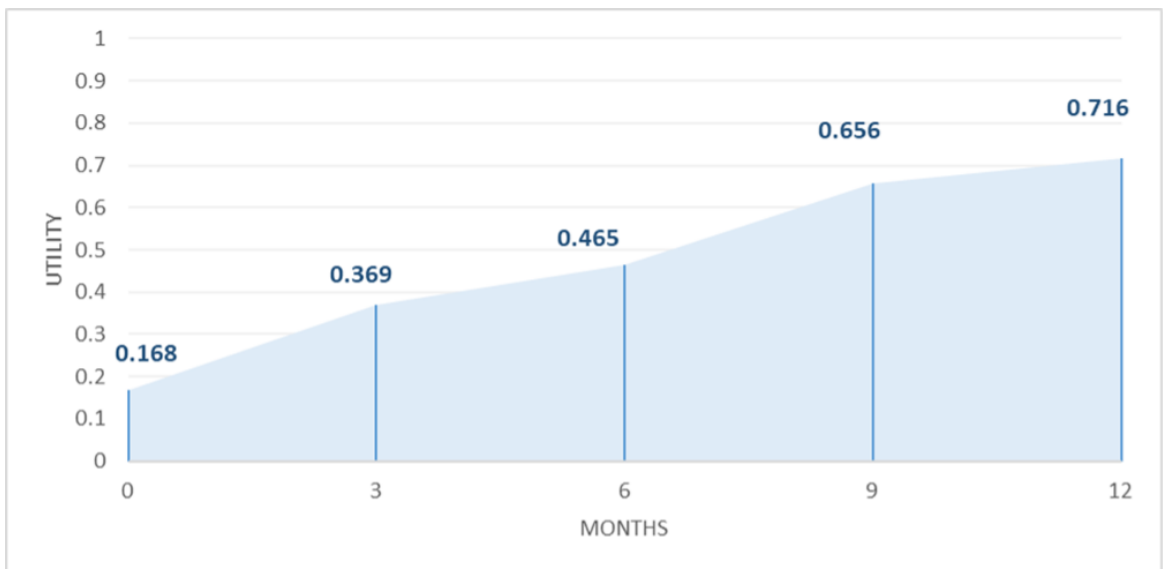
	Disutility due to mobility	Disutility due to self-care	Disutility due to usual activities	Disutility due to pain/discomfort	Disutility due to anxiety/depression
1	0	0	0	0	0
2	0.051	0.046	0.050	0.047	0.044
3	0.064	0.056	0.064	0.088	0.109
4	0.244	0.216	0.225	0.353	0.318
5	0.329	0.257	0.255	0.408	0.322

$$\text{Utility} = 1 - 0 - 0.056 - 0.050 - 0.408 - 0.318 = 0.168$$

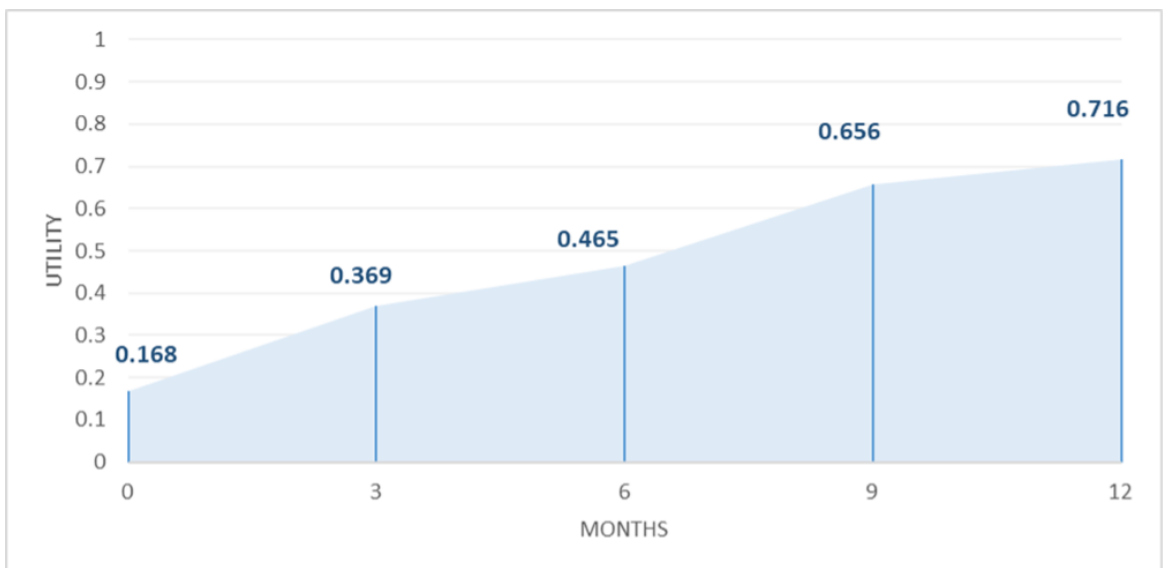
Now suppose that the EQ-5D-5L questionnaire was administered to the same respondent at different time points, for example, every 3 months from baseline to 1 year. Following the steps outlined above, it is possible to estimate the utility associated with each health state at all time points, for example:

Timepoint	Utility values
Baseline	0.168
3 months	0.369
6 months	0.465
9 months	0.656
12 months	0.716

Let's imagine representing the estimated quality of life on a graph, by reporting time on the x-axis and utility values on the y-axis:



By looking at the graph, total QALYs can be calculated by summing the areas of the trapezoids. If the time unit is different from the year, it should be converted to the year (for example, 3 months are equal to 0.25 years). An example of area calculation is provided below:



The total QALYs are therefore computed as follows:

$$\begin{aligned} \text{Total QALYS} &= \frac{(0.168+0.369)*0.25 \text{ years}}{2} + \frac{(0.369+0.465)*0.25 \text{ years}}{2} \\ &+ \frac{(0.465+0.656)*0.25 \text{ years}}{2} + \frac{(0.656+0.716)*0.25 \text{ years}}{2} \\ &= 0.483 \text{ QALYS} \end{aligned}$$

Annex V Appendix D

Brief description of methodological framework for multidimensional assessment of pilots

(linked to the detailed description)

Introduction

The objective of this document is to define a framework to assess the outcomes of pilots undertaken in Work Packages (WP) 6 to 11. This is a brief version of the Detailed description of methodological framework for multidimensional assessment of pilots, the full version can be accessed [here](#).

The framework provides an objective basis for evaluating the outcomes of pilots. These assessments should determine the effects of the interventions under investigation in each pilot on the identified outcome dimensions. The flowchart below presents the roadmap to perform the assessment.

All pilots will be assessed. For a subset of pilot projects, comprising at least one project from each of the technical WP6-11, the assessment will be undertaken by the core team for Task 5.6 (Bocconi University, Milan, Italy; Imperial College, London, UK), in collaboration with the relevant pilot teams, and will involve in-depth and long-term analyses.

The other pilots will be evaluated by the pilot teams themselves. All six dimensions of the framework should be assessed by each pilot except when any of the dimensions is either not relevant or not measurable. In this case, the pilot core team should explain why the assessment was not done. WP6-11 leaders may use the present framework as a reference to find detailed specifications on the pilots' assessment activities. WP6-11 leaders and pilots will be able to benefit from the methodological support and guidance of the 5.6 core team, that can assist the relevant partners in conducting independent analyses on multidimensional health and economic evaluations based on the collected data.

More detailed guidance on each step of the flowchart is available by clicking on it.

Assessment of effects of the interventions

The counterfactual model is a conceptual framework used in the study of causal effects. The counterfactual represents what would have happened (the counterfactual outcome) to each participant if they had received the alternative treatment instead of the one they were assigned to (the observed outcome). The key idea is to create a hypothetical scenario where the individual or group in question did not experience the treatment, intervention, or exposure being studied in the specific pilot. The essential components of the counterfactual model are the following:

- Counterfactual outcome (Y0): this represents the outcome that would have occurred in the absence of the intervention or exposure (e.g., in case of alternative treatment).

- Observed outcome (Y1): this is the actual outcome that occurred when the intervention or exposure was present.
- Causal effect (ΔY): the causal effect is the difference between the counterfactual outcome (Y0) and the observed outcome (Y1). Mathematically, $\Delta Y = Y1 - Y0$. It can be individual-level and Average Causal Effect (ACE).

The assessment of the outcomes of pilots should ideally be made in a **causal inference framework**. This refers to the process of determining whether an observed association truly indicates a cause-and-effect relationship. For each pilot, the assessment should evaluate the **causal effect** of the intervention/program under investigation on at least one of the proposed outcomes (effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability - including scalability/transferability, and additional implementation and process outcomes).

The counterfactual model is crucial for establishing causation because it helps isolate the effect of an intervention (pilot) by comparing what actually happened with what would have happened in its absence. However, it is important to note that directly observing the counterfactual outcome for the same individual is often impossible. Statistical methods, study designs like randomized controlled trials, and sophisticated analytical techniques may be used to estimate and infer causal effects within the counterfactual framework. [\[Back\]](#)

Pilot designs

A pilot design refers to the framework or plan that researchers use to conduct the investigation. It outlines the structure, methods, and procedures that will be employed to collect and analyze data in order to answer the research-specific question. Several study designs are commonly used to assess causality. Each study design has its strengths and limitations, and the choice should depend on factors such as the research question, available resources, and ethical considerations.

The assessment of the outcomes of pilots should ideally be made in a causal inference framework. This refers to the process of determining whether an observed association reflects a cause-and-effect relationship. For each pilot, the assessment should investigate the effect of the intervention/program under investigation on the proposed outcomes (effectiveness – including patient-reported outcomes, patient experience, economic efficiency, equity and diversity, sustainability – including scalability – and additional implementation and process outcomes).

Randomized controlled trials (RCTs) are generally viewed as the gold standard approach in assessing the effects of treatment, program, or exposure [Jacob 2016]. Nevertheless, carrying out an RCT might be impractical for various reasons, such as lack of essential financial or time resources, or when dealing with an exposure or hypothesis that cannot be applied or altered for trial participants due to ethical concerns. When the experimental RCT design is not possible or practical or adequate, causal inference can still be achieved with an observational study design. It's important to note that observational studies may have limitations, such as potential endogeneity and confounding, that can impact the ability to establish causation compared to RCTs.

Randomized controlled trials (RCTs)

Randomized controlled trials (RCTs) are characterized by the random assignment of study participants to intervention and control groups. Organizational (rather than clinical) interventions, that are piloted by JACARDI, may not fit the strict requirements of an RCT. More details can be found in the [full version of the methodology document \(page 17\)](#). [\[Back\]](#)

Observational studies

When the experimental RCT design is not possible or practical or adequate, causal inference can still be achieved with an observational study design. In observational studies, researchers observe and analyze subjects in their natural settings without randomly assigning treatments, which are instead prescribed according to clinical practice. It's important to note that observational studies may have limitations, such as potential endogeneity and confounding, that can impact the ability to establish causation compared to RCTs. Examples of such study designs include:

- Difference-in-Differences (DiD) design. More details can be found in the [full version of the methodology document \(page 17\)](#).
- Regression discontinuity design (RDD). More details can be found in the [full version of the methodology document \(page 18\)](#).
- Instrumental variables analysis. More details can be found in the [full version of the methodology document \(page 18\)](#).

Note: the outcomes collected during a one-arm study should be compared to outcomes of standard of care (ideally standard of care data should be retrieved from administrative data or registries but may also be retrieved from published studies). Then the evaluation is the same as for a two-arms study.

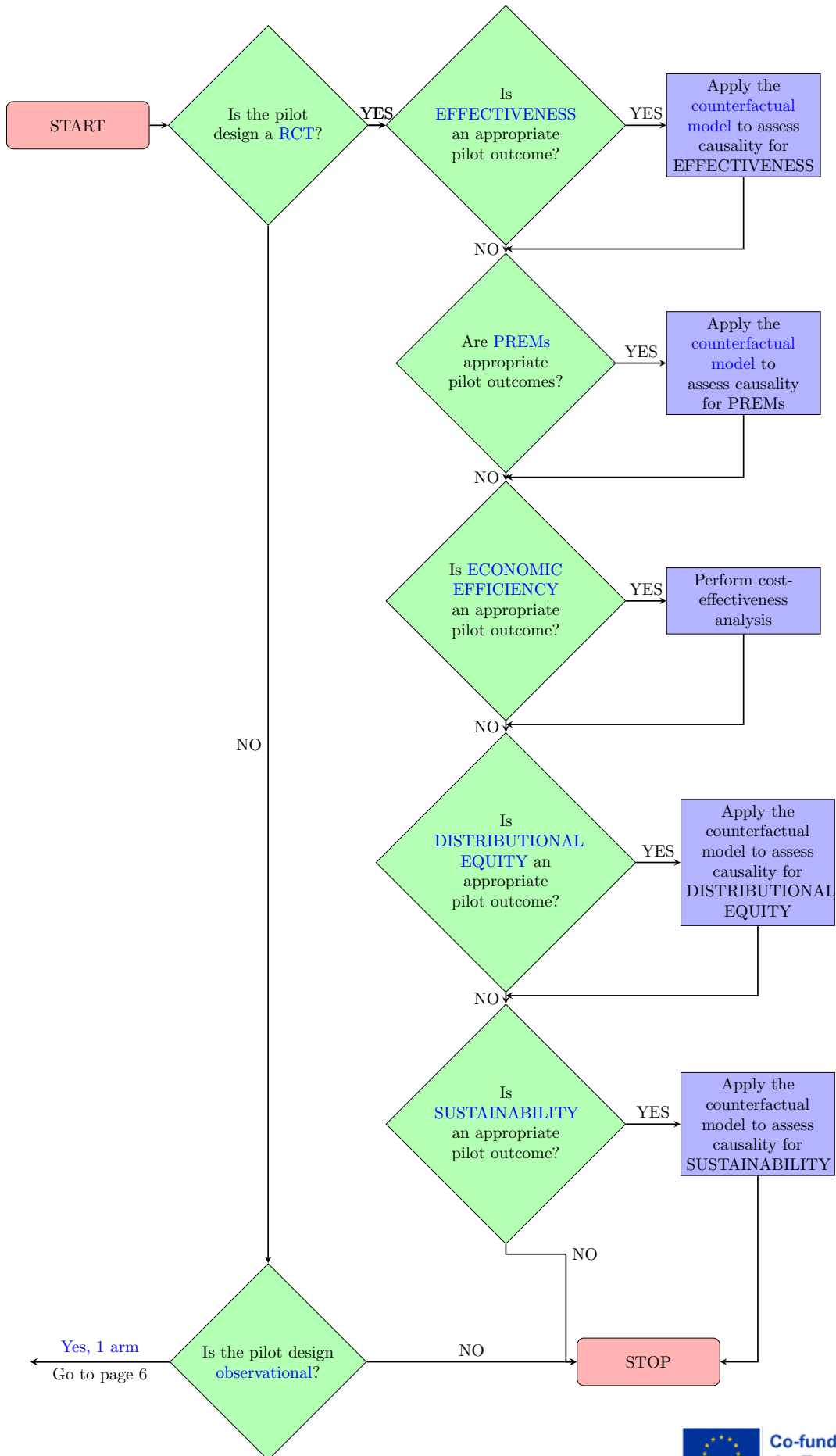
[\[Back\]](#)

