IMPROVE

Framework to IMPROVE the Integration of Patient Generated Health Data to Facilitate Value Based Healthcare

D5.2: Use case detailed study definition and Key Performance Indicators (KPIs)

Version 2.0

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Statement of Originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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Abbreviations and Acronyms

AMD	Age-related Macular Degeneration
B-IVI	Brief Impact of Vision Impairment
BMI	Body Mass Index
CABG	Coronary Artery Bypass Grafting
CAD	Coronary Artery Disease
CIASS	Chronic Illness Anticipated Stigma Scale
CO_2e	Carbon Dioxide Equivalent
COReHealth	COReHealth Platform *(verify official expansion)*
COrO	Cancer Orientation Centre
CRS	Chronic Rhinosinusitis
CSI	Caregiver Strain Index
DWI	Diffusion Weighted Imaging
EC	European Commission
ECG	Electrocardiogram
ECT	Engagement Coordination Team
EHR	Electronic Health Record
EMBRACE	External Beam Radiotherapy and MRI Based Adaptive Brachytherapy in Cervical Cancer
EORTC	European Organisation for Research and Treatment of Cancer
ePROM	Electronic Patient-Reported Outcome Measure
EQ-5D-5L	EuroQol 5 Dimensions 5 Levels
ETDRS	Early Treatment Diabetic Retinopathy Study
FACT-B	Functional Assessment of Cancer Therapy – Breast
HADS	Hospital Anxiety and Depression Scale
HCP	Healthcare Professional
HF	Heart Failure

HLS-EU-Q6	European Health Literacy Survey Questionnaire – 6 item version
HNSCC	Head and Neck Squamous Cell Carcinoma
ICHOM	International Consortium for Health Outcomes Measurement
ICER	Incremental Cost-Effectiveness Ratio
IF-VIG	Índice de Fragilidad (Frailty Index) - Valoración Integral Geriátrica (Comprehensive Geriatric Assessment)
IQ-EMBRACE	Imaging and Quantitative EMBRACE
IVIM	Intravoxel Incoherent Motion
KCCQ-12	Kansas City Cardiomyopathy Questionnaire – 12 item version
KPI	Key Performance Indicator
LVEF	Left Ventricular Ejection Fraction
MAFEIP	Monitoring and Assessment Framework for the European Innovation Partnership
MFIS	Modified Fatigue Impact Scale
MNV	Macular Neovascularisation
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
MSFC	Multiple Sclerosis Functional Composite
mPROM	Manual/Paper Patient-Reported Outcome Measure
NHPT	Nine-Hole Peg Test
NLP	Natural Language Processing
NPS	Net Promoter Score
PASAT	Paced Auditory Serial Addition Test
PCI	Percutaneous Coronary Intervention
PGHD	Patient Generated Health Data
PHQ-2	Patient Health Questionnaire-2
PICS	Patient Information and Communication Satisfaction Questionnaire
PPI	Patient Preference Information

PREMs	Patient-Reported Experience Measures
PROFFIT	Patient-Reported Outcome for Fighting Financial Toxicity
PROMs	Patient-Reported Outcome Measures
PTOPS	Physical Therapy Outpatient Satisfaction Survey
QA	Quality Assurance
QALY	Quality-Adjusted Life Year
qMRI	Quantitative Magnetic Resonance Imaging
QoL	Quality of Life
SAQ-7	Seattle Angina Questionnaire – 7 item version
SEMCD	Self-Efficacy for Managing Chronic Disease Scale
T25FW	Timed 25-Foot Walk Test
TASQ	Toronto Aortic Stenosis Quality of Life Questionnaire
TAVI	Transcatheter Aortic Valve Implantation
TSRQ	Treatment Self-Regulation Questionnaire
UC	Use Case
VAS	Visual Analogue Scale
VBHC	Value-Based Healthcare
VEGF	Vascular Endothelial Growth Factor
WHOQOL-100	World Health Organization Quality of Life – 100 items
WP	Work Package
WPAI-MS	Work Productivity and Activity Impairment – Multiple Sclerosis

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Executive Summary

This deliverable describes the study designs and use-case-specific Key Performance Indicators (KPIs) that will be used to evaluate the clinical, patient-reported, and operational outcomes within each of the nine IMPROVE use cases. These KPIs primarily focus on assessing clinically meaningful improvements and the impact of the interventions or care models implemented in the individual use cases. Project-level IMPROVE KPIs and cross-use-case evaluation metrics, including common and cost-effectiveness-related indicators, are being developed separately and are therefore outside the scope of this deliverable.

Keywords: PGHD, PROMs, PREMs, PPI, Telehealth, Quantitative MRI (qMRI), nAMD monitoring,

1. Introduction

IMPROVE adopts a common methodological framework across all use cases to support the systematic integration of Patient-Generated Health Data (PGHD) into clinical practice and Value-Based Healthcare (VBHC). This framework combines patient-reported outcomes measures (PROMs), patient-reported experiences measures (PREMs), patient preference information (PPI), clinical data, and health system information to generate evidence on outcomes that matter to patients and healthcare providers. The framework is designed to be applicable across multiple disease areas while allowing adaptation to the specific clinical context of each use case.

The clinical use cases described in this deliverable play a dual role within IMPROVE: they provide the real-world data required to develop and refine the framework, and they provide the clinical settings in which its methodologies and evaluation approaches can be tested and validated. Rather than implementing the IMPROVE framework itself, the pilot sites contribute data and evidence to support its development and assessment. This will be carried out in real life settings in several hospitals and research centers in different countries and different disease areas. This is done via use cases covering the following disease areas:

- Oncology
- Ophthalmology
- Cardiovascular
- Neurology
- Chronic inflammation.

Each disease area has one or more specific disease topics which are associated with a unique Use Case (UC), resulting in a total of 9 UCs.

A patient's condition can result from a combination of causes and circumstances. Understanding the scale of the problem and the main contributing factors is essential to devising effective solutions for different contexts and environments. Accordingly, all use cases will conduct experimental studies. Table 1 Overview of the different UCs with their respective UC owners provides an overview of the different UCs with their respective UC owners, organized by disease area.

Disease area	Topic/Use Case	Location	Use Case Owner
Oncology	UC1: Systems for automated radiotherapy trial QA applied to prostate cancer	The Netherlands	NKI, PMS
	UC2: Multicentre quantitative imaging biomarkers for cervical cancer patients	The Netherlands	NKI, PMS
	UC3: Head and Neck Cancer	Germany	UDUS
	UC4: Breast Cancer	Italy	AReSS, DEDA
Ophthalmology	UC5: Age-related Macular Degeneration (AMD)	Slovenia	IER, EYE, ROCHE

Cardiovascular	UC6: VBHC framework for patients with chronic heart failure and coronary artery disease	Slovenia	IER, UKCL
	UC7: Severe Aortic Stenosis / TAVI	Spain	MDT, Vall d'Hebron
Neurology	UC8: VBHC framework for Multiple Sclerosis rehabilitation	Italy	FISM
Chronic Inflammation	UC9: Chronic Rhinosinusitis (CRS)	Germany	UDUS

Table 1 Overview of the different UCs with their respective UC owners

To ensure consistency across the nine use cases, a common structure has been adopted for defining study objectives, methodological design, patient pathways, data collection approaches, and key performance indicators. While the KPIs described in this deliverable are primarily use-case-specific and reflect the clinical and operational objectives of the individual studies, they have been developed within the broader IMPROVE evaluation framework to facilitate future cross-use-case analyses and harmonization activities.

This document details the outcome of Task 5.1 (Detailed study design use cases and KPI definition for the use cases), covering the overall study design, objectives and key performance indicators (KPIs) for each individual use case (UC). The KPIs presented in this deliverable are primarily use-case-specific and are intended to evaluate clinically meaningful outcomes, patient-reported measures, operational aspects and intervention-related effects within the individual studies. Together, they provide a structured basis for the evaluation and validation activities conducted across the IMPROVE use cases.

The KPIs will be distinguished along two lines:

1) Dependent target variables (effectiveness of integrated healthcare solutions), and
2) Independent regular variables (patient-reported outcomes).