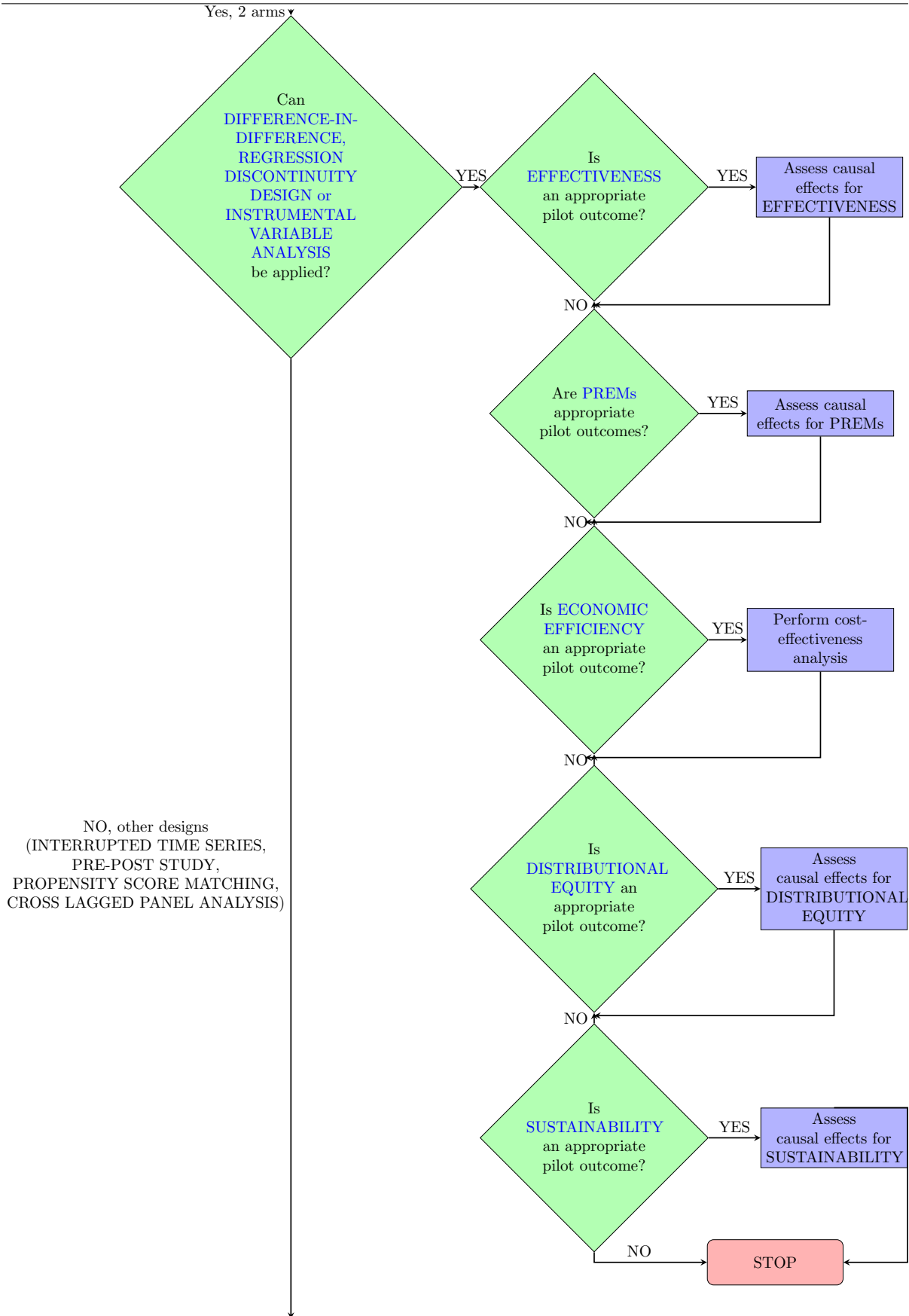
Other observational study designs

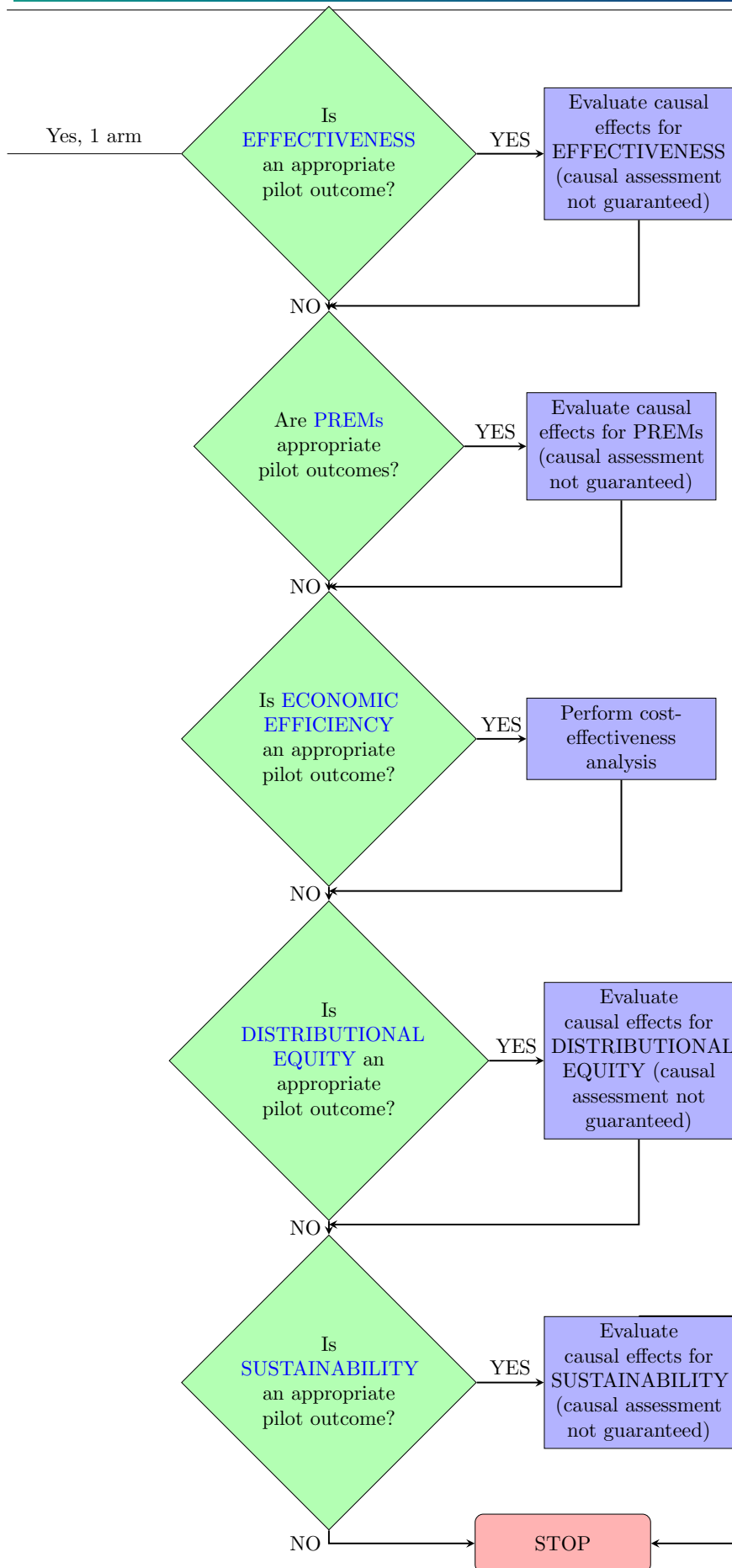
Other observational study designs may be applied if none of the above can be used, but generally, they do not guarantee a causal assessment. These are:

- Pre-post design (including Interrupted time series (ITS) design). More details can be found in the [full version of the methodology document \(page 18\)](#).
- Non-randomized designs with control groups. More details can be found in the [full version of the methodology document \(page 19\)](#).
- Propensity score matching. More details can be found in the [full version of the methodology document \(page 19\)](#).
- Cross-lagged panel analysis. More details can be found in the [full version of the methodology document \(page 19\)](#).[\[Back\]](#)

Flowchart







Definition of outcomes

The performance of the pilots will be evaluated through a multi-dimensional health and economic assessment. The following outcomes should be considered:

EFFECTIVENESS

Effectiveness should be intended with a broad meaning, considering the possible effects of the pilot intervention on relevant health outcomes, including both clinical and patient-reported outcomes.

The first step is to clearly articulate the goals and objectives of the pilot and to specify the intended health outcomes, such as improved health status, improved functioning, reduced disease prevalence, or enhanced well-being.

The second step is to identify and define specific and measurable indicators that can be used to assess the intended health outcomes. These indicators should be quantifiable and aligned with the pilot objectives.

The third step is to implement a robust data collection strategy to gather information on the identified indicators. A combination of quantitative and qualitative methods, such as surveys, interviews, focus groups, and health metrics may be used.

More details can be found in the [full version of the methodology document \(page 3\)](#).

Patient-reported outcomes (PROs) is a broad term that includes direct subjective assessment by the patient of elements of their health, including symptoms, health-related quality of life, and functional status. Patient-reported outcome measures (PROMs) are standardized questionnaires administered directly to patients that allow to collect information on PROs. To ensure greater confidence in the value of PRO data, it is always advisable to choose a PROM that has undergone psychometric validation in the intended language of use.

PROMs are categorized into two main types: condition-specific and generic. The latter focuses on health concepts applicable to a diverse range of patient groups, allowing for aggregation and comparisons across different conditions and settings. Condition-specific and generic PROMs are both important for understanding and improving patient care at multiple levels of the healthcare system. Several examples of PROMs can be found in the [full version of the methodology document \(page 4\)](#).

PROMs are often measured at specific points in a patient's healthcare journey to assess the impact of a health condition or treatment from the patient's perspective. The timing of PROM measurements can vary based on the nature of the condition, treatment plan, and research objectives. The common points when PROMs may be measured are at baseline, post-treatment/post-intervention, at discharge/transition points, and at follow-up appointments.

More details can be found in the [full version of the methodology document \(page 6\)](#). [\[Back\]](#)

PATIENT EXPERIENCES

Patients' or caregivers' experiences can be assessed with patient-reported experience measures (PREMs). Patient experiences - the extent to which the pilot intervention will influence patient and/or caregiver experiences and/or caregiver experiences as assessed with patient-reported experience measures (PREMs). These are instruments designed to capture and assess patients' perceptions, experiences, and interactions with health and social care systems and services. Not all pilots will be designed to have an impact on patient journeys through the health care system and may lead to meaningful and measurable changes in patient experiences. However, the concept of measuring the subjective experience of those who

are targeted by a pilot intervention can be extended to relevant populations, not necessarily involving patients. PREMs are typically implemented in the form of surveys, questionnaires, or interviews.

PREMs can be either relational or functional. Relational PREMs focus on the patient's experience of their relationships during treatment (for example, whether they perceived that the healthcare professionals fully understood their concerns). Functional PREMs examine more practical issues, such as patients' perceptions of the facilities available.

PREMs are typically measured at various points throughout a patient's interaction with the health or social care system. They can be measured during care provision, at the end of a treatment/intervention or after a significant event, at discharge or transition points, and at follow-up appointments.

More details can be found in the [full version of the methodology document \(page 6\)](#). [\[Back\]](#)

ECONOMIC EFFICIENCY

Measuring economic efficiency involves evaluating how well resources are allocated to produce (healthcare) services, aiming to achieve the maximum possible output with the least input.

In general, both (health) outcomes (or any relevant intermediate proxy measures, when health outcomes cannot be observed in the pilot) and resource costs, are necessary to perform the assessment. Common analyses include cost-effectiveness, cost-utility, or cost-benefit analyses.

The data collection on resource utilization must be aligned with ethical standards, including patient privacy and confidentiality. For pilots involving participants actively, obtaining informed consent from them regarding the use of their healthcare data for the scope of the pilots is a mandatory step.

More details can be found in the [full version of the methodology document \(page 8\)](#).

Measuring the use of health and social care resources

Measuring the use of healthcare resources during a pilot involves tracking and analyzing various aspects of resource utilization. This information is crucial for assessing the cost-effectiveness and economic impact of a new treatment or intervention.

The first step is to clearly define a list of the (healthcare) resources that will be considered in the study. This can include hospital admissions, outpatient visits, laboratory tests, medications, procedures, and any other relevant services.

Healthcare resource use should be gathered at the patient or individual level. This may involve reviewing medical records, conducting interviews, or using patient diaries to capture healthcare encounters, treatments, and services.

If a pilot intervention is expected to have an impact on costs that is not limited to the third payer perspective (e.g., national health service, health insurance funds, etc.) but is spread over a variety of stakeholders (e.g., patients and their families, employers, society), data on the consumption of non-healthcare resources may also be collected. These resources may encompass for instance travel, accommodation, and formal and informal care.

More details can be found in the [full version of the methodology document \(page 9\)](#).

Monetary quantification

This phase is related to the assignment of costs to each (healthcare) resource used during a pilot. This may involve obtaining cost information from (healthcare) providers, payer databases, or using standardized cost estimates.

More details can be found in the [full version of the methodology document \(page 10\)](#).

Cost-Effectiveness Analysis (CEA)

In a cost-effectiveness analysis, the costs associated with the implementation of an intervention are compared to the outcomes or benefits it produces. These outcomes are typically measured in terms of a specific unit relevant to the intervention's objectives, such as life-years gained, quality-adjusted life years (QALYs), or units of disease prevented.

More details can be found in the [full version of the methodology document \(page 10\)](#). [\[Back\]](#)

EQUITY AND DIVERSITY (WHO BENEFITS FROM THE INTERVENTION?)

Equity refers to a desirable, or aspirational, distribution of opportunities, resources, or outcomes among individuals and population groups, according to a given set of values or principles. "Diversity" refers to the presence of different characteristics or social dimensions within a group, organization, or community, such as age, gender, race, ethnicity, sexual orientation, socioeconomic status, physical and cognitive abilities, religious beliefs, and cultural background.

The focus will be on identifying and measuring inequalities and diversity in those who are exposed to, and those who benefit from, the interventions deployed in each pilot. This will lead to an assessment of whether, and to what extent, the intervention is likely to mitigate, or exacerbate, existing inequalities in CVD and DM outcomes among individuals and relevant population groups.

The focus of this methodological framework will be on identifying and measuring inequalities and diversity in those who are exposed to, and those who benefit from, the interventions deployed in each pilot. This will lead to an assessment of whether, and to what extent, the intervention is likely to mitigate, or exacerbate, existing inequalities in CVD and DM outcomes among individuals and relevant population groups.

More details can be found in the [full version of the methodology document \(page 12\)](#). [\[Back\]](#)

SUSTAINABILITY

Sustainability in JACARDI is defined as the ability of JACARDI to ensure and sustain project impact after EU funding ends.

The multidimensional assessment framework allows pilots to evaluate the sustainability of resources and capabilities that refer to further exploitation of the pilot results after the end of JACARDI. This can be done using the results of the multidimensional assessment dimensions presented in the document before (budget, funding sources, cost-effectiveness) and the various strategic planning techniques, for example, SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis.

More details can be found in the [full version of the methodology document \(page 13\)](#).

Scalability/transferability

Assessing the scalability of a pilot involves evaluating its potential for expansion and replication to reach a larger population or be implemented in different settings. Guidance on how to assess the scalability of the pilot project can be found in the full version of the document.

Assessing the scalability of a pilot is best done at strategic points throughout its lifecycle, typically before, during, and after implementation.

More details can be found in the [full version of the methodology document \(page 14\)](#). [\[Back\]](#)

ADDITIONAL IMPLEMENTATION OUTCOMES AND PROCESS INDICATORS

Implementation outcomes aim at measuring the success or failure of implementation.

Process indicators might be measured for interventions that are expected to have significant implications not only for the individuals they target but also at the organizational levels.

More details can be found in the [full version of the methodology document \(page 15\)](#).