This report is structured as follows:

- **Chapter 2 – Methodology:** Describes the alignment process followed across the use cases, the common methodological approach adopted within IMPROVE, and the patient pathway framework used to harmonize data collection across disease areas. It also outlines where PROMs, PREMs and PPIs are collected along the patient journey.
- **Chapter 3 – Study Designs:** Presents the detailed study designs for each use case, including the clinical context, methodological design, objectives, patient pathway, and use-case-specific KPIs.
- **Chapter 4 – Summary and Conclusions:** Summarizes the main outcomes of the use case definition process and provides an overview of the maturity and readiness of the IMPROVE pilot studies.

2. Methodology

This chapter describes the methodology adopted in Task 5.1 to define and harmonize the study designs, patient pathways and KPIs across the IMPROVE use cases. A common process was followed to ensure consistency across disease areas while allowing adaptation to the specific clinical context of each use case.

Phase 1 – Alignment and Framework Definition

The first phase focused on establishing a common methodological approach for all use cases. This included defining the reporting structure, agreeing on terminology, identifying common data collection concepts and introducing the patient pathway as a unifying framework across disease areas. The patient pathway was selected as the common denominator to describe the patient journey and to facilitate the alignment of PROM, PREM and PPI collection points across the IMPROVE use cases.

Training and alignment activities were organized to introduce the IMPROVE Evaluation Framework and the overall study design approach. An explanation of the Evaluation Framework and Study Designs was provided during consortium meetings organized by Philips in Amsterdam, where methodological concepts and their implications for the project were discussed.

Phase 2 – Use Case Development

In the second phase, individual use case teams developed their study designs, objectives, patient pathways and preliminary KPI frameworks according to the agreed methodology. To support this process, bilateral and monthly meetings were organized to discuss methodological questions, clarify use-case-specific requirements, and support pilot sites in preparing their study designs and KPI definitions.

IMPROVE includes a large number of user groups and clinical settings across five European countries. Therefore, dedicated support was provided to ensure a common understanding of experimental study design principles, KPI development, measurement approaches and study execution requirements.

Phase 3 – Review and Harmonization

The third phase focused on harmonizing the outputs of the individual use cases. Webinars, workshops and dedicated meetings were organized to discuss methodological consistency, refine KPI definitions and align patient pathway representations across disease areas. These activities included webinars on experimental research principles and KPI development, as well as a dedicated meeting in Slovenia. Supporting materials were shared with partners to facilitate harmonization.

A key outcome of this phase was the development of a common patient pathway framework. In the context of the IMPROVE use cases, patient pathways are not used as evidence-based care pathways but as a harmonization tool to describe the patient journey across different disease areas. Although the clinical context differs between use cases, the major pathway stages and patient-caregiver interactions share common characteristics, enabling the alignment of data collection activities across

disease areas. PROMs, PREMs and PPIs can be collected at different stages of the pathway, providing insight into individual care steps as well as the overall patient journey. For each use case, a graphical patient pathway was developed indicating the collection points for PROMs, PREMs and PPIs. A purple star indicates PROM collection, a yellow star PREM collection and a green star PPI collection (Figure 1). Collectively, these pathway representations provide an overview of PROM, PREM and PPI coverage across the IMPROVE use cases.

Consensus on the patient pathway framework was achieved through discussions during the Barcelona workshop meeting and Best consortium meeting and further refined through monthly WP5 meetings and bilateral discussions with the use case teams. These activities supported the gradual development and harmonization of the pathway approach across all participating disease areas.

Phase 4 – Consolidation and Methodological Framework

The final phase consolidated the outcomes into a common methodological framework. Particular emphasis was placed on the patient pathway concept, which provides a common representation of the patient journey across all disease areas and allows the mapping of PROMs, PREMs and PPIs throughout the care process. The resulting aligned pathways form the basis for the study designs and KPI frameworks presented in this deliverable and support future implementation and evaluation activities within IMPROVE.

Figure 1: Star colour coding of PREM/PROM/PPI collection

3. Study designs

In this chapter, the detailed study design for each of the nine use cases is presented, organized by disease area and differentiated according to the clinical context of each disease topic, while following a common reporting structure so that the use cases can be read consistently. For every use case, the chapter sets out the Study (the clinical and technical rationale), the Methodological Design (study type, patient population, data sources and timeline), the Objectives, the Patient Pathway — along which patient-reported outcome measures (PROMs), patient-reported experience measures (PREMs) and patient preference indicators (PPIs) are collected — and the Key Performance Indicators. In line with the framework introduced in Chapter 2, these KPIs distinguish dependent target variables, capturing the effectiveness and efficiency of the integrated healthcare solutions, from independent variables spanning patient-, condition-, therapy- and health-system-related as well as socio-economic factors; together they form the evidence base through which each use case is tested and validated within the overall IMPROVE evaluation framework across the five disease areas.

Each use case is presented using a common reporting structure comprising the study rationale, methodological design, objectives, patient pathway and key performance indicators (KPIs). Due to differences in clinical context, study maturity and implementation status, the level of detail and granularity may vary between use cases. Where PROMs, PREMs or PPI instruments have already been selected, these are explicitly described; where selection is still ongoing, this is indicated within the respective use case. The objectives and KPIs presented reflect the current state of development of each use case and may be further refined during implementation.

3.1 Oncology

Use Case 1: Systems for automated radiotherapy trial QA applied to prostate cancer

Study

Radiotherapy is one of the treatment options for prostate cancer and a wide variety of technical solutions are available for this purpose.

The optimal treatment strategy for an individual patient depends on disease characteristics, including MRI biomarkers, as well as the available radiotherapy options. These factors can influence both clinical outcomes and patient-reported outcomes. Earlier generations of radiotherapy were associated with greater treatment delivery uncertainty, limiting personalized treatment counselling and reducing the precision with which treatment effects could be linked to outcome measures.

As informed decision making depends on such details, technical quality of the treatment needs to be high and reporting needs to be sophisticated, which will be tested in this use case. Beyond retrospective PROMs data analysis (WP4) in connection with quantitative imaging, we will seek to apply automated radiotherapy trial QA in a prospective multi-centre clinical trial.

Methodological Design

We will use data from about 50 patients who already have been included in the hypo-FLAME 3.0 trial on radiotherapy of prostate cancer to develop and evaluate models that allow individualized predictions of treatment outcome for several radiotherapeutic treatment options, comparing standard

radiotherapy with a C-arm linac with more elaborate treatment methods, such as MRI-guided radiotherapy, use of invasive devices such as hydrogel spacers to reduce rectal toxicity, and focal brachytherapy.

Multi-parametric MRI, using quantitative techniques such as intra-voxel incoherent motion (IVIM) MRI and dynamic contrast-enhanced MRI is used to localize and characterize the cancer. This will be used as input to assess the radiosensitivity of the cancer and the risk of recurring disease for a specific radiotherapeutic dose. Machine learning models will be applied to estimate the maximum achievable dose for a specific treatment method.

The results of these models will be used for individualized predictions of treatment outcome of the collection of treatment options. These predictions for each of the treatment options will be offered to panels of radiation oncologists and patients to acquire both physician and patient preference information. This will provide data on the expected practice variation as well as the potential consequences for outcome.

The project will be conducted between January 1, 2025 and January 1, 2027.

Patient Pathway

The patient pathway for a prostate cancer patient is provided in Figure 2: Patient pathway for the prostate oncology use case. PPI are collected at therapy and PROMs at follow up. As the use case is focusing on radiotherapy treatment for prostate cancer patients, PROMs are collected only during the therapy phase as well as during follow-up, up to five years after treatment initiation.