Extended assessment of selected pilots

The methodological framework for the multidimensional assessment of pilots offers an objective basis for evaluating the outcomes of all pilots. For a subset of pilots (at least one from each work package, WPs 6 to 11), an in-depth evaluation will be conducted by the central team for Task 5.6. This assessment will be based on the same framework but will extend the analysis to consider scaled-up scenarios.

To support this, a microsimulation model will be developed to project health outcomes and costs, providing multiple cross-sectional representations of the population over time, even beyond the data collection period. The goal is to capture the key dynamics and interactions between health parameters or risk factors and their impact on both health outcomes and costs.

More details can be found in the [full version of the methodology document \(page 21, “EXTENDED ASSESSMENT OF SELECTED PILOTS”\)](#).



JACARDI

Joint action
cardiovascular diseases
and diabetes

ANNEX VI: Methodological guidance: Steps I to XV (templates in Word)

JACARDI WP 5



Co-funded by
the European Union

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1. Introduction

This document provides templates in Word format for core pilot teams to use at their convenience. These templates are meant as a guiding tool and for data collection. The WP6-11 leadership teams adapt them to their needs or use other templates if seen as a better solution. They are not obligatory for reporting as the REDCap application will be used. According to the recent advancements, a Booklet to support documenting the pilot journey will be developed for core pilot teams, together with the WP2 - work package on communication and dissemination. This Annex may thus be less important in the future use of this Deliverable and its Annexes.

2. Methodological guidance: Steps I to XV (templates in Word version)

2.1 Step I: JACARDI core pilot team

JACARDI, WPX, Pilot xx			
Step I. JACARDI core pilot team members			
Role	Name Surname/initials (apply GDPR)	Institution	Area(s) of expertise
Organiser			
Expert			
Add lines			
Decision maker			
Add lines			

Template 1. STEP 1: JACARDI core pilot team members

2.2 Step II: Definition of the problem and general objective

JACARDI, WPX, Pilot xx

Step II. General objective

The general objective is:
Xxx

Template 2. STEP II: General objective

2.3 Step III: Situation analysis at the site of the implementation including key stakeholder analysis

JACARDI, WPX, Pilot xx			
Step III. Situation analysis			
At national/regional level			
Current situation		Future	
Positive	Negative	Positive	Negative
1	1	1	1
Add lines			

Template 3. STEP III: Situation analysis (at national/regional level)

JACARDI, WPX, Pilot xx			
Step III. Situation analysis			
At the level of pilot setting			
Current situation		Future	
Positive	Negative	Positive	Negative
1	1	1	1
Add lines			

Template 4. STEP III: Situation analysis (at the level of the pilot setting)

JACARDI, WPX, Pilot xx			
Step III. Key stakeholders			
Key stakeholders and their level of involvement			
Institution/person (Initials)	Contact known yes/no¹	Level of involvement²	Comments

¹ Contact details should be known to the organiser, here report just yes (known) or no (not known yet).

² Levels of involvement: full participation, consultation, informed.

Add lines			
-----------	--	--	--

Template 5. STEP III: Key stakeholders and their level of involvement

2.4 Step IV: Refinement of the general objective

JACARDI, WPX, Pilot xx	
Step IV. Identification of strengths and weaknesses	
Characteristics identified within Step III that are within the power of the JACARDI core pilot team and/or the fully involved stakeholders	
Positive = strengths	Negative = weakness
1	1
Add lines	

Template 6. STEP IV: Identification of strengths and weaknesses

JACARDI, WPX, Pilot xx	
Step IV. Identification of opportunities and threats	
Characteristics identified within Step III that are not within the power of the JACARDI core pilot team and/or the fully involved stakeholders or are in the future	
Positive = opportunities	Negative = threats
1	1
Add lines	

Template 7. STEP IV: Identification of opportunities and threats

JACARDI, WPX, Pilot xx

Step IV. Refined general objective

Based on this assessment, by embracing strengths, seizing opportunities, minimising weaknesses, and reducing the impact of the threats, the **general objective** is:
xxx

Template 8. STEP IV: Refined general objective

2.5 Step V: Definition of specific objectives

JACARDI, WPX, Pilot xx	
Step V. Definition of specific objectives	
Based on the general objective (Step IV), the specific objectives are:	
1.	
2.	
3.	

Template 9. STEP V: Definition of specific objectives

2.6 Step VI: Pilot implementation plan No. 1

JACARDI, WPX, Pilot xx				
Step VI. Pilot Implementation Plan No.1				
GENERAL OBJECTIVE	Please write your general objective (Step IV)			
Specific Objective 1	Please write one of your specific objectives (Step V)			
<i>Activities</i>	<i>What?</i> <i>Brief description of what has to be done to achieve the specific objective?</i>	<i>Who?</i> ³ <i>Who does what, and who is responsible for implementation?</i>	<i>When?</i> <i>Deadline for the completion</i>	<i>Indicator for the accomplishment of the activity</i> <i>How will you know that the activity was realised as planned?</i>
Activity 1.1				
Add lines if needed.				
Specific Objective 2	Please write one of your specific objectives (Step V)			
<i>Activities</i>	<i>What?</i>	<i>Who?</i>	<i>When?</i>	<i>Indicator</i>
Activity 2.1				
Add lines if needed.				
Specific Objective 3	Please write one of your specific objectives (Step V)			
<i>Activities</i>	<i>What?</i>	<i>Who?</i>	<i>When?</i>	<i>Indicator</i>
Activity 3.1				
Add lines if needed.				

Template 10. STEP VI: Pilot implementation plan No. 1

JACARDI, WPX, Pilot xx					
Step VI. Multidimensional assessment plan					
Primary and secondary outcomes of the pilot					
	Description of the outcome	Definition of the measure/indicator	Data collection approach	Timing for data collection	Timing for reporting
Primary outcome 1					
Add lines					
Secondary outcome 1					
Add lines					

³ The organiser should know this but reporting names is not required.

Dimensions for the assessment of the pilot					
Effectiveness					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Health outcome/patient-reported outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Patient experience					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Patient-reported experience measure 1					
Add lines					
If not relevant or applicable, provide justification:					
Economic efficiency					
	Description of the outcome	Definition of the measure/indicator and the analytical method and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Economic efficiency-related outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Equity and diversity					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Equity and diversity-related outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Sustainability, including scalability and/or transferability					
	Approach chosen	Approach to collect information	Approach to reach conclusions (for example, SWOT analysis)		
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends					
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends					

This dimension is relevant for all pilots in JACARDI.			
Implementation and process outcomes			
	Approach chosen	Approach chosen to collect information	Approach to reach conclusions (for example, facilitators and barriers identified)
Implementation or process outcome 1			
Add lines			
If not relevant or applicable, provide justification:			
Ethical and legal issues are identified, addressed and reported in the chapter on Ethical considerations in the Final implementation report.			

Template 11. STEP VI: Multidimensional assessment plan

2.7 Step VII: Roll-out of actions and monitoring

JACARDI, WPX, Pilot xx	
Step VII: Roll-out of actions and monitoring	
What is going on? What went well? What job was accomplished?	
Is anything going wrong? What will you do? How can the WP leadership team help? Is adaptation of the plan needed (At the level of an action, at the level of a specific objective, or in some previous steps)?	
Anything unexpected (positive, negative) happened?	

Template 12. STEP VII: Roll-out of actions and monitoring

2.8 Step VIII: Intermediate report No. 1

JACARDI, WPX, Pilot xx			
Step VIII. Intermediate report No.1 - progress status			
GENERAL OBJECTIVE			
Specific Objective 1			<i>Progress status (0%-25%-50%-75%-100%)</i>
<i>Activities</i>	<i>Description of progress based on the chosen indicator for the accomplishment of the activity</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add)</i>
Activity 1.1			
Add lines, if needed.			
Specific Objective 2			<i>Progress status (0%-25%-50%-75%-100%)</i>
<i>Activities</i>	<i>Description of progress ...</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add)</i>
Activity 2.1			
Add lines, if needed.			
Specific Objective 3			<i>Progress status (0%-25%-50%-75%-100%)</i>
<i>Activities</i>	<i>Description of progress ...</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add)</i>
Activity 3.1			
Add lines, if needed.			

Template 13. STEP VIII: Intermediate report No. 1

JACARDI, WPX, Pilot xx		
Step VIII. Multidimensional assessment report No. 1		
Primary and secondary outcomes of the pilot		
	Intermediary results	Interpretation and implications
Primary outcome 1		
Add lines		
Secondary outcome 1		
Add lines		
Dimensions for the assessment of the pilot		
Effectiveness		
	Intermediary results	Interpretation and implications
Health outcome/patient-reported outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Patient experience		
	Intermediary results	Interpretation and implications
Patient-reported experience measure 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Economic efficiency		
	Intermediary results	Interpretation and implications
Economic efficiency-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Equity and diversity		
	Intermediary results	Interpretation and implications
Equity and diversity-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Sustainability, including scalability and/or transferability		
	Intermediary results	Interpretation and implications
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		

This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis, and interpretation:

Implementation and process outcomes

	Intermediary results	Interpretation and implications
Implementation or process outcome 1		
Add lines		

Barriers and enablers of data collection, analysis, and interpretation:

Template 14. STEP VIII Multidimensional assessment report No. 1

2.9 Step IX: Pilot implementation plan No. 2

JACARDI, WPX, Pilot xx				
Step IX. Pilot implementation Plan No. 2				
GENERAL OBJECTIVE				
Specific Objective 1				
Activities	What?	Who? ⁴	When?	Indicator for the accomplishment of the activity
	<i>A brief description of what has to be done to achieve the specific objective</i>	<i>Who does what, and who is responsible for implementation?</i>	<i>Deadline for the completion</i>	<i>How will you know that the activity was realised as planned?</i>
Activity 1.1				
Add lines if needed.				
Specific Objective 2				
Activities	What?	Who?	When?	Indicator for the accomplishment of the activity
Activity 2.1				
Add lines if needed.				
Specific Objective 3				
Activities	What?	Who?	When?	Indicator for the accomplishment of the activity
Activity 3.1				
Add lines if needed.				

Template 15. STEP IX: Pilot implementation plan No. 2

⁴ The organiser should know this but reporting names is not required.

2.10 Step X: Roll-out of actions and monitoring

JACARDI, WPX, Pilot xx	
Step X: Roll-out of actions and monitoring	
What goes wrong? What will you do? How can the WP leadership team help? Is adaptation of the plan needed (At the level of an action, at the level of a specific objective, or in some previous steps?)?	
What is going on? What went well? What job was accomplished?	
Anything unexpected (positive, negative) happened?	

Template 16. STEP X: Roll-out of actions and monitoring

2.11 Step XI: Intermediate report No. 2

JACARDI, WPX, Pilot xx			
Step XI. Intermediate report No. 2 - progress status			
GENERAL OBJECTIVE			
Specific Objective 1		<i>Progress status (0%-25%-50%-75%-100%)</i>	
<i>Activities</i>	<i>Description of progress, based on the chosen indicator for the accomplishment of the activity</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add) in light of the continuation of the pilot and/or scalability/transferability</i>
Activity 1.1			
Add lines if needed.			
Specific Objective 2		<i>Progress status (0%-25%-50%-75%-100%)</i>	
<i>Activities</i>	<i>Description of progress...</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add)) in the light of the continuation of the pilot and/or scalability/transferability</i>
Activity 2.1			
Add lines if needed.			
Specific Objective 3		<i>Progress status (0%-25%-50%-75%-100%)</i>	
<i>Activities</i>	<i>Description of progress...</i>	<i>Summary of deviations</i>	<i>Decision on potential changes (adopt-adapt-abandon-add) in light of the continuation of the pilot and/or scalability/transferability</i>
Activity 3.1			
Add lines if needed.			

Template 17. STEP XI: Intermediate report No. 2

JACARDI, WPX, Pilot xx		
Step XI. Multidimensional assessment report No. 2		
Primary and secondary outcomes of the pilot		
	Intermediary results	Interpretation and implications
Primary outcome 1		
Add lines		
Secondary outcome 1		
Add lines		
Dimensions for the assessment of the pilot		
Effectiveness		
	Intermediary results	Interpretation and implications
Health outcome/patient-reported outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Patient experience		
	Intermediary results	Interpretation and implications
Patient-reported experience measure 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Economic efficiency		
	Intermediary results	Interpretation and implications
Economic efficiency-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Equity and diversity		
	Intermediary results	Interpretation and implications
Equity and diversity-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis, and interpretation:		
Sustainability, including scalability and/or transferability		
	Intermediary results	Interpretation and implications
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		

This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis, and interpretation:

Implementation and process outcomes

	Intermediary results	Interpretation and implications
Implementation or process outcome 1		
Add lines		

Barriers and enablers of data collection, analysis, and interpretation:

Template 18. STEP XI: Multidimensional assessment report No. 2

2.12 Step XII: Final implementation report

Specific objective 1 description	Progress status assessment:		
Activity 1 description	Description of the progress based on the chosen indicator/means for the accomplishment of the activity	Summary of deviations	Decision on potential changes (adopt-adapt-abandon-add) in the light of pilot continuation and/or scalability/transferability
Add lines			

Template 19. Step XII. Final report – overall progress status

Primary and secondary outcomes of the pilot			
	Final results	Interpretation and implications	
Primary outcome 1			
Add lines			
Secondary outcome 1			
Add lines			
Dimensions for the assessment of the pilot			
Effectiveness			
	Final results	Interpretation and implications	
Health outcome/patient-reported outcome 1			
Add lines			
Barriers and enablers of data collection, analysis and interpretation:			
Patient experience			
	Final results	Interpretation and implications	
Patient-reported experience measure 1			
Add lines			
Barriers and enablers of data collection, analysis and interpretation:			
Economic efficiency			
	Final results	Interpretation and implications	
Economic efficiency-related outcome 1			
Add lines			
Barriers and enablers of data collection, analysis and interpretation:			
Equity and diversity			
	Final results	Interpretation and implications	
Equity and diversity-related outcome 1			
Add lines			
Barriers and enablers of data collection, analysis and interpretation:			
Sustainability, including scalability and/or transferability			
	Final results (for example, SWOT analysis)	Interpretation and implications	
Feasibility of the continuation of the pilot (or its outcome) within			

the same setting after JACARDI ends					
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends					
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis and interpretation:					
Implementation and process outcomes					
	Final results (for example, facilitators and barriers)		Interpretation and implications		
Implementation or process outcome 1					
Add lines					
Barriers and enablers of data collection, analysis and interpretation:					

Template 20. STEP XII: Multidimensional overall assessment

Stakeholder	Level of involvement	Comments

Template 21. STEP XII: Template to report key stakeholders and their involvement during the implementation

Description of activity (What)	Final results	Interpretation and implications
Add lines		

Template 22. STEP XII: Template to report the final results of sustainability-supporting activities

General areas of contextual characteristics that potentially support sustainability	Sustainability-supporting contextual characteristics of the pilot
Existing health strategies/policy frameworks with strong connections to the pilot	
Potential holders/owners of sustainability	
Existing processes that support collaboration, consensus-seeking and engagement of stakeholders	

Template 23. STEP XII: Template to report on the sustainability-supporting contextual characteristics at the end of implementation

2.13 Step XIII: Focus on key stakeholder’s engagement in building sustainability

JACARDI, WPX, Pilot xx			
Step XIII. Focus on key stakeholders’ engagement in building sustainability			
Revisiting key stakeholders and their level of involvement			
Key stakeholders identified in Step III and their level of involvement	Key stakeholders identified during the implementation and their level of involvement	Key stakeholders identified in the present Step XIII and their level of involvement	
Final implementation report, Table 1	Final implementation report, Table 16	Institution/ person (Initials)	Level of involvement

Template 24. STEP XIII: Revisiting key stakeholders and their level of involvement