Figure 2: Patient pathway for the prostate oncology use case. PPI are collected at therapy and PROMs at follow up. Concept: PMS, Design. ius

Key Performance Indicators

Dependent target variables:

Category	KPIs	Definition
Treatment	Automated radiotherapy	Impact of automated radiotherapy trial QA on treatment quality and delivery certainty
	Treatment quality	Estimate of impact of treatment quality variation on outcome
	Individual outcome prediction	Estimate of impact of models for individual outcome prediction on practice variation
	PPI	Prototype tool to support shared decision making based on model predictions

Table 2 KPIs for prostate oncology use case

Use Case 2: Multicentre quantitative imaging biomarkers to harness outcome parameters relevant for cervical cancer patients

Study

Quantitative MRI (qMRI) has promising applications within radiotherapy. For example, a combination of diffusion and perfusion imaging can be used to visualize hypoxia in the tumour. However, clinical validation is hindered by the lack of multi-centre reproducibility of the qMRI measurements. Within a sub study of EMBRACE-II (IQ-EMBRACE) we have collected quantitative imaging of cervical cancer patients in a multi-centre setting. At the start of the trial, a phantom QA framework was developed and performed in 15 institutes with MRI scanners from 3 different vendors. Next generation MRI platforms are available or will become available during the course of this project, and we will ensure cross-platform validity of robust biomarkers, compatible with these new systems.

Methodological Design

Under this study, we will perform three projects. The primary objective of the first project is to investigate the prognostic value of qMRI parameters for treatment outcome in cervical cancer in a multi-centre setting. The motivation for this project is that the radiotherapy field is moving towards treatment by de-escalation of the treatment for low-risk patients and intensifying for high-risk patients where accurate patient stratification is critical. However, stratification based on only clinical characteristics is not sufficient. For this purpose, we will use the multi-centre patient data of IQ-EMBRACE (n=99, 7 institutes), where standard imaging data was collected as well as diffusion weighted MRI, dynamic contrast-enhanced MRI and T2 mapping. During the course of this project 5-year overall survival data will become available, which will be used to determine the prognostic value of the single and/or combination of qMRI parameters to predict treatment outcome.

The second project focuses on the measurement of the inherent T1 and T2 relaxation times and diffusion weighted imaging (DWI), which might hold prognostic value for tumour aggressiveness. However, current state-of-the art T1 and T2 mapping and DWI techniques are slow or imprecise. With advanced AI-augmented MR reconstruction, faster and more reliable mapping techniques will be developed and are becoming available with improved image quality. The primary objective of the second project is to investigate the technical performance of several T1 and T2 mapping techniques as well as DWI. The evaluation will be performed with a T1/T2 mapping phantom to assess accuracy and in-vivo test-retest data in healthy volunteers (n=26) to assess repeatability.

The third project aims to develop a validated questionnaire to measure and monitor the experience of people undergoing MRI scanning. This questionnaire can be used to assess initial experience, but also to monitor the experience of people who repeatedly undergo MRI scans. Experience aspects to be monitored for example are Time Perception, Sound Perception, Physical Comfort, Thermal Comfort, and Staff Support. The questionnaires can be used for the development of new MRI technology like patient support hardware or new MRI sequence that have a more software nature. On top of that, the questionnaires can potentially also be used after installation in hospitals for real patient experience monitoring.

The three projects address complementary aspects of the same goal: improving the use of quantitative MRI in cervical cancer. Project 1 evaluates clinical value, Project 2 ensures technical reliability of the imaging biomarkers, and Project 3 assesses patient experience during MRI examinations. The projects will be conducted between November 1, 2025 and November 1, 2028

Patient pathway

The patient pathway for a cervix cancer patient is provided in Figure 3.

Figure 3 : Cervix cancer patient pathway. PREMs and PPI are collected at the diagnosis and staging phase, PROMs during therapy and follow-up. Concept: PMS, Design. ius

Key performance indicators

Dependent target variables:

Category	KPIs	Definition
Clinical value	Prognostic value	Realize an estimate of prognostic value of qMRI for outcome in cervical cancer

Table 3 Dependent target variables for cervical oncology use case

Independent regular variables:

Category	KPIs	Definition
Efficiency	Acquisition time	Reducing the acquisition time of qMRI with 50% without compromising accuracy and repeatability with advanced MRI reconstruction techniques
Patient experience	Questionnaires	Validated MRI experience questionnaires - Covering the most important aspects involved in experiencing MRI examinations - That can be filled in within 5 minutes - That are available at least in English and Dutch

Table 4 Independent regular variables for cervical oncology use case

Use Case 3: Head and Neck Cancer

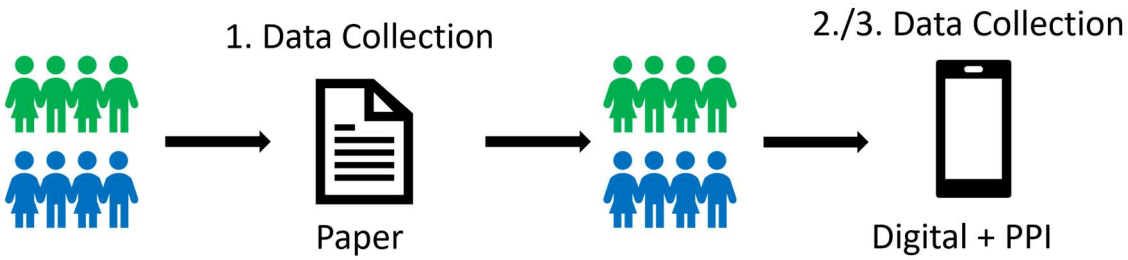
Study

Use Case 3, the Oncological IHI IMPROVE Case Study, focuses on Head and Neck Cancer. The treatment modalities for primary HNSCCs mainly comprises surgery, a combination of radiation and platin-based chemotherapy and, on the uprising, several immunotherapeutic drugs. Unfortunately, PGHD have not yet been sufficiently implemented in routine care of these patients, and thus there is a strong need for improvement for this use case. Currently, outcome assessment respecting the patient's true needs is not yet implemented in routine care, despite need for PGHD to be further evaluated for HNSCC patients. This use case covers the full spectrum of HNSCC patients and engages multiple stakeholders to assess the implementation and value of patient-generated health data in routine clinical practice.

Methodological Design

The study is designed as a longitudinal observational study aimed at collecting Patient-Reported Outcome Measures (PROMs) in combination with clinical data to get a better impression of how far QoL and disease related QoL as well as distress impact patients with HNSCC. All patients complete the existing questionnaires for the HNSCC use case on paper. The second and third data collections, which are scheduled as part of routine patient appointments, will be conducted digitally using iPads available at the clinic. The digital questionnaires are designed so that there is a playful variation of one or two

questionnaires available, while the others are identical to the existing paper questionnaires. Additionally, the option to complete questionnaires with digital assistance may be provided. As a second focus, we will investigate the patient's and healthcare provider's view on the impact and usability of PROMs within the clinical setting and therefore implement additional questionnaires that address these points. To determine which type of PROM (Patient-Reported Outcome Measure) integration patients prefer (paper vs. digital; playful vs. traditional), a Patient Preference information (PPI) questionnaire is being designed/planned, which each patient will complete at the end of the second or third data collection. Additionally, heath care providers will be asked to answer a questionnaire regarding their preferred method of evaluation of the questionnaire, the implementation of the automated scoring, and longitudinal presentation of the scores. The second and third data collections will be conducted digitally to evaluate patient acceptance and the feasibility of integrating digital PROM collection into routine care. Follow-up assessments are scheduled according to the individual treatment pathway and typically occur at 6 weeks, 3 months, 6 months, or 1 year.



- Technology Used:

Data collection within the clinical setting. Pre-studies are performed on paper; integration of ePROMs will be established within the project together with BETTER and implemented as soon as possible.

- Intervention details:

The intervention includes the use of PROMs and the evaluation of their impact on clinical decisions, disease perception, perception on the usability, integration, and added value of PROMs determined by patients and healthcare providers.

- Recruitment period:

The recruitment phase will last approximately 10-12 months, targeting 25-60 patients for primary implementation.

- Follow-up period:

The follow-up period will be between 6 weeks to 24 months to further monitor the patients' course of disease as well as potential changes within. Limits are relative since the study will be performed in "running cohorts" of UDUS.

- Time Horizon for Analysis:

The analysis will cover a period of 36 months defined by the project timeline.

- Number of participants:

Patients are recruited during clinical routine primarily and follow-up. Therefore, we aim to integrate 25-60 patients. Eligible participants are consenting adults (≥18 years) with a diagnosis of HNSCC. The study population reflects the routine HNSCC patient cohort and includes patients of any adult age and gender.

- Randomization procedure: N/A
- Groups: N/A

Objectives

With the project, we would like to integrate PGHD into the routine consultation. The comparison to mPROMs, ePROMs and an automatized evaluation process is aimed to exploit the opportunities for health care improvement. The timely visualization could additionally be used to discuss specific changes of symptoms or quality of life aspects with the patient and support the joint efforts to live up to the patient´s true needs. In addition, we would like to support the patient´s access and joint patient-orientated path through improved design and interactive tools.

- **Primary objectives**
  1. To evaluate the QoL and disease related QoI and distress in relation to the disease.
  2. To evaluate added value of PROMs from the patient´s perspective.
  3. To evaluate added value of PROMs from the health care providers' perspective.

- **Secondary objectives**
  1. To evaluate the usability and feasibility of PROMs within the clinical setting in two forms: A) Paperwork and B) ePROMS designed by BETTER and the use of tablet computers.
  2. To evaluate the relative effort of PROMs within the clinical setting
  3. To evaluate the change within PROM rating in relation to the course of disease and treatment

Patient Pathway

The patient pathway for a head and neck cancer patient is provided in Figure 4.

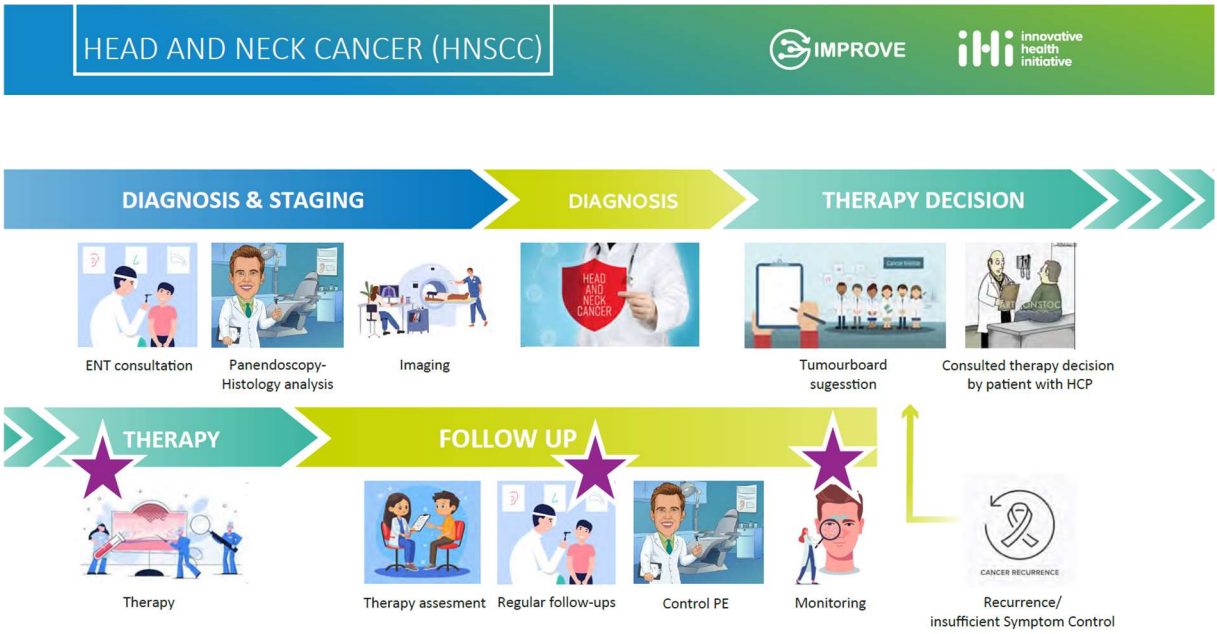


Figure 4: Head and Neck cancer patient pathway. PROMs are collected at the therapy and follow up stages. Concept: PMS/UDUS, Design. ius

Key performance indicators*Independent regular variables:*

Category	KPIs	Definition
Adherence	Completion rate	PROM completion rate (paper vs. ePROMs)
	QoL change	Change in QoL and distress scores
Quality	Tool usability	Usability of PROM tools
	Preference clarity	Patient preference clarity (paper vs digital)
Efficiency	Complete time	Perceived time burden for PROM completion

Table 5 Independent regular variables for head and neck cancer use case

Use Case 4: Breast cancer

Study

The Breast Cancer Use Case focuses on the systematic integration of Patient-Generated Health Data, with particular reference to Patient-Reported Outcome Measures, Patient-Reported Experience Measures and Patient Preference Information, into the care pathway of patients with early-stage breast cancer within the Apulia Regional Oncology Network.

The study will be conducted in a real-world clinical setting and will involve the regional network of Breast Units and Cancer Orientation Centres, known as COrOs, which represent the main access and

orientation points of the oncology network. The Use Case will rely on COReHealth, the regional telemedicine platform provided by Dedalus and already used within the Apulia Oncology Network to support patient enrolment and the management of oncology care pathways.

The prospective phase builds on the retrospective activities already carried out within WP4 of the IMPROVE project. In that context, historical data related to breast cancer care pathways were analysed to assess the current availability and use of Patient-Generated Health Data, identify the main information gaps and define the additional data needed for the prospective phase. The retrospective work also supported the preliminary analysis of the clinical pathway and the identification of the most appropriate points at which patient-reported information could be collected. This retrospective analysis, conducted within the IMPROVE project, explores value-based data and evaluates the potential use of PROs (PREMs and PROMs) as tools to assess patient experience in the Cancer Network and guide system decisions. The retrospective analysis covered the period from 1 January 2022 to the cut-off date of 30 March 2025, corresponding to approximately 39 months overall.

The prospective study is designed as a multicentre, observational and non-interventional study conducted in routine clinical practice. It aims to assess the feasibility, acceptability and potential value of introducing the systematic collection of PROMs and PREMs into the care pathway of patients with early-stage breast cancer in a real-world setting1.

More specifically, the study will investigate which Patient-Generated Health Data are most useful to collect, how and when they should be collected, and how they can be integrated into the COReHealth platform and the IMPROVE framework. It will also assess how PROMs and PREMs may contribute to quality improvement and Value-Based Healthcare, how patient-reported indicators may support clinical, organisational and economic evaluation, and whether their systematic use may provide useful information for the governance and monitoring of the Regional Breast Unit Network.

Attention will be paid to the inclusiveness of the data collection process. Since an exclusively digital approach could exclude or under-represent patients with limited digital literacy, assisted or alternative collection methods may be used where necessary. Digital competence will therefore not be considered a prerequisite for participation.

Objectives

The primary objective of the study is to evaluate the feasibility of systematically implementing PROMs and PREMs within the participating Breast Units and, where appropriate, within the COrOs involved in the breast cancer pathway.

The study will assess whether patient-reported data can be collected in a consistent, standardised and sustainable way across the different stages of the care pathway and whether these data can support the evaluation of outcomes, patient experience and the value generated for patients in accordance with Value-Based Healthcare principles. Moreover, the evaluation of Digital transformation of a system

[1] The role of patient-reported outcome measures in the continuum of cancer clinical care: ESMO Clinical Practice Guideline Ann Oncol 2022 (9): 878-892; M DiMaio, E. Basch, F. Denis et al on behalf of the Esmo Guidelines Committee

remains an opportunity to identify health needs for better planning (elderly to younger pts, presence of social frailty or not, polypharmacy and system accessibility).

The secondary objectives are to assess the contribution of PROMs as standardized instruments for monitoring patient-reported outcomes and support improvements in the quality of care provided to patients with early-stage breast cancer. The study will also evaluate health-related quality of life and breast-specific outcomes at predefined stages of the care pathway, as well as patients' experience across the different phases of care through the systematic use of PREMs.