JACARDI, WPX, Pilot xx	
Step XIII. Focus on key stakeholders’ engagement in building sustainability	
STAKEHOLDER BOARD CONSULTATION MEETING: PLANNING FOR SUSTAINABILITY BEYOND JACARDI Annotated Tentative Agenda	
Introduction(s) and objectives of the meeting Key information on JACARDI Key information on sustainability as a principle	Presenters: Meeting organiser, Pilot Organizer, visible stakeholders (e.g., a representative of the Ministry of Health)
The key results, outcomes, and key findings of the pilot implementation and its sustainability-related achievements, as well as existing needs and gaps within the country/region that may benefit from the pilot’s key findings	Presenters: The core pilot team
Session I: consultation with participants (1) on the needs of the country/regions relevant to the pilot key finding, (2) on the potentially supporting context characteristics, (3) on potential other key stakeholders not yet identifies, and (4) on potential communication opportunities.	Moderator + Rapporteur Participants: All Stakeholder board members
Session II: The identification and ranking of priority areas for the	

future use of the pilot’s results and outcomes (1) within the setting of the pilot project, (2) for scaling up to other settings with similar target population/similar characteristics, (3) for transfer them to other target population, different settings or to include them in policies at the local, regional or national level.	
Session III: The identification and ranking of opportunities within the identified priority areas	
Session IV: Brainstorming on suggestions for key sustainability-supporting actions (including communication and dissemination) and related responsibilities to be included in the Sustainability Action Plan	
The following steps with information on the timeline of the Sustainability Action Plan development, including a consensus meeting of the Stakeholder board	Presenter: Meeting organiser/Pilot leader
The conclusion of the meeting	

Template 25. STEP XIII: Stakeholder board meeting: planning for sustainability beyond JACARDI – Annotated tentative agenda

JACARDI, WPX, Pilot xx		
Step XIII. Focus on key stakeholders’ engagement in building sustainability		
Step XIII. STAKEHOLDER BOARD CONSULTATION MEETING RESULTS		
Priority areas for the future continuation/sc ale-up/transfer of the pilot’s results, outcomes and key findings	List of priority areas	Ranking according to potential impact (high/mid/low)
	<ul style="list-style-type: none"> • ... • ... • ... • ... 	
Opportunities related to the priority areas	List of opportunities	Ranking according to potential impact (high/mid/low)
	<ul style="list-style-type: none"> • ... • ... • ... • ... 	
	PROPOSAL FOR ACTIVITIES	LEADING STAKEHOLDER, RESPONSIBLE STAKEHOLDER(s)

Key sustainability-supporting activities for Sustainability Action Plan 2027-28		

Template 26. STEP XIII: Stakeholder board consultation meeting results

2.14 Step XIV: Sustainability action plan

JACARDI, WPX, Pilot xx

Step XIV. Sustainability Action Plan

Check Annex VII

Template 27. STEP XIV: Sustainability action plan

2.15 Step XV: Celebrate the success

JACARDI, WPX, Pilot xx	
Step XV. Celebrating the success	
STAKEHOLDER BOARD CONSENSUS MEETING: TAKING SUSTAINABILITY ACTION PLAN ON BOARD Annotated Tentative Agenda	
Introduction(s) and objectives of the meeting	Presenters: Meeting organiser, Pilot organiser
Recap of the general outline of the Sustainability Action Plan with a focus on its general and specific objectives and the importance of proactive stakeholder involvement	Presenters: Core pilot team
Presentation I: Key stakeholder no. 1 presents their role in implementing the Sustainability Action Plan, adopting the responsibility for at least one concrete activity. (ensure representation of diversity among speakers)	Moderator: Meeting organiser Presenters: Representatives of key stakeholders Participants: All Stakeholder Board members
Presentation II: Key stakeholder no. 2 presents their role in implementing the Sustainability Action Plan, adopting the responsibility for at least one concrete activity. (ensure representation of diversity among speakers)	
Presentation III: Key stakeholder no. 3 presents their role in implementing the Sustainability Action Plan, adopting the responsibility for at least one concrete activity. (ensure representation of diversity among speakers)	
[Add agenda items as needed]	Moderator: Meeting organiser/Pilot organiser Participants: All Stakeholder Board members
Panel discussion ⁵ acknowledging the work completed during JACARDI and the key stakeholders' future support for and ownership of the pilot's results and outcomes.	

Template 28. STEP XV: Stakeholder board consensus meeting - Annotated tentative agenda

⁵ Consider adding a user/person with lived experience testimonial. The power of storytelling and testimonials of first-hand experience goes a long way.

2.16 Overview of Steps

JACARDI, WPX, Pilot xx			
Steps	Date of Completion	Organizer	Comments
I			
II			
III			
IV			
V			
VI			
VII			
VIII			
IX			
X			
XI			
XII			
XIII			
XIV			
XV			

Template 29. Overview of Steps



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JACARDI

Joint action
cardiovascular diseases
and diabetes

ANNEX VII: Final implementation report and Sustainability action plan guidance and templates

JACARDI WP Task 5.7



Co-funded by
the European Union

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Glossary of Acronyms

Acronym	Description
JA	Joint Action
DG SANTE	Directorate-General for Health and Food Safety
EU	European Union
GDPR	General Data Protection Regulation
JACARDI	Joint Action on Cardiovascular Diseases and Diabetes
WP	Work Package

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Executive summary

Annex VII provides guidance and templates for the Final implementation report and Sustainability action plan. It is a comprehensive document that encapsulates the key elements of pilot implementation reporting within the JACARDI project. It offers a thorough overview of the final reporting process, including sustainability strategies, the underlying methodology, and the significance of these activities.

This document's primary goals are to centralise and standardise the reporting of pilot activities, streamline the dissemination of findings for scientific publication, and support the sustainability and scalability of successful interventions.

The Final implementation report adheres to the SQUIRE 2.0 guidelines and aligns with the format established by DG SANTE within the EU Portal of Best and Promising Practices for practices evaluation process. This ensures that the information is presented in a format suitable for both internal use within the JACARDI consortium and external dissemination to a wider audience, including policymakers and healthcare practitioners, with an emphasis on the potential recognition of these pilots as Best Practices within the EU Portal.

The Sustainability action plan outlined in this document details specific strategies and actions designed to preserve and amplify the impact of the pilot results. The report underscores the importance of incorporating equity and diversity considerations throughout the project.

In summary, this document is an essential tool for capturing the lessons learned from the JACARDI pilots, guiding future initiatives, and fostering the long-term impact of the project's outcomes.

1. Introduction

1.1 Purpose and scope of the document

The Final implementation report and Sustainability action plan serve as the principal instruments for documenting the implementation of each pilot within the JACARDI project and supporting the sustainability of pilot results and outcomes. In addition, the template with General information helps to identify the JACARDI pilot and the team running it during the JACARDI period.

The main objectives are as follows:

1. To digitally compile essential information on the pilot, streamlining the process for the core pilot team to generate the Final implementation report and Sustainability action plan. Once all pertinent data is inputted into the digital platform, the Final implementation report and Sustainability action plan are automatically generated for download.
2. To assist the core pilot team in synthesizing the gathered information and formatting it for various dissemination purposes, including scientific publication, as well as supporting sustainability actions planning and execution.
3. To standardise and centralise the information reported within the Final implementation report and Sustainability action plan, avoiding the duplication of reports for individual tasks.
4. Support the WP6-11 leaders in compiling the final report on all pilots and the roadmap for scaling up as the main final deliverables of the respective WP6-11.
5. To facilitate the core pilot team in applying for recognition as Best Practices within the EU Portal of Best and Promising Practices
6. To clearly support the sustainability-supporting process after JACARDI funding ends.

1.2 Structure of the document

This document is structured as follows:

1. Introduction: Outlines the scope and purpose, the structure of the document, and its relation to other work in the project.
2. Development process of the single reporting system: Describes the process used to develop the Final implementation reporting
3. Single reporting system: Provides an overview of the Final implementation report, highlighting how the reporting is structured and presented.
4. Conclusions and Recommendations: Provides final thoughts and suggestions for future actions
5. Appendices on the guidance to prepare the information to submit the pilot project for evaluation at the EU Portal of Best and Promising Practices (Appendix A), and how transversal approaches are reported (sustainability – Appendix B, multidimensional assessment – Appendix C).

1.3 Relation to other work in the project

This document is directly related to other work packages (WPs), specifically technical WP6-11, which focus on compiling the final report of pilots and the roadmap for scaling up. It integrates information from various tasks (Tasks 5.3, 5.4, 5.6, WP4 and WP2) to support a unified reporting approach.

2. Development process of the single-reporting system

2.1 Development process

This document was developed through a structured and systematic process that aligns with the reporting framework mandated for all XV Steps (Task 5.4) of the JACARDI project. The structure of the Final implementation report adheres to the SQUIRE 2.0 guidelines, ensuring that the information is not only consistent and transferable but also formatted for seamless integration into scientific publications. This facilitates the effective dissemination of each project's results. The template provided for the reports is designed to be a reliable and efficient tool for extracting essential data from each pilot, streamlining the creation of the Final implementation report. Integrated within Steps I to XII, this template also incorporates key information on pilot assessment (Task 5.6), diversity and equity inclusion (Task 5.3), and communication and dissemination activities (WP2). This comprehensive approach was chosen to support the core pilot teams by eliminating redundancies and simplifying the reporting process.

The Sustainability action plan specifically addresses planning and reporting from Steps XIII to XV, ensuring that all aspects of sustainability are thoroughly documented.

Furthermore, the Final implementation reports and Sustainability action plans are integral to the compilation of the WP6-11 Deliverables as the "Final report of pilots and roadmap for scaling up." WP6-11 leaders have the ability to access and download both reports from each pilot, which can be easily integrated into the deliverable. This also allows them to extract specific fields related to equity and diversity, assessment, and sustainability, including potential scalability.

The development of the Final implementation report also draws on the established format used by DG Santé within the EU Portal of Best and Promising Practices for evaluating Best Practices. This alignment not only encourages JACARDI pilot projects that are not yet featured in the portal to apply as promising or best practices but also ensures consistency with the reporting scheme requested by the Portal. By adhering to this standardized format, pilots can efficiently compile and present their evidence in the European application process.

Overall, the integrated approach to reporting across all phases of pilot design, implementation, and assessment, combined with sustainability planning, ensures that the reporting process is streamlined and efficient, minimising duplication of effort and enhancing the quality and coherence of the final reports.

2.2 Audience benefits from the reporting

The information gathered through these reporting templates yields various benefits across different levels. Primarily, it serves to reduce the reporting burden for members of the pilot project teams in delivering the Final implementation report and the Sustainability action plan. Secondly, it aids WP6-11 leaders by facilitating the compilation of the Deliverable "Final report of pilots and roadmap for scaling up". Thirdly, it proves advantageous for members of WP2, WP4, and WP5, as it enables them to access vital information for their respective tasks, assessments, and evaluations drawn from Task 5.3, 5.6, WP2, and the Sustainability action plan.

Moreover, the reporting process benefits the overall Consortium and its impact at both national and European levels. It streamlines scientific publications, dissemination activities, and the potential application as best

practice within the EU Portal of Best and Promising Practices. Additionally, it enhances policy discussions by providing comprehensive and standardised data.

2.3 Single-reporting system principle

To ease the demanding task of reporting actions, results, and caveats for each of the planned pilot projects, the JACARDI Task 5.7 team has envisioned a single reporting system. This supports that all reporting related to the topics of different tasks across WP2 (Pilot communication report), WP4 (sustainability principle along Steps I to XII and development of Sustainability action plan in Steps XIII to XV) and WP5 (Equity and diversity principle integration (Task 5.3), Achievements at the level of individual Steps (Tasks 5.4 and 5.5), multidimensional assessment (Task 5.6) as well as within relevant WP6-11, follows the same structure, requesting the same information so as to ease the work of the core pilot team.

GENERAL INFORMATION STRUCTURE

Pilot identification details

FINAL IMPLEMENTATION REPORT STRUCTURE

Title and abstract

Introduction

Methods

Results

Discussion

Other information

Annex: Pilot communication report

SUSTAINABILITY ACTION PLAN STRUCTURE

Title and a short summary

Introduction

Process of development

Action plan

Communication and dissemination

Box 1. A single-reporting system structure

2.4 Platform to be used

RedCap is an online software chosen for the creation of the digital platform for collection of General information, and to develop the Final implementation report and Sustainability action plan. The platform will be developed starting from September 2024 and, after the testing period, available to all JACARDI pilots by January 2025. RedCap was chosen for its reliability and ease of use, as well as its compliance to the standards developed by the GDPR for data collection and privacy.

The final products will be three reports having harmonised structure across pilots, in pdf version: General Information, Final implementation report, and Sustainability action plan.

The tentative structure of the RedCap platform will include several types of fields with different functions:

- 1) white box with text in bold, with fixed text, that defines the general structure of the document. These boxes include the title of the chapter/subchapter and will be shown in the pdf file when downloaded.
Example:

Title of the (sub)chapter

- 2) dark grey box, with fixed text, that describes which Step(s) cover the information needed. These boxes provide the information to the core pilot teams on what information should be developed within the specific Step and specify exactly to the pilot organiser (s) which Steps to cover while developing the report. These boxes will not be shown in the pdf file when downloaded. Example:

Fill in with information from Step X

- 3) light grey box, with fixed text, that describes all details, that should be included in the respective subchapter. The details on the structure of the text may be given (for example, that the preformatted table should be used), or that the number of characters is limited, and similar. These boxes will not be shown in the pdf file when downloaded. Example:

Description; text limited to xxxx characters

- 4) white box, where the information required will be collected by the pilot organiser (s). Some fields may have a limited number of characters, and in some cases, exemplary sentences may be provided to help harmonise the reporting across all pilots or may include preformatted tables with predefined characteristics and/or drop/down menus. These boxes will be shown in the pdf file when downloaded. Example:

[insert text]

- 5) dark and light blue boxes, with fixed text, in this document provide the title of the respective report and titles of its sections, just for the clarity of the template in Word format; in the final technical solution, it will be solved in another way.
- 6) In summary, instructions will be included in dark and light grey boxes, for example:

Fill in with information from Step X

Description; text limited to xxxx characters

And the report itself after downloading will include only the information from white boxes, for example:

Title of the (sub)chapter

[insert text]

3. Single-reporting system

The main outcome of this phase of the project is the successful development of a comprehensive structure for the Final implementation report and Sustainability action plan. This structure not only meets the project's objectives but also integrates essential elements from Task 5.3 (diversity and equity inclusion), Task 5.6 (pilot assessment), and WP2 (communication and dissemination activities).

The creation of the template marks a significant achievement, as it provides a standardised and efficient tool for compiling and reporting on the pilot activities. The template ensures that all relevant aspects of each pilot are thoroughly documented, including the assessment of outcomes, strategies for sustainability, and efforts to promote equity and inclusion. By incorporating these critical components into a unified reporting format, the project has streamlined the documentation process, making it more efficient and reducing the potential for redundancies.

This structured approach has also facilitated the alignment of the report with broader dissemination goals, ensuring that the information is presented in a format that is not only suitable for internal use but also for external stakeholders, including scientific publications and the EU Portal of Best and Promising Practices. The development of this integrated template represents a key step forward in the project, laying a solid foundation for consistent and coherent reporting across all pilot activities.

3.1 Structure of the template (General information, Final implementation report)

General Information	
Pilot project Identification details	
Pilot project Code	
fill in with information from Step I	
Use the harmonised JACARDI coding system as defined by JACARDI project management plan	
[insert text]	
Pilot project Title	
fill in with information from Steps I to V (working title), and potentially update in Steps VIII (working title) and XII (final title)	
Describe title of the pilot	
[insert text]	
Name and Surname of Pilot Organiser(s)	
fill in with information from Steps I to V, and potentially update in Steps VIII and XII	
Insert the name and surname of the member of core pilot team, that takes over the role of an Organiser; add names and surnames if the role is taken from over by another person	
[insert text]	
Institution of Pilot Organiser	
fill in with information from Steps I to V, and potentially update in Steps VIII and XII	
Insert the name of the institution of the pilot organiser; add institutions if the role is taken from over by another person from another institution	
[insert text]	
JACARDI core pilot team	
fill in with information from Steps I to V, and potentially update in Steps VIII and XII	
Describe core pilot team members (Table A ¹). If core pilot team changes, add the new information.	
[insert text]	

Final implementation report	
Title and Abstract	
Title	
fill in with information from Steps I to V, and potentially update in Steps VIII and XII	
Start from the title of the pilot project (in General information part) and potentially adapt it to better reflect the main topic of the pilot project at the final reporting step (Step XII). The title should clearly state, that the pilot project's aim was related to the improvement of healthcare (addressing for example quality, safety, effectiveness, patient- centeredness, timeliness, cost, efficiency, and equity of healthcare) or improvement in other systems of settings, related to the specific topic.	
[insert text]	
Abstract	
fill in with all existing information within Step XII	
Write the abstract when other sections are almost finalised. Summarize all key information from various sections of the report using the structured abstract format (background, problem, methods, description of the pilot project, results, conclusions). Explicitly describe equity and diversity and sustainability as overarching principles. Adjustment of the format may be needed when developing the final text, based on the recommendations by the respective journal. Provide adequate information to aid in searching and indexing. Limit character count to be added (TBA).	
[insert text]	

¹ Table A: Core pilot team members

Keywords	
fill in with all existing information within Step XII	
Write down up to 10 key words (according to the MeSH Terms) that describe your pilot	
[insert text]	
Introduction	<i>Why did you start?</i>
Problem Description	
fill in with information from Steps I to V	
Describe the nature and significance of the problem. Describe needs of the country/region based on country-level context analysis ² . Limit character count TBA	
[insert text]	
Reflect on the equity and diversity aspect of the problem ³ .	
[insert text]	
Available knowledge	
fill in with information from Steps I to V	
Summarise, what is currently (at the time of performing Steps I to V) known about the problem, including relevant previous studies and practices. Limit character count TBA.	
[insert text]	
Rationale including general objective	
fill in with information from Steps I to V, with focus to Steps II and IV, potentially update in Steps VIII and XII	
Describe frameworks (formal, informal), models, concepts and/or theories used to explain the problem, any reasons or assumptions that will be used to develop the pilot and reasons why the pilot is expected to work. Include learnings from practices from other settings and contexts (EU Best Practices, other validated practices), referring to Effectiveness and efficiency of the intervention, Equity, Transferability, Sustainability, Participation or Intersectoral collaboration (at least one of those). Describe purpose of JACARDI ⁴ including the aims of respective WP6-11. Describe the purpose of the pilot. Define general objective, including target population. Limit character count TBA	
[insert text]	
Reflect on the equity and diversity as an overarching principle in JACARDI ⁵ . Describe, how you applied equity and diversity principle in problem definition [Step II], in EU best practice/other practice selection [Step V], in general objective [Step II], and within the refinements of general objective [Step IV], use Equity and diversity matrix ⁶ .	
[insert text]	
Describe the most relevant changes in general objective during time period from Step V to Step XII.	
[insert text]	
Specific objectives	
fill in with information from Steps I to V, with focus to Step V, potentially update in Steps VIII and XII	
Describe specific objectives (up to 3 preferably). Limit character count TBA.	
[insert text]	
Reflect on how you applied equity and diversity principle in defining specific objectives [Step V].	

² General information on country level needs assessment is provided in Deliverable 5.2 State of the art – Report of findings from the review and context analysis (in WP5 Teams folder Deliverables and Milestones) and in detailed reports within respective milestone in WP6-11 (in WP6-11 Teams folder Deliverables and Milestones: Milestone 19 WP6 -Mapping of available best practices/interventions on health literacy and health promotion and awareness to local needs and situation of pilot sites/countries; Milestone 24 WP7 – Mapping to identify gaps and needs for pilots' implementation; Milestone 28 WP8 – Mapping of available best practices/interventions on screening and situation of pilot site/countries; Milestone 33 WP9 - Mapping of patient care and service pathways implementation needs at all implementation sites identified; Milestone 37 WP10 – Mapping self-management support needs; Milestone 41 WP11-Mapping of factors affecting labour participation of people with NCDs in piloting countries).

³ Exemplary text to be added (TBA)

⁴ Exemplary text TBA

⁵ Exemplary text TBA

⁶ Equity and diversity matrix is included in each Step of JACARDI methodological framework (Deliverable 5.1).

[insert text]	
Describe the most relevant changes in specific objectives during time period from Step VI to Step XII	
[insert text]	
Methods	<i>What did you do?</i>
Situation analysis including key stakeholder analysis	
fill in with information from Step III, and potentially update in Steps VIII and XII	
Describe contextual elements from situation analysis considered important at the stage of pilot development, related to the characteristics of the intervention, outer and inner setting, characteristics of the individuals involved and the implementation process itself. Describe key stakeholders and their level of involvement in Table 1 ⁷ . Limit character count TBA	
[insert text]	
Describe sustainability - supporting contextual characteristics including existing health strategies/policy frameworks with strong connections, potential holders/owners of sustainability and processes that support collaboration, consensus seeking and engagement of stakeholders at the planning phase in Table 2 ⁸ .	
[insert text]	
Describe, how you applied equity and diversity principle in situation analysis including key stakeholder analysis [Step III] in Table 3 ⁹ , using Equity and diversity matrix.	
[insert text]	
Describe the most relevant changes in contextual characteristics as well as key stakeholder analysis (identification and/or level of involvement) during time period from Step III to Step XII.	
[insert text]	
Specifics of the team involved in the work	
fill in with information from Step I, and update in Steps VIII and XII	
Describe core pilot team members per role and expertise, do not include personal data, and apply GDPR; add other members of pilot project team, for example those directly involved in activities as defined in pilot implementation plan, all reported in Table 4 ¹⁰ . Describe the strengths of the team with regards to building sustainability ("sustainability lens", Step I). Limit character count TBA.	
[insert text]	
Describe, how you applied equity and diversity principle within core pilot team [Step I] in Table 5 ¹¹ , using Equity and diversity matrix.	
[insert text]	
If the pilot team membership changes, add the new information. Describe the most relevant changes during time period from Step I to Step XII	
[insert text]	
Description of the pilot	
fill in with information from Steps II to VI, and update in Steps VIII and XII	
Describe general information on pilot project implementation: country or region of the pilot implementation, duration of the pilot ¹² as start date and ending date, geographical scope ¹³ and general type of the intervention ¹⁴ . Describe target population in detail ¹⁵ .	

⁷ Table 1. Key stakeholders and their involvement in planning phase

⁸ Table 2. Sustainability-supporting contextual characteristics in planning phase

⁹ Table 3. Integration of equity and diversity principle in situation analysis including key stakeholder analysis

¹⁰ Table 4. Team involved in the work

¹¹ Table 5. Integration of equity and diversity principle in composing a team

¹² Start date is the starting month and year of the start of Step I, that is organising of the core pilot team. Ending date is the end of last activity in Step X, that is the end of roll out of activities.

¹³ Multiple answers are possible: National, Regional, Local

¹⁴ Types of intervention as defined by EC Best practice portal (multiple answers possible): Information/Awareness Raising Campaign, E-health including mHealth, Policy, Research project, Service delivery, Tool/Instrument, Guideline, Training, Intervention, Screening, Other (specify in a sentence)

¹⁵ Target population are persons or entities who were positively affected by the action. A proper target group specification provides a clear definition of inclusion and exclusion criteria, including information about the demographic characteristics, the needs and social norms with

[insert text]
Describe the pilot project and pilot activities in sufficient detail that others could reproduce it ¹⁶ . Limit character count TBA.
[insert text]
Describe (at least one) activity(-ies) to increase the potential for sustainability in Table 6 ¹⁷ , including the activity related to stakeholders board.
[insert text]
Describe, how you applied equity and diversity principle in defining the general objective, specific objectives and pilot activities within pilot implementation plan [Steps II, IV, V and VI] in Table 7 ¹⁸ , using Equity and diversity matrix.
[insert text]
Describe the most relevant changes during time period from Step VI to Step XII. Describe the changes introduced to further increase the potential for sustainability, and to integrate better the equity and diversity principle.
[insert text]
Approaches and/or measures to assess the pilot project results
fill in with information from Step VI, and update in Steps VIII and XII
Describe the means of verification of progress status at the level of specific objectives ¹⁹ and at the level of activities [Step VI] in Table 8 ²⁰ .
[insert text]
Describe approaches and/or measures to assess the pilot project outcomes , including rationale for choosing them. By applying the methodological framework for multidimensional pilot assessment describe the essential information from Multidimensional assessment plan in Table 9 ²¹ :
[insert text]
Describe the approach(es) to assess the ongoing scanning of the contextual elements that have the potential to contribute to the success, failure, efficiency and cost, and thus to have the potential to have an influence on sustainability of the pilot (including scalability and/or transferability ²²) after JACARDI ends, such as existing health strategies/policy frameworks with strong connections, potential holders/owners of sustainability (among stakeholders), and processes that support collaboration, consensus seeking and engagement of stakeholders.
[insert text]
Describe the self-assessment approach, that you applied for integration of equity and diversity principle in planning each of the Step, and in assessing of each Step within reporting ²³ .
[insert text]
Analytical methods
fill in with information from Step VI, and update in Steps VIII and XII
Describe the analytical methods to analyse the progress status at the level of specific objectives and at the level of activities ²⁴ .
[insert text]

regard to the health problem(s) of interest, the size (i.e., the numbers that will be reached by the action), and the method to reach and select these people.

¹⁶ Describe for example how the treatment group of the pilot is defined, what intervention will they receive, how is the control group (counterfactual) defined, what intervention will they receive; how are the treatment group participants selected and how are the control group participants selected; what is the timeline of the intervention and for its assessment.

¹⁷ Table 6. Sustainability supporting activities

¹⁸ Table 7. Integration of equity and diversity principle in developing general objective, specific objectives and pilot activities in pilot implementation plan

¹⁹ Exemplary text TBA

²⁰ Table 8. Approach to verify the progress status of specific objectives and roll-out of activities

²¹ Table 9. Multidimensional assessment plan

²² Assessing scalability of a pilot involves evaluating its potential for expansion and replication to reach a larger population or be implemented in different settings. Transferability refers to the extent to which the findings and outcomes of the pilot can be applied to other settings, populations, or contexts beyond the original pilot environment.

²³ Exemplary text TBA

²⁴ Exemplary text TBA

Describe analytical methods to analyse the pilot outcomes, the analytical methods that will be used to draw inferences from the data/information, the methods for understanding the variation within the data, including time as a variable ²⁵ .	
[insert text]	
Describe analytical methods to assess the potential for sustainability of the pilot/its results/outcomes ²⁶ .	
[insert text]	
Describe analytical methods to assess the integration of equity and diversity principle ²⁷ .	
[insert text]	
Describe the institution that undertook the evaluation and their level of independence from the pilot, and how was it carried out. Describe specifically which methods included self-assessment approaches and provide justification for this approach.	
[insert text]	
Ethical Considerations	
fill in with information from Step VI, and update in Steps VIII and XII	
Describe ethical aspects of implementing the pilot and studying the results, and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest. Explicitly include statement on ethics standard in JACARDI ²⁸	
[insert text]	
Results	<i>What did you find?</i>
Intermediary results	
fill in with information from Step VIII and XI	
Describe the relevant intermediary results related to the progress status at the level of specific objectives and at the level of activities in Table 10 ²⁹ and Table 11 ³⁰ .	
[insert text]	
Describe relevant intermediary results at the level of pilot outcomes in Table 12 ³¹ and Table 13 ³² by applying the methodological framework for multidimensional pilot assessment, if applicable based on their planned timing for reporting.	
[insert text]	
Describe intermediary results related to sustainability of the pilot: describe intermediary results of activity(-ies) that were planned to increase the potential for sustainability. Describe potential sustainability- supporting changes of contextual characteristics (existing health strategies/policy frameworks with strong connections, potential holders of sustainability (among stakeholders), and processes that support collaboration, consensus seeking and engagement of stakeholders).	
[insert text]	
Describe, how you applied equity and diversity principle in the first roll-out of actions and monitoring [Step VII], and in the first intermediate reporting [Step VIII] in Table 14 ³³ , and in adaptations to second pilot implementation plan [Step IX], second roll-out of actions and monitoring [Step X], and in the second intermediate reporting [Step XI] in Table 15 ³⁴ using Equity and diversity matrix.	
[insert text]	

²⁵ Exemplary text TBA

²⁶ Exemplary text TBA

²⁷ Exemplary text TBA

²⁸ Obligatory statement to be included: "JACARDI pilot was implemented with the highest standards of ethics and in full compliance with the General Data Protection Regulation (GDPR) in the European Union, using standardised procedure, defined by project management plan and under supervision of JACARDI Coordination team."

²⁹ Table 10. Intermediary results 1 of the progress status

³⁰ Table 11. Intermediary results 2 of the progress status

³¹ Table 12. Multidimensional assessment intermediary report No 1

³² Table 13. Multidimensional assessment intermediary report No 2

³³ Table 14. Integration of equity and diversity principle in the first roll-out of actions and monitoring and intermediate reporting

³⁴ Table 15. Integration of equity and diversity principle in adaptation to second pilot implementation plan, second roll-out of actions and monitoring and intermediate reporting

Describe, how initial general objective, specific objectives and/or actions evolved and/or other elements were modified based on the results at the stage of first intermediate reporting, including the intermediate results related to sustainability, and intermediate results related to equity and diversity.	
[insert text]	
Final Results	
fill in with all existing information within Step XII	
Describe, how initial general objective, specific objectives and/or actions, desired pilot outcomes evolved and/or other elements were modified based on the results at the stage of final reporting, including the results related to sustainability, and results related to equity and diversity.	
[insert text]	
Describe how contextual elements interacted with the pilot and the observed associations to the pilot itself and the outcomes, related for example to the characteristics of the intervention, outer and inner setting, of the individuals involved and the implementation process itself. Describe unplanned issues, such as unexpected benefits, problems, failures, or costs associated with the intervention. Describe key stakeholders and their level of involvement in Steps VI to XII in Table 16 ³⁵ . Describe details on Stakeholders board : month and year of its establishment, their engagement in Steps VI-XI.	
[insert text]	
Describe the final result (overall, covering both implementation cycles) related to the progress status at the level of specific objectives and at the level of activities in Table 17 ³⁶ .	
[insert text]	
Describe final results (overall, covering both implementation cycles) at the level of pilot outcomes in Table 18 ³⁷ by applying the methodological framework for multidimensional pilot assessment .	
[insert text]	
Describe final results related to sustainability of the pilot (overall, covering both implementation cycles): describe final results of activity(-ies) that were planned to increase the potential for sustainability in Table 19 ³⁸ , including the activity related to stakeholders board. Specifically describe final results of all other activity(-ies) with the potential to increase sustainability. Describe sustainability-supporting contextual characteristics at the end of the implementation in Table 20 ³⁹ .	
[insert text]	
Describe, how you applied equity and diversity principle in the final reporting [Step XII] in Table 21 ⁴⁰ , using Equity and diversity matrix. Reflect on how you applied equity and diversity principle along all steps.	
[insert text]	
Discussion	<i>What does it mean?</i>
Summary	
fill in with all existing information within Step XII	
Describe key results and outcomes of the pilot, with reference to the rationale, general objective and specific objectives. Explicitly describe key findings. Specify usefulness of pilot findings as response to country/region needs as well as to the situation of the pilot as described in Methods. Describe strengths of JACARDI, include the sustainability , and equity and diversity as overarching principles. Describe the strengths of the pilot.	
[insert text]	
Interpretation	
fill in with all existing information within Step XII	
Describe the nature of the association between the pilot and the outcomes/results. Compare of the outcomes/results with findings from other publications. Describe the impact of the pilot on the people	