A further objective is to collect and characterize Patient Preference Information, also through the structured involvement of patient and advocacy organizations. The study will seek to identify unmet needs and potential areas for clinical and organizational improvement, assess the acceptability and usability of the selected data collection tools among patients and healthcare professionals, and verify the technical feasibility of integrating Patient-Generated Health Data into COReHealth and the IMPROVE framework.

The study will also explore the applicability of the MAFEIP tool for estimating the cost-utility of the proposed care model. The overall aim is to generate evidence that may support the possible adoption of PROMs, PREMs and Patient Preference Information as quality indicators and governance tools within the Regional Breast Unit Network and, more broadly, within the Regional Oncology Network. The results will be used to formulate recommendations for the routine implementation of patient-reported data collection in regional breast cancer pathways.

Methodological Design

The study will be prospective, multicentre, observational and non-interventional and will be conducted in routine clinical practice. No modification will be made to the standard diagnostic, therapeutic or care procedures.

Patients will be enrolled consecutively among those accessing the participating centres and meeting the eligibility criteria. Data collection will follow the main stages of the patient pathway, from entry into the Regional Oncology Network and Breast Unit intake through treatment and follow-up. The planned data collection period is 12 months.

The study will be conducted in three Breast Units belonging to the Apulia Regional Breast Unit Network: the Breast Unit of the "Dimiccoli" Hospital in Barletta, ASL BT; the Breast Unit of the "San Paolo" Hospital, ASL Bari; and the Breast Unit of the "A. Perrino" Hospital in Brindisi.

The centres were identified by AReSS Puglia as "pilot sites" since their experience in using the COReHealth platform, their capacity to recruit patients within regional oncology care pathways and their consolidated experience in multidisciplinary breast cancer management.

Other relevant criteria included compliance with the organisational requirements established for Breast Units, participation in regional and national outcome-monitoring systems, territorial distribution within the Regional Breast Unit Network and the availability of functional links with the corresponding COrOs.

The centres have undergone clinical and organisational audits conducted by AReSS Puglia and comply with the quality standards established by national and regional regulations.

Study Population

The study population will consist of adult patients with histologically confirmed invasive breast carcinoma who are managed within one of the participating Breast Units.

The prospective study will focus on early-stage breast cancer treated in real-world clinical practice. The eligible population will include patients with Stage I–II disease and may include selected Stage III patients where this is compatible with the study pathway and treatment plan. Patients must be managed within a curative-intent pathway, including surgery and, where clinically indicated, chemotherapy and/or radiotherapy.

Patients will be eligible if they have a histologically confirmed diagnosis of invasive breast carcinoma, are referred to and clinically managed within one of the participating Breast Units and have early-stage disease managed within a curative-intent pathway. Eligibility will also require formal discussion and treatment planning within the multidisciplinary tumour board, age of at least 18 years, the ability to understand the study procedures and the provision of written informed consent for participation and personal data processing.

Patients with confirmed metastatic breast cancer, Stage IV, will be excluded. Pregnancy confirmed by a positive pregnancy test, inability to provide informed consent and any clinical or organisational condition preventing completion of the planned data collection pathway will also constitute exclusion criteria.

Section	Criteria
Target population	Adult patients with histologically confirmed invasive breast carcinoma managed within one of the participating Breast Units
Disease stage	Stage I–II early breast cancer; possible inclusion of selected Stage III patients subject to finalº protocol confirmation
Treatment pathway	Curative-intent pathway, including surgery and, where clinically indicated, chemotherapy and/or radiotherapy
Main inclusion criteria	Histological confirmation; management within a participating Breast Unit; multidisciplinary discussion; age ≥18 years; written informed consent
Main exclusion criteria	Stage IV disease; pregnancy; inability to provide informed consent; clinical or organisational conditions preventing completion of the planned data collection
Planned sample	Approximately 40–60 patients

Table 6 Patient selection criteria for breast cancer use case

The study is expected to enrol approximately 40–60 women. This estimate is considered feasible in view of the annual activity volumes reported by the participating Breast Units. Historical data for 2023 indicate approximately 972 patients undergoing surgery for early breast cancer across the three selected centres: 428 at the "A. Perrino" Hospital, 421 at the "San Paolo" Hospital and 123 at the "Dimiccoli" Hospital. These figures will be verified and updated using the most recent available activity data before the protocol is finalised.

Patient Enrolment and Data Collection

All consecutive eligible patients accessing the participating Breast Units during routine clinical practice will be considered for enrolment.

Patient-reported data will be collected at predefined points along the care pathway. The collection framework will combine global, cancer-related and breast-specific measures. PROMs will be selected by considering both the type of outcome measured and the characteristics of the target population. This means distinguishing between global and domain-specific measures, as well as between generic oncology instruments and measures specifically designed for breast cancer.

The proposed tools include the EQ-5D-5L for the assessment of global health-related quality of life and for health-economic evaluation, the EORTC QLQ-C30 as a cancer-specific global measure, subject to final methodological confirmation, and the BREAST-Q for the assessment of breast-specific quality of life and patient satisfaction.

A structured PREM tool will be used to assess patient experience across the regional oncology pathway. A dedicated approach to Patient Preference Information will also be defined in order to collect patient preferences and to support the involvement of patient associations in identifying relevant outcomes, research priorities and the interpretation of results.

FACT-B was considered during the methodological assessment as an alternative breast cancer-specific instrument. The final selection of disease-specific PROMs will take into account methodological consistency, burden of administration, licensing requirements, compatibility with COReHealth and comparability with the other IMPROVE Use Cases.

Measure	Type	Main dimension assessed	Proposed use in the study
EQ-5D-5L	Generic PROM	General health-related quality of life	Longitudinal outcome assessment and health-economic evaluation
EORTC QLQ-C30	Cancer-specific PROM	Cancer-related quality of life, functioning and symptoms	Assessment of general cancer-related outcomes
BREAST-Q	Breast-specific PROM	Breast-specific quality of life and patient satisfaction	Assessment of outcomes related to breast cancer care and treatment
PREM tool	PREM	Patient experience of access, information, communication, treatment and continuity of care	Evaluation of the patient experience across the pathway

PPI questions	PPI	Preferences regarding information, decision-making and data collection	Exploration of patient preferences within the care pathway

Table 7 Data collection measures and proposed use in breast cancer study

Data will be collected through the COReHealth digital platform. Where necessary, assisted digital completion, support from trained healthcare professionals or alternative collection modalities may be used to ensure the inclusion of patients with limited digital literacy.

The collected data will subsequently be processed and prepared for integration into the IMPROVE framework in accordance with project procedures and applicable data protection requirements.

Data Collection Time Points

The proposed data collection schedule is organised around four main time points.

At T0, corresponding to entry into the Regional Oncology Network and/or Breast Unit intake, baseline information will be collected. This may include baseline PROMs, PREMs concerning access, information, orientation and initial experience, the BREAST-Q at Breast Unit intake, baseline demographic and clinical information and initial Patient Preference Information.

PROMs and PREMs may be administered in both settings where the COrO directly intercept patients with breast cancer. This would require specific training for the healthcare professionals involved in both the Breast Units and the COrOs.

T1 corresponds to the multidisciplinary discussion and the communication of the treatment plan to the patient. At this stage, data collection may include the EQ-5D-5L, the EORTC QLQ-C30 if confirmed in the final instrument set, PROMs related to health status and treatment burden, PREMs concerning information, communication and shared decision-making, and Patient Preference Information related to treatment preferences and information needs.

T2 corresponds to the treatment phase and hospital discharge. The main common reference point will be discharge after surgery, to maintain a consistent and analysable time point across the participating centres. Additional treatment-specific data may be collected for patients receiving chemotherapy or radiotherapy, although any subgroup analysis will depend on methodological appropriateness and the availability of a sufficient number of patients.

At this stage, data collection may include PROMs after treatment or discharge, PREMs concerning treatment, continuity of care, information and discharge, treatment-specific experience indicators and operational data related to questionnaire administration. Even if T2 is considered too early for definitive outcome evaluation, the data may still be collected and used as part of the longitudinal analysis.

T3 will correspond to the one-year follow-up. At this stage, data collection may include the EQ-5D-5L, the BREAST-Q or another selected breast-specific PROM, PREMs related to follow-up and continuity of care, Patient Preference Information where appropriate, clinical follow-up information and the health-economic data required for the MAFEIP analysis.

Time point	Phase of the patient pathway	Setting	Data to be collected	Purpose
T0	Entry into the Regional Oncology Network and/or Breast Unit intake	COrO and/or Breast Unit	Baseline demographic and clinical data; baseline PROMs; PREMs concerning access, orientation, information and initial experience; BREAST-Q at Breast Unit intake; initial Patient Preference Information	To establish the patient's baseline health status, breast-specific outcomes and initial experience of accessing the oncology pathway
T1	Multidisciplinary Team discussion and communication of the care plan	Breast Unit	EQ-5D-5L; EORTC QLQ-C30, if confirmed in the final instrument set; PREMs concerning information, communication and shared decision-making; Patient Preference Information related to treatment preferences and information needs	To assess health status and the patient's experience of receiving and discussing the proposed treatment plan
T2	Treatment phase and hospital discharge	Surgical unit and, where appropriate, chemotherapy or radiotherapy unit	PROMs after treatment or discharge; PREMs concerning treatment, information, continuity of care and discharge; breast-specific outcomes where appropriate; treatment-related experience indicators; questionnaire administration data	To assess the patient's experience of treatment and discharge and to collect an intermediate measure for subsequent longitudinal analysis
T3	One-year follow-up	Breast Unit and follow-up services	EQ-5D-5L; BREAST-Q or another selected breast-specific PROM; EORTC QLQ-C30, if included; PREMs concerning follow-up and continuity of care; Patient Preference Information where appropriate; clinical follow-up data; health-economic data required for MAFEIP	To assess changes in health-related and breast-specific outcomes, the overall care experience and the information required for health-economic evaluation

Table 8 Data collection timepoints in the breast cancer use case

The final schedule will be harmonised across the three participating centres after completion of the local pathway analyses.

Patient Pathway

The patient pathway for a breast cancer patient is provided in Figure 5.

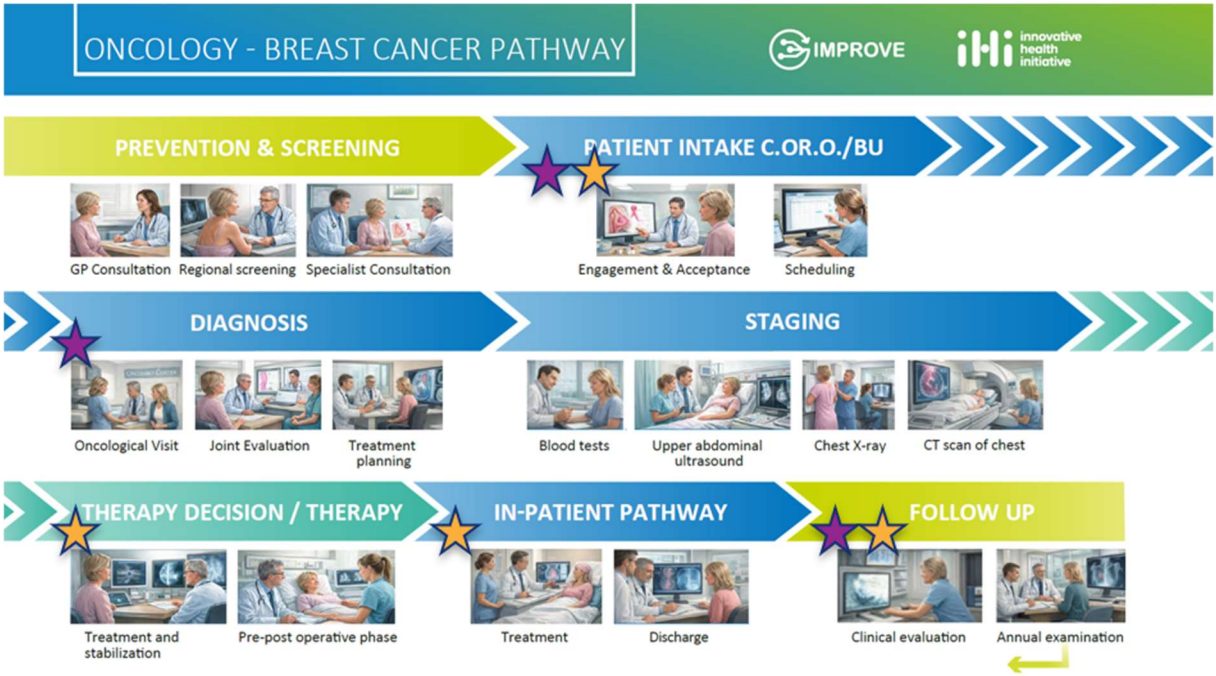


Figure 5: Breast cancer patient pathway. Concept: PMS/DEDA, Design. ius

Study Endpoints

The primary endpoint is the feasibility of routinely implementing PROMs, PREMs and Patient Preference Information collection within the participating Breast Units and relevant COrOs.

Feasibility will be assessed by considering the proportion of eligible patients offered participation, the proportion enrolled, the proportion of patients receiving questionnaires and the proportion of scheduled questionnaires completed at each predefined time point.

The analysis will also consider longitudinal adherence to the data collection programme, completeness and consistency of the information collected, overall data quality, the technical feasibility of integrating Patient-Generated Health Data into COReHealth and the IMPROVE framework, and the acceptability and usability of the tools among patients and healthcare professionals.

Operational burden, compatibility with routine workflows and the ability to include patients independently of their digital literacy will also be assessed. The sustainability of the proposed model will be explored in relation to continued participation, workflow integration, resource requirements and staff burden.

Secondary endpoints will include PROM scores and changes in PROM scores across the predefined phases of the care pathway; PREM scores collected at the relevant time points and the distribution and characterisation of Patient Preference Information.

The study will also examine unmet needs and potential areas for clinical and organisational improvement, compare aggregated patient-reported indicators across centres and, where methodologically appropriate, across the IMPROVE Use Cases, and explore differences in outcomes and experience according to patient characteristics, care pathway and treatment.

The health-economic analysis will include an estimation of the Incremental Cost-Effectiveness Ratio using the MAFEIP methodology. The final analysis will support the formulation of evidence-based recommendations for routine implementation within the Regional Breast Unit Network and the Regional Oncology Network.

Expected Results

The study is expected to demonstrate whether PROMs, PREMs and Patient Preference Information can be integrated into routine breast cancer care pathways in public hospitals.

It should also support the identification of the most appropriate instruments and collection points, the definition of a standardised workflow for the three participating Breast Units and the improvement of the availability and quality of patient-reported information within COReHealth.

The study is also expected to identify barriers related to digital literacy, workflow integration and patient participation, and to provide evidence on patient-reported outcomes and experience from diagnosis through follow-up.

The results should support continuous quality improvement within the Regional Breast Unit Network, provide preliminary evidence on the value and cost-effectiveness of the proposed model, and contribute to the development of recommendations for regional adoption and possible transferability to other oncology pathways.

Operational and Methodological Issues

Before implementation, several aspects will require final confirmation. These include the final definition of the eligible population, particularly the possible inclusion of selected Stage III patients, and the final selection and licensing of the PROM and PREM instruments.

The method for collecting Patient Preference Information will also need to be defined, as will the final T0–T3 assessment schedule across the three participating centres. The respective roles of the Breast Units and COrOs in recruitment and data collection must be clarified, together with the procedures for assisted and non-digital completion.

Other elements requiring completion include confirmation of the sample size using updated activity data, validation of the KPI thresholds, completion of the pathway analysis for centers involved (Barletta, Brindisi and Bari), technical adaptation of COReHealth and definition of the relevant data flows and data protection responsibilities.

Finally, implementation will require approval of the study protocol and informed consent documentation, identification of the study sponsor and completion of the applicable ethical and regulatory procedures.