³⁵ Table 16. Key stakeholders and their level of involvement during implementation

³⁶ Table 17. Final results of the progress status at the level of specific objectives and activities

³⁷ Table 18. Final report of multidimensional assessment

³⁸ Table 19. Final results of sustainability supporting activities

³⁹ Table 20. Sustainability-supporting contextual characteristics at the end of the implementation

⁴⁰ Table 21. Integration of equity and diversity principle in final reporting

<p>and on systems. Describe reasons for any differences between observed and anticipated outcomes/results, including the influence of the context, focusing to related to the characteristics of the pilot, outer and inner setting, of the individuals involved and the implementation process itself. Interpret the costs and strategic trade-offs, including opportunity costs. Describe the interpretation of the results, implications and justification including the key findings. Describe their benefits to address the country/region needs, as well as the characteristics of the situation of the pilot project as described in Methods.</p>
[insert text]
<p>Describe the sustainability characteristics of the pilot, explicitly outlining key sustainability supporting achievements (interpretation of results as captured using measures within sustainability dimension of multidimensional framework, results of sustainability-supporting activity(-ies), sustainability supporting changes in contextual characteristics), other observations. Describe the added value of Stakeholders board. Describe relevant situation within the country/region with identification of existing needs related to the topic of the pilot, based on the results of country profiles produces within JACARDI. Present, how pilot results and outcomes are addressing those needs. Describe those characteristics of the pilot, that show how equity and diversity principle was applied in practice.</p>
[insert text]
Limitations
fill in with all existing information within Step XII
<p>Describe limitations to the generalizability of the work. Describe factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis.</p> <p>Describe efforts made to minimize and adjust for limitations.</p>
[insert text]
Conclusions including sustainability
fill in with all existing information within Step XII
<p>Describe briefly the results and key findings. Describe usefulness of the work, specifically addressing the respective region/country needs, as well as how it responds to identified characteristics of the pilot situation. Describe implications for practice and for further study in the field. Reflect on the equity and diversity as an overarching principle of the pilot and include the main message. Describe sustainability potential of the pilot's results/outcomes including the potential for scalability and/or transferability to other contexts, and how scalability and/or transferability were considered in a systematic way. Specify details about any synergies, compatibilities or any conflicts between the pilot and any other similar practice implemented in the same context/region/country. Define suggested next steps, with focus the process to develop Sustainability action plan (including the plan for anchoring of the ownership and increased visibility)⁴¹.</p>
[insert text]
Other information
Funding
fill in with all existing information within Step XII
<p>Funding: funding of JACARDI⁴² including cofounding relevant institution within the country; potential other funding sources (define the role of other organisations in the design, implementation, interpretation and reporting).</p>
[insert text]
Annex
Pilot communication report
fill in with information from Step I to XII

⁴¹ Exemplary sentence TBA

⁴² Exemplary standard sentence on cofounding from EC TBA

Describe shortly the main aim of the communication and the goal(s); describe information on main communication and dissemination activities in Table 22⁴³.

[insert text]

Structure of the Tables

Table A: Core pilot team members:

Name Surname/Initials (apply GDPR)	Institution	Role in core team	Area(s) of expertise
Add lines			

Table 1. Key stakeholders and their involvement in planning phase

Stakeholder	Level of involvement	Comments

Table 2. Sustainability-supporting contextual characteristics in planning phase

General areas of contextual characteristics, that potentially support sustainability	Sustainability-supporting contextual characteristics of the pilot
Existing health strategies/policy frameworks with strong connections to the pilot	
Potential holders/owners of sustainability	
Existing processes that support collaboration, consensus seeking and engagement of stakeholders	

Table 3. Integration of equity and diversity principle in situation analysis including key stakeholder analysis

	Self-assessment: (drop-down menu)	Description (drop-down menu)	Comments
Conduct a pilot-level stakeholder analysis			
Meaningfully engage diverse stakeholders			
Identify the impact on diverse end users/ end beneficiaries			

Table 4. Team involved in the work

Name Surname/Initials (apply GDPR)	Institution	Role in core team	Area(s) of expertise
Add lines			

⁴³ Table 27. Pilot communication report

Table 5. Integration of equity and diversity principle in composing a team

	Self-assessment: (drop-down menu)	Description (drop-down menu)	Comments
Compose a diverse core pilot team			
Strengthen capacity in equity and diversity within the core pilot team			

Table 6. Sustainability supporting activities

Description of activity (What)	Timeline (When)	Indicator/means for the accomplishment
Add lines		

Table 7. Integration of equity and diversity principle in developing general objective, specific objectives and pilot activities in pilot implementation plan

	Self-assessment: (drop-down menu)	Description (drop-down menu)	Comments
Apply equity and diversity principles in the definition of the problem and the general objective			
Engage diverse stakeholders in refinement of the general objective			
Apply the equity and diversity perspectives in the definition of specific objectives			
Consider equity and diversity when selecting EU best practices/other evidence-based practices			
Engage diverse stakeholders in development of the pilot implementation plan			
Integrate equity and diversity perspectives in the pilot implementation plan			
Integrate equity and diversity perspectives in the pilot communication			

Table 8. Approach to verify the progress status of specific objectives and roll-out of activities

Specific objectives	Activities
Progress status is self-assessed semi quantitatively based on the perceived progress towards the specific objective, using the scale:	Progress status is self-assessed, based on the chosen indicator/means for the accomplishment
0% - NOTHING DONE: No progress towards the objective or initial steps taken 25% - BEGINNING: Initial progress made and preliminary activities are completed 50% - MIDWAY: The objective is halfway achieved with several key activities accomplished 75% - ADVANCED: The objective is mostly accomplished with most activities completed 100% - COMPLETED: The objective is fully achieved and all activities completed	

Table 9. Multidimensional assessment plan

Primary and secondary outcomes of the pilot					
	Description of the outcome	Definition of the measure/indicator	Data collection approach	Timing for data collection	Timing for reporting
Primary outcome 1					
Add lines					
Secondary outcome 1					
Add lines					
Dimensions for the assessment of the pilot					
Effectiveness					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Health outcome/patient-reported outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Patient experience					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Patient-reported experience measure 1					
Add lines					
If not relevant or applicable, provide justification:					
Economic efficiency					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting

Economic efficiency-related outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Equity and diversity					
	Description of the outcome	Definition of the measure/indicator and the analytical method	Data collection approach	Timing for data collection	Timing for reporting
Equity and diversity related outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Sustainability, including scalability and/or transferability					
	Approach chosen	Approach to collect information	Approach to reach conclusions (for example SWOT analysis)		
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends					
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends					
This dimension is relevant for all pilots in JACARDI					
Implementation and process outcomes					
	Approach chosen	Approach chosen to collect information	Approach to reach conclusions (for example facilitators and barriers identified)		
Implementation or process outcome 1					
Add lines					
If not relevant or applicable, provide justification:					
Ethical and legal issues are identified, addressed and reported in chapter on Ethical considerations in Final implementation report.					

Table 10. Intermediary results 1 of the progress status

Specific objective 1 description	Progress status assessment:		
Activity 1 description	Description of the progress based on the chosen indicator/means for the accomplishment of activity	Summary of deviations	Decision on potential changes (adopt-adapt-abandon-add)
Add lines			

Table 11. Intermediary results 2 of the progress status

Specific objective 1 description	Progress status assessment:		
Activity 1 description	Description of the progress based on the chosen indicator/means	Summary of deviations	Decision on potential changes (adopt-adapt-abandon-add) in the

	for the accomplishment of activity		light of pilot continuation, and/or scalability/transferability
Add lines			

Table 12. Multidimensional assessment intermediary report No. 1

Primary and secondary outcomes of the pilot			
	Intermediary results	Interpretation and implications	
Primary outcome 1			
Add lines			
Secondary outcome 1			
Add lines			
Dimensions for the assessment of the pilot			
Effectiveness			
	Intermediary results	Interpretation and implications	
Health outcome/patient-reported outcome 1			
Add lines			
Barriers and enablers of data collection, analysis and interpretation:			
Patient experience			
	Intermediary results	Interpretation and implications	
Patient-reported experience measure 1			
Add lines			
Barriers and enablers of data collection, analysis and interpretation:			
Economic efficiency			
	Intermediary results	Interpretation and implications	
Economic efficiency-related outcome 1			
Add lines			
Barriers and enablers of data collection, analysis and interpretation:			
Equity and diversity			
	Intermediary results	Interpretation and implications	
Equity and diversity related outcome 1			
Add lines			
Barriers and enablers of data collection, analysis and interpretation:			
Sustainability, including scalability and/or transferability			
	Intermediary results	Interpretation and implications	
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends			
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends			
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis and interpretation:			
Implementation and process outcomes			
	Intermediary results	Interpretation and implications	

Implementation or process outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		

Table 13. Multidimensional assessment intermediary report No. 2

Primary and secondary outcomes of the pilot		
	Intermediary results	Interpretation and implications
Primary outcome 1		
Add lines		
Secondary outcome 1		
Add lines		
Dimensions for the assessment of the pilot		
Effectiveness		
	Intermediary results	Interpretation and implications
Health outcome/patient-reported outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		
Patient experience		
	Intermediary results	Interpretation and implications
Patient-reported experience measure 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		
Economic efficiency		
	Intermediary results	Interpretation and implications
Economic efficiency-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		
Equity and diversity		
	Intermediary results	Interpretation and implications
Equity and diversity related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		
Sustainability, including scalability and/or transferability		
	Intermediary results	Interpretation and implications
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis and interpretation:		
Implementation and process outcomes		
	Intermediary results	Interpretation and implications

Implementation or process outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		

Table 14. Integration of equity and diversity principle in the first roll-out of actions and monitoring and intermediate reporting

	Self-assessment: (drop-down menu)	Description (drop-down menu)	Comments
Identify how equity and diversity principles will be monitored			
Apply equity and diversity perspectives during roll-out of actions			
Continue strengthening capacity in equity and diversity within the pilot team			
Consider core pilot team composition			
Engage diverse stakeholders in evaluation of intermediate results			
Integrate equity and diversity perspectives in intermediate reporting			
Integrate equity and diversity perspectives in intermediate reporting on pilot communication			

Table 15. Integration of equity and diversity principle in adaptation to second pilot implementation plan, second roll-out of actions and monitoring and intermediate reporting

	Self-assessment: (drop-down menu)	Description (drop-down menu)	Comments
Engage diverse stakeholders in development of pilot implementation plan			
Integrate equity and diversity perspectives in the pilot implementation plan			
Integrate equity and diversity perspectives			

in the pilot communication			
Monitor (and if needed revise) equity and diversity principles			
Apply equity and diversity perspectives during roll-out of actions			
Continue strengthening capacity in equity and diversity within the pilot team			
Consider core pilot team composition			
Engage diverse stakeholders in evaluation of intermediate results			
Integrate equity and diversity perspectives in intermediate reporting			
Integrate equity and diversity perspectives in intermediate reporting on pilot communication			

Table 16. Key stakeholders and their involvement during the implementation

Stakeholder	Level of involvement	Comments

Table 17. Final results of the progress status at the level of specific objectives and activities

Specific objective 1 description	Progress status assessment:		
Activity 1 description	Description of the progress based on the chosen indicator/means for the accomplishment of activity	Summary of deviations	Decision on potential changes (adopt-adapt-abandon-add) in the light of pilot continuation, and/or scalability/transferability
Add lines			

Table 18. Final report of multidimensional assessment

Primary and secondary outcomes of the pilot		
	Final results	Interpretation and implications
Primary outcome 1		
Add lines		

Secondary outcome 1		
Add lines		
Dimensions for the assessment of the pilot		
Effectiveness		
	Final results	Interpretation and implications
Health outcome/patient-reported outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		
Patient experience		
	Final results	Interpretation and implications
Patient-reported experience measure 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		
Economic efficiency		
	Final results	Interpretation and implications
Economic efficiency-related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		
Equity and diversity		
	Final results	Interpretation and implications
Equity and diversity related outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		
Sustainability, including scalability and/or transferability		
	Final results (for example SWOT analysis)	Interpretation and implications
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis and interpretation:		
Implementation and process outcomes		
	Final results (for example facilitators and barriers)	Interpretation and implications
Implementation or process outcome 1		
Add lines		
Barriers and enablers of data collection, analysis and interpretation:		

Table 19. Final results of sustainability supporting activities

Description of activity (What)	Final results	Interpretation and implications
Add lines		

Table 20. Sustainability-supporting contextual characteristics at the end of the implementation

General areas of contextual characteristics, that potentially support sustainability	Sustainability-supporting contextual characteristics of the pilot
Existing health strategies/policy frameworks with strong connections to the pilot	
Potential holders/owners of sustainability	
Existing processes that support collaboration, consensus seeking and engagement of stakeholders	

Table 21. Integration of equity and diversity principle in final reporting

	Self-assessment: (drop-down menu)	Description (drop-down menu)	Comments
Return results to the community and engage diverse stakeholders in evaluation of results			
Integrate equity and diversity perspectives in reporting			
Integrate equity and diversity perspectives in reporting on pilot communication			

Table 22. Pilot communication report

Activity name	Short description/Key message(s)	Communication channel	Target audience	Date	Outcome /reach	Subjective evaluation
Activity No 1						
Add lines						

3.2 Structure of the template (Sustainability action plan)

Sustainability action plan	
Title	Describe the title of the Sustainability action plan. It should be clear, concise, and indicative of its purpose. It should be aligned with the general objective of Sustainability action plan and may reflect on “what”, “where” and “when”.
	[insert text]
List of contributors	Include all individuals, involved at any stage of sustainability-supporting work within Steps I to XV and/or contributed to the development of Sustainability action plan in Table I ⁴⁴ .
	[insert text]
Short summary	Main messages from the Sustainability action plan should be summarised: rising burden of cardiovascular diseases and diabetes, JACARDI as a response of EU and EU countries, needs and gaps in the country/region, key findings of JACARDI pilot project, process of development including integration of equity and diversity principle, identified priority areas and opportunities, general objective and specific objectives, overview of the actions including communication and dissemination.
	[insert text]
Introduction	
Burden of the cardiovascular diseases and diabetes	Describe shortly the problem of rising burden of the cardiovascular diseases and diabetes. Emphasize the groups, that are most impacted. Use the information from Final implementation report (Introduction), and add relevant updates.
	[insert text]
JACARDI as a response of EU and European countries	Describe shortly the mission of JACARDI. Describe overall aims of your respective WP6-11, relevant for the pilot project. Use the information from Final implementation report (Introduction).
	[insert text]
Needs and gaps of the country/region	Describe shortly the main needs of your country, based on country-level context analysis ⁴⁵ . Use the information from Final implementation report (Introduction, Discussion). Update with relevant information from consultation meeting(s) with Stakeholder board.
	[insert text]
Results and outcomes of JACARDI pilot project	Describe shortly the main results of the pilot. Use the information from Final implementation report (Final results, Discussion).
	[insert text]
Key sustainability supporting achievements of JACARDI pilot project	Describe shortly the main sustainability supporting achievements of JACARDI pilot project in Table II ⁴⁶ Explicitly underline the consideration of equity and diversity perspectives and engagement of

⁴⁴ Table I. List of contributors

⁴⁵ General information on country level needs assessment is provided in Deliverable 5.2 State of the art – Report of findings from the review and context analysis (in WP5 Teams folder Deliverables and Milestones) and in detailed reports within respective milestone in WP6-11 (in WP6-11 Teams folder Deliverables and Milestones: Milestone 19 WP6 -Mapping of available best practices/interventions on health literacy and health promotion and awareness to local needs and situation of pilot sites/countries; Milestone 24 WP7 – Mapping to identify gaps and needs for pilots’ implementation; Milestone 28 WP8 – Mapping of available best practices/interventions on screening and situation of pilot site/countries; Milestone 33 WP9 - Mapping of patient care and service pathways implementation needs at all implementation sites identified; Milestone 37 WP10 – Mapping self-management support needs; Milestone 41 WP11-Mapping of factors affecting labour participation of people with NCDs in piloting countries).