Key performance indicators

The study will monitor the feasibility of implementation, the level of patient participation, questionnaire completion, data quality, digital inclusion, patient-reported outcomes, patient experience, usability, technical integration and the potential contribution of the collected data to health-economic evaluation and regional governance.

The preliminary targets identified during the methodological work will be treated as provisional and will be confirmed during final protocol development. In particular, the proposed thresholds concerning the increase in COReHealth enrolment, the proportion of eligible patients receiving questionnaires and longitudinal completion rates will need to be reviewed in relation to the final sample size, the characteristics of the participating centres and the selected data collection workflow.

Category	KPI	Definition and method of calculation	Data source / tool	Preliminary target	Patient pathway step
Recruitment	Increase in breast cancer patients enrolled in COReHealth	Percentage increase in patients with early-stage breast cancer registered in COReHealth compared with the baseline period	COReHealth administrative data	Indicative increase of 10%	Entire pathway
Reach	Eligible patients offered participation	Number of eligible patients invited to participate divided by the total number of eligible patients identified	Screening and study records	At least 50%	T0
Participation	Enrolment rate	Number of patients providing informed consent divided by the number of eligible patients invited	Study records	To be confirmed in the final protocol	T0
Baseline completion	Completion of initial questionnaires	Number of enrolled patients completing the scheduled T0 questionnaire set divided by the number of enrolled patients	COReHealth / study database	To be confirmed in the final protocol	T0

Questionnaire completion (Target)	Completion rate at each time point	Number of questionnaires completed at each scheduled assessment divided by the number of questionnaires expected at that time point	COReHealth / study database	Preliminary minimum 20%, with a trend towards 25% for the complete longitudinal set	T0, T1, T2 and T3
Longitudinal adherence	Completion of the planned assessment pathway	Number of patients completing all mandatory assessment points divided by the number of patients enrolled at baseline	Study database	To be reported overall and by centre	T0–T3
Retention	Completion of one-year follow-up	Number of patients completing T3 divided by the number enrolled at T0	Study database	To be confirmed in the final protocol	T3
Data quality	Completeness of returned questionnaires	Proportion of required questionnaire items completed and proportion of records with calculable scores	Study database	Missing-item threshold to be defined according to the scoring rules	Entire pathway
Data consistency	Internal consistency of collected information	Identification of incomplete, inconsistent or implausible records and verification of consistency between questionnaire data and scheduled time points	Study database and data quality controls	Descriptive assessment	Entire pathway
PROM – global dimension	Health-related quality of life	EQ-5D-5L scores and changes across predefined assessment points	EQ-5D-5L	Descriptive and longitudinal analysis	Baseline, treatment and one-year follow-up
PROM – cancer-	Cancer-related quality of life	EORTC QLQ-C30 domain scores and changes over time,	EORTC QLQ-C30	Descriptive and	T0/T1, T2 and T3

related dimension		if confirmed in the final instrument set		longitudinal analysis	
PROM – breast-specific dimension	Breast-specific quality of life and satisfaction	BREAST-Q domain scores and changes across relevant stages of the pathway	BREAST-Q	Descriptive and longitudinal analysis	Breast Unit intake, post-treatment and follow-up
PREM	Patient experience	Scores relating to access, orientation, information, communication, treatment, discharge and continuity of care	Selected structured PREM tool	Analysis by domain, time point and centre	T0, T1, T2 and T3
Digital inclusion	Participation according to digital literacy	Comparison of recruitment, completion and retention according to digital literacy and data collection modality	Study records and usability data	No systematic exclusion of patients with limited digital literacy	Entire pathway
Collection modality	Use of digital, assisted or alternative methods	Proportion of assessments completed digitally, with professional assistance or through alternative collection methods	COReHealth and study records	Descriptive assessment	Entire pathway
Patient usability	Acceptability and usability of the tools	Patient assessment of clarity, accessibility, burden and overall acceptability of the questionnaire process	Patient usability questionnaire	Threshold to be defined in the final protocol	T0–T3
Completion burden	Time required for questionnaire completion	Time needed to complete the questionnaire set at each assessment point	Platform logs or patient-reported completion time	To be defined according to the final questionnaire set	T0–T3
Technical feasibility	Integration into COReHealth	Successful acquisition, storage, management and	Technical logs and integration reports	Successful implementation in all three centres	Entire pathway

		preparation of PROM and PREM data for integration into the IMPROVE framework			
Health-economic evaluation	Feasibility of cost-utility analysis	Availability of the clinical, quality-of-life and resource-use data required for MAFEIP analysis and estimation of ICER, where appropriate	EQ-5D-5L, resource-use data and MAFEIP	Completion of exploratory health-economic analysis	Entire pathway
Governance value	Usefulness for regional monitoring	Ability of the integrated PROM and PREM indicators to support recommendations for monitoring and governance of the Breast Unit Network	Integrated analysis and stakeholder assessment	Evidence-based recommendations produced	Final analysis

Table 9 Key Performance Indicators for the breast cancer use case

Technological Platform and Data Management

Data collection and management will be supported by the COReHealth digital platform, developed by Dedalus and operational within the Apulia Regional Oncology Network since 2021. The platform supports patient enrolment, care pathway planning and the monitoring of activities included in the regional Diagnostic, Therapeutic and Care Pathways.

Within the present study, COReHealth will be used to support the structured collection and management of PROMs, PREMs and the main clinical and organisational information required to describe the breast cancer care pathway. The platform will allow patient-reported data to be linked to the relevant phases of care, including Breast Unit intake, multidisciplinary assessment, treatment, discharge and follow-up.

COReHealth will also support the monitoring of questionnaire administration, completion and longitudinal participation across the predefined study time points. Where necessary, patients may be supported by healthcare professionals or use alternative collection methods, in order to avoid excluding those with limited digital skills.

The platform will also make it possible to combine patient-reported information with relevant clinical and pathway data, such as tumour stage, main clinicopathological characteristics, treatment planning and follow-up information. This will support the analysis of feasibility, patient outcomes, care experience and organisational performance across the participating centres.

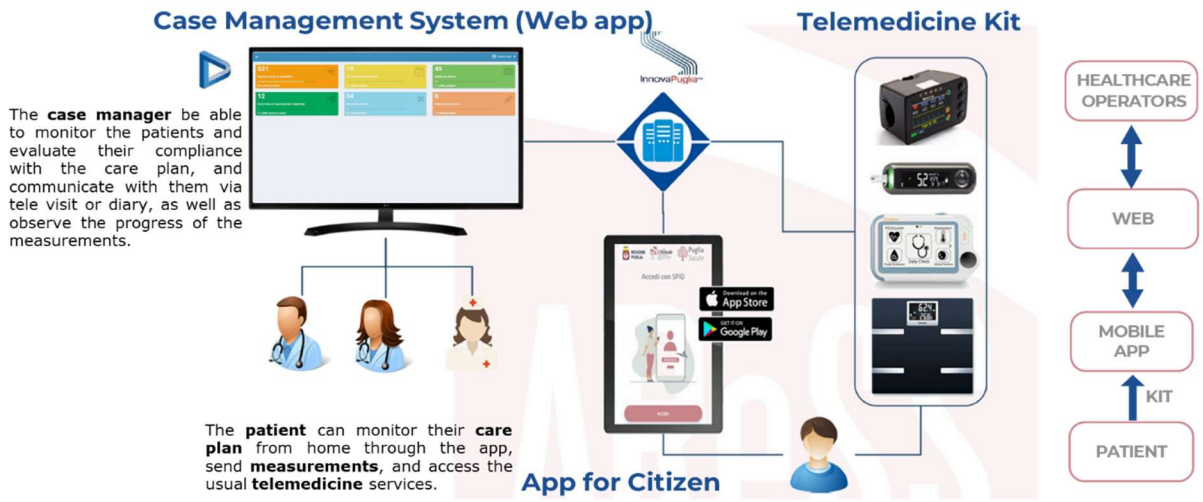


Figure 6 Components of COReHealth platform

The collected data will subsequently be prepared for integration into the IMPROVE framework, in accordance with project procedures, data governance requirements and applicable data protection regulations.