⁴⁶ Table II. Key sustainability-related achievements of the pilot project, after consultation with Stakeholder board

diverse stakeholders, including end users/end beneficiary groups to guide pilot actions for maximum social impact. Use the information from Final implementation report (Final results, Discussion) and update with relevant information from consultation meeting(s) with Stakeholder board.
[insert text]
Process of development
Describe, how the sustainability principle was integrated in all steps of development, implementation, monitoring and reporting of pilot project. Describe how this principle was applied in the respective pilot by using the information from Final implementation report (Final results, Discussion).
[insert text]
Describe essential information on Stakeholder board consultation meeting(s), the development of the draft Sustainability action plan by core team members and on consensus meeting with Stakeholder board in Table III ⁴⁷ .
[insert text]
Equity and diversity in action
Describe, that equity and diversity principle was integrated in all steps of development, implementation, monitoring and reporting of pilot project by applying critical reflection, context and data, co-design, and inclusive and accessible communication. Describe how this principle was applied in the respective pilot Describe how this principle was applied in the respective pilot by using the information from Final implementation report (Final results, Discussion).
[insert text]
Describe, by applying Equity and diversity matrix, how the principle is integrated in stakeholder's engagement in building sustainability (Step XIII), in development of this document (Step XV) and in supporting its communication and dissemination events to strengthen ownership and increase visibility (Step XV) in Table IV ⁴⁸ .
[insert text]
Priority areas and their ranking
Define priority areas for future uptake of JACARDI pilot project results, based on assessment of feasibility for the continuation of the pilot's result or its outcome within the same setting, and/or for scalability/transferability ⁴⁹ after JACARDI ends. List them according to their level of impact (high, medium, low). Input information coming from Table 18 in Final implementation report with updates from relevant information from consultation meeting(s) with Stakeholder board, and from sustainability supporting contextual characteristic from Table 20 in Final implementation report with updates from relevant information from consultation meeting(s) with Stakeholder board).
[insert text]
Opportunities
Describe the opportunities as identified during consultation meeting(s) with Stakeholder board, and list them according to their level of impact in (high, medium, low). Describe, how opportunities minimise the weaknesses of JACARDI pilot project results and outcomes, and incorporate the strengths of the pilot results or outcomes. Describe threats and the plans to leverage them. Input information coming from Table 18 in Final implementation report with updates from relevant information from consultation meeting(s).
[insert text]
Action plan
General objective and specific objectives

⁴⁷ Table III. Process of development

⁴⁸ Table IV. Integration of equity and diversity principle in stakeholder's engagement, in development of Sustainability action plan and in the actions to strengthen ownership and increase visibility

⁴⁹ Assessing scalability of a pilot involves evaluating its potential for expansion and replication to reach a larger population or be implemented in different settings. Transferability refers to the extent to which the findings and outcomes of the pilot can be applied to other settings, populations, or contexts beyond the original pilot environment.

Describe general objective and specific objectives of Sustainability action plan in Table V ⁵⁰ . They should refer to priority areas and embrace opportunities with highest level of impact, while building on the strengths of JACARDI pilot project and limiting the treats. Apply critical reflection, context and data, co-design, and inclusive and accessible communication.
[insert text]
Actions
Define the actions within predefined Table VI ⁵¹ . They should be aligned to the general and specific objectives of Sustainability action plan.
[insert text]
Communication and dissemination
Define communication and dissemination activities to support implementation of Sustainability action plan within JACARDI (Step XV) and beyond (up to 2 years) in Table VII ⁵² . Focus to further engagement of key stakeholders to anchor ownership, and to increase visibility of the pilot project achievements. Apply skills of efficient science to policy communication and engagement, acquired in the JACARDI course. Apply inclusive and accessible communication guidelines ⁵³ . Follow general practical advice on how to communicate effectively and efficiently (“Communication guide for JACARDI pilots”), tips to consider specifically in communication and dissemination activities in Sustainability action plan, and examples of relevant activities, provided in Step XIII in Deliverable 5.1 Methodological framework.
[insert text]

⁵⁰ Table V. General and specific objectives

⁵¹ Table VI. Sustainability action plan

⁵² Table VII. Communication and dissemination activities

⁵³ Guidelines and a checklist for inclusive and accessible communication in the JACARDI project, Teams area of WP2, folder Deliverables and Milestones.

Structure of the tables

Table I. List of contributors

Name and surname	Institution	Role/function/expertise	Contributions (core writing group member, consultant, reviewer, member of Stakeholder Board etc)
Add lines			

Table II. Key sustainability-related achievements of the pilot project, after consultation with Stakeholder board

	Final results after consultation with Stakeholder board	Interpretation and implications
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		
Results of sustainability-supporting activities		
Existing health strategies/policy frameworks with strong connections to the pilot project		
Potential holders/owners of sustainability		
Existing processes that support collaboration, consensus seeking and engagement of stakeholders		

Table III. Process of development

Stakeholder board consultation meeting(s)				
Objectives	Date	Number of participants	Stakeholders represented	Moderator, rapporteur
<ul style="list-style-type: none"> - to share key results, outcomes and key findings of pilot project - to share key sustainability-related achievements of pilot project - to consult on country/region needs, potentially related to pilot project findings - to consult on potentially supporting context characteristics 				

<ul style="list-style-type: none"> - to consult on other key stakeholders, and communication opportunities - to identify priority areas for future continuation /scale-up/transfer, and rank them based on potential impact - to identify opportunities for future continuation /scale-up/transfer, and rank them based on potential impact - to collect suggestions for key sustainability-supporting actions - to agree on Stakeholder board consensus meeting 				
Add lines				
Draft Sustainability action plan development				
Who (per role in core pilot team and/or per expertise and/or per institution etc)				When
Add lines				
Stakeholder board consensus meeting(s)				
Objectives	Date	Number of participants	Stakeholders represented	Moderator, rapporteur
<ul style="list-style-type: none"> - to reach consensus on Sustainability action plan - to confirm buy-in - to anchor the ownership - to assure commitment to its execution - to increase visibility 				
Add lines				

Table IV. Integration of equity and diversity principle in stakeholder's engagement, in development of Sustainability action plan and in the actions to strengthen ownership and increase visibility

	Self-assessment: (drop-down menu)	Description (drop-down menu)	Comments
Focus on the key stakeholders' engagement in building sustainability			
Revisit (and if needed revise) the key stakeholder analysis			
Apply equity and diversity perspectives in dissemination of results and sustainability actions			
Apply inclusivity and accessibility guidelines in material presented to the stakeholder board			
Sustainability action plan			
Apply equity and diversity perspectives in development of the sustainability action plan			
Integrate equity and diversity perspectives in the sustainability action plan			
Integrate inclusive and accessible			

communications in the sustainability action plan			
Celebrate the success			
Engage diverse stakeholders in planning final dissemination events			
Consider representation among the speakers in the final dissemination events			
Apply the principles of inclusive and accessible communications in final dissemination events			

Table V. General and specific objectives

General objective:	
Specific objectives:	
	Add lines

Table VI. Sustainability action plan

Description of activity (What)	Stakeholder responsible (Who)	Other stakeholders involved (Who else)	Timeline (When)	Means to verify the accomplishment of the activity
Add lines				

Table VII. Communication and dissemination activities

Communication and dissemination objective(s) of the activity	Target audience	Tools and channels	Key message(s)	Timeline	Estimated reach	Responsible person (apply GDPR)
Add lines						

4. Conclusions and Recommendations

The integrated approach to reporting has been adopted to be highly effective in covering all phases of pilot design, implementation, and assessment, while also incorporating comprehensive sustainability planning. This methodology has streamlined the reporting process, significantly reducing duplication of effort and enhancing the overall quality and coherence of the final reports. By ensuring that each phase of the pilot is documented and assessed, the project can produce detailed and consistent reports that are valuable for both internal and external stakeholders.

A key strength of this approach lies in the alignment with Steps I to XII, which ensures that the reporting template is both structured and adaptable. The inclusion of critical elements such as pilot assessment (Task 5.6), diversity and equity inclusion (Task 5.3), and communication and dissemination activities (WP2) within the template has further simplified the reporting process. By integrating these components, the project has effectively eliminated redundancies, making it easier for core pilot teams to compile their reports efficiently and comprehensively.

Moreover, the Sustainability action plan, which focuses on planning and reporting from Steps XIII to XV, plays a crucial role in ensuring that all aspects of sustainability are thoroughly addressed and documented. This foresight in planning for sustainability not only supports the long-term impact of the pilots but also facilitates the seamless integration of pilot outcomes into broader strategic initiatives and potential scalability efforts.

In conclusion, the comprehensive and integrated reporting approach has not only streamlined the process but has also enhanced the clarity and coherence of the final outputs. This approach has provided robust support to the core pilot teams, ensuring that all necessary information is captured without unnecessary repetition. The successful incorporation of sustainability planning into the reporting process further strengthens the project's outcomes, ensuring that the benefits of the pilots are preserved and potentially expanded upon in the future. The project's reporting methodology serves as a model for future initiatives, demonstrating the value of a structured, inclusive, and sustainability-focused approach to project documentation and assessment. It will be extensively supported by Learning sessions, webinars, workshops and within relevant meetings of WP6-11 leadership teams with core pilot teams of their pilot projects.

Technical note:

This Annex should be regarded as a standard methodological reference for the final reporting process. Nevertheless, given the dynamic nature of the project and the need to ensure full alignment with their evolving reporting requirements, the template may be subject to minor adjustments throughout the course of the project. Such adaptations will not alter the methodological foundation but will allow for greater consistency, accuracy, and responsiveness to the operational context. Accordingly, this Annex represents a flexible yet robust framework, designed to balance methodological rigor with the practical demands of reporting.

Appendices

Appendix A. Guidance to prepare the information to submit the pilot project for evaluation at the EU Portal of Best and Promising Practices

Full up to date guidance is available in “Guide for submitting Best and Promising Practices to the Public Health Best Practice Portal, March 2023”⁵⁴ In short, submitted practices are evaluated against several criteria:

Table I. Set of criteria for evaluation at EU Portal of Best and Promising Practices

Set of criteria for the assessment:
Exclusion criteria
Relevance
Practice characteristics
Evidence and theory based
Ethical aspects
External expert evaluators during evaluation process assign score by evaluating the following aspects: (1) Priority public area, strategy or response to an identified problem; (2) Target population clearly described; (3) Specific, measurable, achievable, realistic, and timebound objectives; (4) Contribution of the target population, carers, health professionals and stakeholders appropriately planned, supported and resourced; (5) Adequate estimation of human, material and budget resources; (6) Evaluation plan with elements of effectiveness, efficiency, and equity; (7) Methodology properly documented; (8) Well-founded theory and evidence-based; (9) Expected benefits superseding potential harm; (10) Individual rights protected; (11) Basic bioethical principles of autonomy, non-maleficence, beneficence and justice; (12) Stated conflicts of interest
Core criteria
Effectiveness and efficiency of the intervention
Equity
External expert evaluators during evaluation process assign score by evaluating the following aspects: (1) Independent evaluation and consideration of social and economic aspects of target population and stakeholders; (2) Evaluation objectives and outcomes relevant for stated goals; (3) Practice implemented proportionally to the target groups' needs; (4) Improvements in comparison to the baseline; (5) Evaluated from an economic point of view; (6) Possible negative effects identified and addressed; (7) Dimensions of equity considered throughout the process; (8) Elements to promote empowerment of the target population
Qualifier criteria
Transferability
Sustainability
Intersectoral collaboration
Participation
External expert evaluators during evaluation process assign score by evaluating the following aspects: (1) Documentation of the instruments (guidelines, protocols or manual); (2) Main organizational elements, limits and actions to overcome barriers; (3) Contextual elements of the beneficiaries; (4) Communication strategy and dissemination plan; (5) Already transferred; (6) Economic report; (7) Continuation ensured through institutional anchoring, ownership by stakeholders; (8) Sustainability strategy; (9) Multidisciplinary and collaborative approach; (10) Structure, organisation, and content defined together with the target pop or stakeholders or civil society

⁵⁴ https://webgate.ec.europa.eu/dyna/bp-portal/build/documents/Questions_and_Submitter_Guide.pdf

When submitting the practice, a structured questionnaire has to be filled in and several documents attached during the next step. Majority of the information needed is already reported within Final implementation report and Sustainability action plan, as presented in Table II. Slight nuances in definitions of some items are emphasized, too. Nevertheless, actual guide at the actual time of submission has to be consulted.

Table II. Structured questionnaire for evaluation at EU Portal of Best and Promising Practices

Questionnaire	Source of information
1. Title of the practice	Final implementation report: Title
2. Personal details of the person submitting the practice	To be defined at the time of submission
3. Responsible person of the initiative	To be defined at the time of submission
4. Key words (MeSH)	Final implementation report: Keywords
5. Geographical scope of the initiative ⁵⁵	Final implementation report: Description of the pilot
6. Start and end of the practice	Final implementation report: Description of the pilot
7. Indicate, if the practice has been assessed ⁵⁶	Should be YES for all JACARDI pilots
8a. Short summary of the practice (structure should cover subheadings 8b to 8f)	Final implementation report: Abstract, Summary
8b. Overall goal, general objective and specific objectives ⁵⁷	Final implementation report: Introduction
8c. Indicators ⁵⁸	Final implementation report: Introduction: Approaches and/or measures to assess the pilot results
8d. Target population ⁵⁹	Final implementation report: Description of the pilot
8e. Method ⁶⁰	Final implementation report: Description of the pilot
8f. Main outcomes ⁶¹	Final implementation report: Final results
9a. Description of evaluation and outcomes (details in Guide ³⁷)	Final implementation report: Approaches and/or measures to assess the pilot results, Analytical methods, Results
9b. Description of unexpected/unintended/negative effects (details in Guide ³⁷)	Final implementation report: Results, Discussion
10. Choose the broad health area (s) that the practice addresses (details in Guide ³⁷)	To be defined at the time of submission
11. Choose the work area(s) that apply to the practice (details in Guide ³⁷)	To be defined at the time of submission
12. Describe the type of stakeholders concerned with your practice (details in Guide ³⁷)	To be defined at the time of submission

⁵⁵ International, European, National or Regional, see details in the Guide

⁵⁶ Yes or No. This answer indicates, whether the practice would be evaluated as a »best practice« or a »promising practice«

⁵⁷ The overall goal is the general indication of the practice's contribution to society in terms of its longer-term benefits. The general objective has to correlate with the different specific objectives. These are concrete statements describing what the practice was trying to achieve in order to reach the overall goal.

⁵⁸ Indicators are variables measuring the performance of an action and the level to which the set objectives are reached. Process, output and outcome/impact should be reported.

⁵⁹ Target population are persons or entities who were positively affected by the action. A proper target group specification provides a clear definition including information about the demographic characteristics, the needs and social norms with regard to the health problem(s) of interest, the size (i.e., the numbers that will be reached by the action), and the method to reach these people.

⁶⁰ Methods should be explicitly linked to the objectives. They should describe how the (specific) objectives were reached, what were the essential tasks performed, eg intervention protocol, survey methods, panel of experts, training developments etc.

⁶¹ The outcomes are the changes that have occurred because of the practice i.e. when the specific objectives/overall goal are reached.

13. Describe the involvement of the stakeholders including target population in each part of the practice (details in Guide ³⁷)	Final implementation report: Situation analysis including key stakeholder analysis, Results, Discussion
14. Describe, how equity and bioethical principles have been respected throughout the practice (details in Guide ³⁷)	Final implementation report: Introduction, Methods, Results, Discussion
15a. Define the type of funding (details in Guide ³⁷)	Final implementation report: Funding
15b. Describe the ability of your practice to be sustained ⁶² in the long term with the available resources (details in Guide ³⁷)	Final implementation report: Methods, Results, Discussion; Sustainability action plan
16a. Choose the level of transferability and/or scalability ⁶³ of the practice (details in Guide ³⁷)	Final implementation plan: Discussion; Sustainability action plan
16b. Describe the transferability/scalability facilitators and barriers (details in Guide ³⁷)	Final implementation plan: Results, Discussion; Sustainability action plan
17. Describe synergies, compatibilities or any conflicts between the practice and other similar practices (details in Guide ³⁷)	To be defined at the time of submission

⁶² The definition in the Guide is: Sustainability is the ability of the practice to be maintained in the long-term with the available resources, adapting to social, economic and environmental requirements of the context in which it is developed. A sustainability strategy needs to describe how the practice has been adapted to the economic requirements of the practice's context, details about the funding, duration of the funding; if possible, present a justifying economic report.

⁶³ The definition in the Guide is: Transferability considers the extent to which the implementation results are systematized and documented, making it possible to transfer it to other contexts/settings/countries or to scale it up to a broader target population/geographic context.

Appendix B. Sustainability-related information available in Final implementation report

Sustainability-related information available in Final implementation report	37
(1) Key stakeholders and their level of involvement in planning phase	38
(2) Sustainability-supporting contextual characteristics in planning phase	38
(3) Strengths of the team in building sustainability	38
(4) Sustainability supporting activities including stakeholders board	39
(5) Description of adaptation of the pilot project to increase the potential for sustainability	39
(6) Defined approach to assess sustainability within multidimensional assessment plan and in ongoing scanning of the contextual elements	39
(7) Defined analytical method to assess the potential for sustainability	40
(8) Reporting of intermediary results within multidimensional intermediary reports	40
(9) Reporting of intermediary results of sustainability reporting activity	40
(10) Reporting of intermediary assessment of contextual characteristics	40
(11) Key stakeholders and their involvement during the implementation	41
(12) Reporting of final results within multidimensional final report	41
(13) Final results of sustainability supporting activities including stakeholders board	41
(14) Sustainability-supporting contextual characteristics at the end of the implementation	41

Integration of the sustainability principle in JACARDI pilot projects is included in the Final implementation report. The report covers:

- a) key stakeholders and their level of involvement
- b) relevant contextual characteristics
- c) strengths of the core pilot team in achieving sustainability
- d) specific sustainability supporting activities, including stakeholders board
- e) sustainability as one of the dimensions within multidimensional assessment
- f) and interpretation, implications and key findings relevant to sustainability.

(1) Key stakeholders and their level of involvement in planning phase

(2) Sustainability-supporting contextual characteristics in planning phase

Table 1. Key stakeholders and their involvement in planning phase

Methods	What did you do?	
Situation analysis including key stakeholder analysis		
fill in with information from Step III, and potentially update in Steps VIII and XII		
Describe contextual elements from situation analysis considered important at the stage of pilot development, related to the characteristics of the intervention, outer and inner setting, characteristics of the individuals involved and the implementation process itself. Describe key stakeholders and their level of involvement in Table 1 ⁶⁴ . Limit character count TBA		
[insert text]		
Describe sustainability - supporting contextual characteristics including existing health strategies/policy frameworks with strong connections, potential holders/owners of sustainability and processes that support collaboration, consensus seeking and engagement of stakeholders at the planning phase in Table 2 ⁶⁵ .		
[insert text]		
Stakeholder	Level of involvement	Comments

Table 2. Sustainability-supporting contextual characteristics in planning phase

General areas of contextual characteristics, that potentially support sustainability	Sustainability-supporting contextual characteristics of the pilot
Existing health strategies/policy frameworks with strong connections to the pilot	
Potential holders/owners of sustainability	
Existing processes that support collaboration, consensus seeking and engagement of stakeholders	

(3) Strengths of the team in building sustainability

Specifics of the team involved in the work
fill in with information from Step I, and update in Steps VIII and XII
Describe core pilot team members per role and expertise, do not include personal data, and apply GDPR; add other members of pilot project team, for example those directly involved in activities as defined in pilot implementation plan, all reported in Table 4 ⁶⁶ . Describe the strengths of the team with regards to building sustainability (“sustainability lens”, Step I). Limit character count TBA.
[insert text]

⁶⁴ Table 1. Key stakeholders and their involvement in planning phase

⁶⁵ Table 2. Sustainability-supporting contextual characteristics in planning phase

⁶⁶ Table 4. Team involved in the work

(4) Sustainability supporting activities including stakeholders board

(5) Description of adaptation of the pilot project to increase the potential for sustainability

Description of the pilot
fill in with information from Steps II to VI, and update in Steps VIII and XII
Describe (at least one) activity(-ies) to increase the potential for sustainability in Table 6 ⁶⁷ , including the activity related to stakeholders board.
[insert text]
Describe the most relevant changes during time period from Step VI to Step XII. Describe the changes introduced to further increase the potential for sustainability , and to integrate better the equity and diversity principle.
[insert text]

Table 6. Sustainability supporting activities

Description of activity (What)	Timeline (When)	Indicator/means for the accomplishment
Add lines		

(6) Defined approach to assess sustainability within multidimensional assessment plan and in ongoing scanning of the contextual elements

Approaches and/or measures to assess the pilot project results
fill in with information from Step VI, and update in Steps VIII and XII
Describe approaches and/or measures to assess the pilot project outcomes , including rationale for choosing them. By applying the methodological framework for multidimensional pilot assessment describe the essential information from Multidimensional assessment plan in Table 9 ⁶⁸ .
[insert text]
Describe the approach(es) to assess the ongoing scanning of the contextual elements that have the potential to contribute to the success, failure, efficiency and cost, and thus to have the potential to have an influence on sustainability of the pilot (including scalability and/or transferability) after JACARDI ends, such as existing health strategies/policy frameworks with strong connections, potential holders/owners of sustainability (among stakeholders), and processes that support collaboration, consensus seeking and engagement of stakeholders.
[insert text]

Table 9. Multidimensional assessment plan – *only sustainability dimension included here*

Sustainability, including scalability and/or transferability			
	Approach chosen	Approach to collect information	Approach to reach conclusions (for example SWOT analysis)
Feasibility of the continuation of the pilot (or its outcome) within			

⁶⁷ Table 6. Sustainability supporting activities

⁶⁸ Table 9. Multidimensional assessment plan

the same setting after JACARDI ends			
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends			
This dimension is relevant for all pilots in JACARDI			

(7) Defined analytical method to assess the potential for sustainability

Analytical methods
fill in with information from Step VI, and update in Steps VIII and XII
Describe analytical methods to assess the potential for sustainability of the pilot/its results/outcomes ⁶⁹ .
[insert text]

(8) Reporting of intermediary results within multidimensional intermediary reports

(9) Reporting of intermediary results of sustainability reporting activity

(10) Reporting of intermediary assessment of contextual characteristics

Results	<i>What did you find?</i>
Intermediary results	
fill in with information from Step VIII and XI	
Describe relevant intermediary results at the level of pilot outcomes in Table 12 ⁷⁰ and Table 13 ⁷¹ by applying the methodological framework for multidimensional pilot assessment, if applicable based on their planned timing for reporting.	
[insert text]	
Describe intermediary results related to sustainability of the pilot: describe intermediary results of activity(-ies) that were planned to increase the potential for sustainability. Describe potential sustainability- supporting changes of contextual characteristics (existing health strategies/policy frameworks with strong connections, potential holders of sustainability (among stakeholders), and processes that support collaboration, consensus seeking and engagement of stakeholders).	
[insert text]	

Table 12. Multidimensional assessment intermediary report No 1 – *only sustainability dimension included here*

Sustainability, including scalability and/or transferability		
	Intermediary results	Interpretation and implications
Feasibility of the continuation of the pilot (or its outcome) within		

⁶⁹ Exemplary text TBA

⁷⁰ Table 12. Multidimensional assessment intermediary report No 1

⁷¹ Table 13. Multidimensional assessment intermediary report No 2

the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis and interpretation:		

Table 13. Multidimensional assessment intermediary report No 2 – *only sustainability dimension included here*

Sustainability, including scalability and/or transferability		
	Intermediary results	Interpretation and implications
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends		
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends		
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis and interpretation:		

(11) Key stakeholders and their involvement during the implementation

(12) Reporting of final results within multidimensional final report

(13) Final results of sustainability supporting activities including stakeholder board

(14) Sustainability-supporting contextual characteristics at the end of the implementation

Final Results
fill in with all existing information within Step XII
Describe how contextual elements interacted with the pilot and the observed associations to the pilot itself and the outcomes, related for example to the characteristics of the intervention, outer and inner setting, of the individuals involved and the implementation process itself. Describe unplanned issues, such as unexpected benefits, problems, failures, or costs associated with the intervention. Describe key stakeholders and their level of involvement in Steps VI to XII in Table 16 ⁷² . Describe details on Stakeholders board : month and year of its establishment, their engagement in Steps VI-XI.
[insert text]
Describe final results at the level of pilot outcomes in Table 18 ⁷³ by applying the methodological framework for multidimensional pilot assessment.
[insert text]
Describe final results related to sustainability of the pilot: describe final results of activity(-ies) that were planned to increase the potential for sustainability in Table 19 ⁷⁴ , including the activity related to stakeholders board. Specifically describe final results of all other activity(-ies) with the potential to

⁷² Table 16. Key stakeholders and their level of involvement during implementation

⁷³ Table 18. Final report of multidimensional assessment

⁷⁴ Table 19. Final results of sustainability supporting activities

increase sustainability. Describe sustainability-supporting contextual characteristics at the end of the implementation in Table 20 ⁷⁵ .
[insert text]

Table 16. Key stakeholders and their involvement during the implementation

Stakeholder	Level of involvement	Comments

Table 18. Final report of multidimensional assessment – *only sustainability dimension included here*

Sustainability, including scalability and/or transferability				
	Final results (for example SWOT analysis)		Interpretation and implications	
Feasibility of the continuation of the pilot (or its outcome) within the same setting after JACARDI ends				
Feasibility for scalability/transferability of pilot outcomes after JACARDI ends				
This dimension is relevant for all pilots in JACARDI. Barriers and enablers of data collection, analysis and interpretation:				

Table 19. Final results of sustainability supporting activities

Description of activity (What)	Final results	Interpretation and implications
Add lines		

Table 20. Sustainability-supporting contextual characteristics at the end of the implementation

General areas of contextual characteristics, that potentially support sustainability	Sustainability-supporting contextual characteristics of the pilot
Existing health strategies/policy frameworks with strong connections to the pilot	
Potential holders/owners of sustainability	
Existing processes that support collaboration, consensus seeking and engagement of stakeholders	

⁷⁵ Table 20. Sustainability-supporting contextual characteristics at the end of the implementation

Appendix C. Multidimensional assessment - information available in Final implementation report

Responses to the facilitatory questions, used during development of Multidimensional assessment plan

Approaches and/or measures to assess the pilot outcomes	
General questions	
Facilitatory questions	Information in Final implementation report
Pilot code in JACARDI (e.g., WP9_BE_87)	General information
Describe the target group of the pilot (who is expected to directly benefit from the intervention): <ul style="list-style-type: none"> - Age profile - occupation (if any specific group is targeted, e.g., health professionals) - specific characteristics (e. g., patients with diabetes) 	Description of the pilot
How many targeted individuals will be reached by the intervention? (If you have several target groups, specify the number for each of them)	Description of the pilot
Where does the intervention take place? Please specify the type of setting that the intervention takes place in.	Description of the pilot
How are the targeted individuals selected? (e.g. through hospital discharge lists/health practitioner lists/etc.)	Description of the pilot
What are the inclusion criteria?	Description of the pilot
What are the exclusion criteria?	Description of the pilot
Questions about the study design for the assessment of the pilot.	
How is the treatment group of the pilot defined? What intervention will they receive?	Description of the pilot
How is the counterfactual (control group) defined? What intervention will they receive?	Description of the pilot
How are the treatment group participants selected? Please describe if this is done through randomization among all the potential participants or any other way.	Description of the pilot
How are the control group participants selected? Please describe if this is done through randomization among all the potential participants or any other way.	Description of the pilot
What is the timeline of the intervention and for its assessment?	Description of the pilot
Questions about the assessment dimensions.	
What are the primary expected outcomes of the intervention that is planned to be piloted?	Table 9, Multidimensional assessment plan
What are the secondary outcomes, if any?	Table 9, Multidimensional assessment plan
How do you measure the primary outcomes (what outcome measures, what data collection approach, at what time points has the outcome been measured)? If there is more than one primary outcome, please provide this information for each outcome.	Table 9, Multidimensional assessment plan
How do you measure the secondary outcomes (what outcome measures, what data collection	Table 9, Multidimensional assessment plan

approach, at what time points has the outcome been measured)? If there is more than one secondary outcome, please, provide this information for each outcome.	
Will patient or individual experiences be assessed? If so, specify what measure(s) will be used, how the data will be collected, and at what time points.	Table 9, Multidimensional assessment plan
What costs of pilot implementation will it be possible to measure (e.g. equipment/tests performed/surveys/etc.) How do you plan to measure those costs? Will you be able to measure costs for the intervention and for the counterfactual separately?	Table 9, Multidimensional assessment plan
Will an economic evaluation be done? If so, please, describe the type of evaluation, what efficiency measure will be calculated, and what data will be used in the calculations.	Table 9, Multidimensional assessment plan
Which sociodemographic characteristics of the subjects will be measured during the pilot? (e.g. age, gender, income level, area of residence, migrant status, disability status, etc.)	Table 9, Multidimensional assessment plan
What measures will be used for sociodemographic characteristics, and how will the relevant data be collected?	Table 9, Multidimensional assessment plan
Will your assessment determine if the pilot intervention can continue after the end of JACARDI (sustainability), and can be extended to other sites and countries (scalability/transferability)? On what basis do you plan to reach that conclusion?	Table 9, Multidimensional assessment plan
Will you assess implementation outcomes in the pilot (e.g. acceptability, appropriateness, feasibility, adoption, fidelity, penetration)? If so, please, specify which measures you will use, how the data will be collected, and at what points in time.	Table 9, Multidimensional assessment plan

Overall reporting, relevant for Multidimensional assessment plan

Item	Section of Final implementation report
General objective	Rationale including general objective
Specific objectives	Specific objectives
Detailed information on pilot project	Description of the pilot
Multidimensional assessment as one of the analytical approaches used including multidimensional assessment plan	Approaches and/or measures to assess the pilot project results Table 9 Analytical methods
Ethics in multidimensional assessment	Ethical consideration
Intermediary results of the multidimensional assessment including multidimensional intermediary reports 1 and 2 (if applicable to the relevant pilot)	Intermediary results Table 12 Table 13
Final results of the multidimensional assessment including final reports of multidimensional assessment	Final results Table 18

Interpretation, implications, key findings	Discussion
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