3.2 Ophthalmology

Use Case 5: Age-related Macular Degeneration (AMD)

Study

Age-related macular degeneration can result in significantly decreased vision, subsequently impacting a patient's independence with activities of daily living, social relationships, financial security, and general mental well-being. An understanding of the concerns, experiences, and perspectives of patients with wet MD is critical in delivering patient-centered care and improving life quality over a long period. Examination of the patient's visual acuity in isolation is inadequate in understanding the impact on everyday activities and results in disagreement between the doctor and the patient's perspectives and priorities. Despite the availability of numerous resources providing information on wet MD, patients continue to report poor understanding of their condition and dissatisfaction with the level of information provided by health-care services. There is a clear need to identify such shortcomings in patients' understanding of wet MD, its treatment, and its impact on the individual's quality of life. IER, ROCHE, and EYE intend to apply PGHD with wet MD in a real-world clinical setting. The aims are to understand the experience and motivation of patients in relation to age, sex, level of vision, and management.

Methodological Design

This will be an observational study aimed at collecting Patient-Reported Outcome Measures (PROMs) in combination with clinical data to better assess the treatment impact on patients with wet AMD.

- Technology Used:

Data collection will be facilitated using tablet computers to collect PROMs from patients UKC Ljubljana. The ICHOM standard set for AMD will be implemented.

- Intervention details:

The intervention will include the collection and validation of PROM questionnaires from AMD patients in UKC Ljubljana, linking this data with clinical indicators to form a comprehensive dataset.

- Recruitment period:

The recruitment phase will last approximately 2 months, targeting 100–300 patients for questionnaire validation in the first phase (completed, 200 patients.).

- Follow-up period:

There will be a follow-up period of up to 24 months post-intervention to monitor the patients' health outcomes and the impact of integrated care practices.

- Time Horizon for Analysis:

The analysis will cover a period of 36 months, from M25 to M60, as defined by the project timeline.

- Number of participants:

The study aims to recruit approximately 500 patients, with a focus on collecting both clinical data and PROMs.

No randomization will be conducted, as this is an observational study focusing on real-world data collection. The study will not have a control group. Instead, all participants will be included in a single group for the collection of both clinical and patient-reported outcomes.

Objectives

- **Primary objectives**
  1. To identify gaps in patients' understanding of AMD and its treatment.
  2. To evaluate the impact of AMD on patients' quality of life through the integration of clinical data and PROMs.
  3. To demonstrate the feasibility of using personal health data in managing wet AMD in clinical settings.

- **Secondary Objectives**
  1. To assess the effectiveness of integrated care models in ophthalmology.
  2. To explore the potential for scaling up the data collection model to a national level.
  3. To contribute insights for broader value-based healthcare approaches through the proof-of-concept.

Patient Pathway

The patient pathway for a patient with AMD is provided in Figure 7.

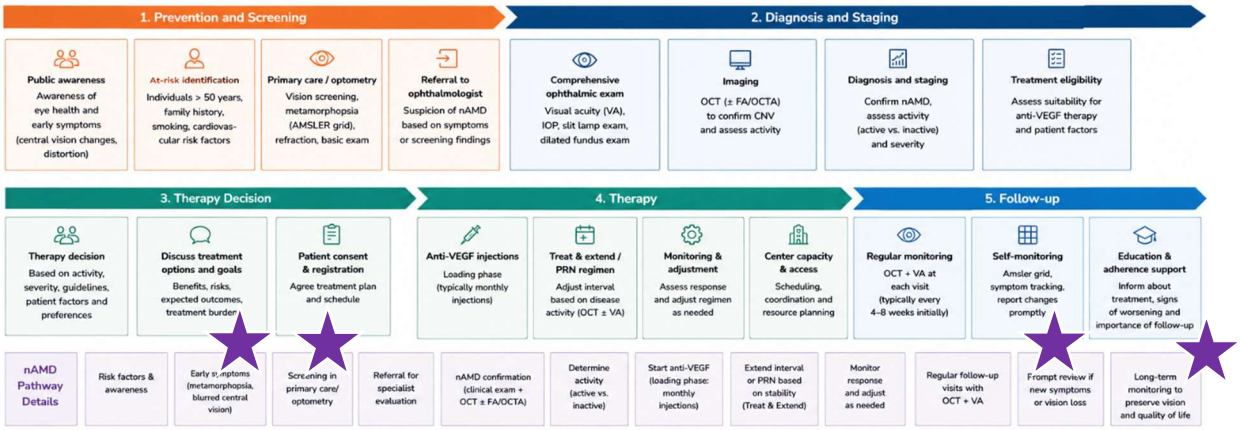


Figure 7: Ophthalmology patient pathway. PROMs are collected during the therapy decision and follow up stages.

Key Performance Indicators for AMD Monitoring

The primary objective of the ophthalmology use case is to evaluate treatment effectiveness by combining objective clinical outcomes with patient-reported outcomes. The core KPI framework therefore consists of a limited number of high-level outcome indicators that reflect visual function, disease control, and patient-perceived benefit. In addition to these primary KPIs, several derived indicators will be calculated to support more detailed analyses, benchmarking, and evaluation of treatment pathways. These derived indicators include responder analyses, domain-specific PROM analyses, and integrated clinical–PROM measures, which provide additional insight into treatment effectiveness but are not considered primary performance indicators. The following indicators will be derived from the primary KPIs and used for more detailed analyses of treatment effectiveness and patient-centred outcomes:

- proportion of patients gaining or losing ≥5 ETDRS letters;
- proportion of patients losing ≥15 ETDRS letters;
- proportion of patients achieving functional vision (≥65 ETDRS letters);
- mean baseline and follow-up ETDRS values;
- B-IVI domain scores (Visual Functioning and Emotional Well-being);
- changes in individual PROM domains;
- correlation between ETDRS change and B-IVI improvement;
- PROM–clinical discordance (patients demonstrating objective clinical improvement without corresponding improvement in patient-reported quality of life).

KPI	Category	Definition	Measurement
Mean change in ETDRS score	Clinical outcome	Average change in best-corrected visual acuity between baseline and 12-month follow-up. Represents the primary measure of functional visual improvement following treatment.	Mean ΔETDRS

Clinically meaningful visual improvement	Clinical outcome	Proportion of patients achieving a clinically meaningful improvement in visual acuity (gain ≥15 ETDRS letters).	% patients
Disease control	Clinical outcome	Proportion of patients with inactive macular neovascularisation and no evidence of retinal fluid at follow-up, indicating successful anatomical disease control.	% patients
Time to disease control	Clinical outcome	Time from treatment initiation to the first documented evidence of disease control (inactive MNV and/or absence of retinal fluid).	Months
Mean change in B-IVI score	Patient-reported outcome	Average change in Rasch-scaled B-IVI score between baseline and follow-up, reflecting improvement in vision-related quality of life.	Mean ΔB-IVI
Clinically meaningful PROM improvement	Patient-reported outcome	Proportion of patients achieving a clinically meaningful improvement in vision-related quality of life based on the predefined B-IVI threshold.	% patients

Table 10. Key Performance Indicators for Age-related macular degeneration: dependent target variables

Independent KPIs describe patient characteristics, disease severity, treatment intensity, and care delivery processes that may influence clinical and patient-reported outcomes. These indicators are not considered outcome measures themselves but provide essential context for interpreting treatment effectiveness, adjusting comparative analyses, and identifying factors associated with better or worse patient outcomes. Together with the dependent KPIs, they form the basis for value-based evaluation and continuous quality improvement. Additional explanatory variables will be used in adjusted statistical analyses and subgroup comparisons, including:

- age;
- sex;
- baseline B-IVI score;
- lesion characteristics (where available);
- anti-VEGF agent used;
- treatment regimen (e.g. fixed, PRN, Treat-and-Extend);
- duration of treatment;
- bilateral versus unilateral disease;
- previous ophthalmic treatment;
- missed appointments and delayed follow-up visits.

KPI	Category	Definition	Measurement
Baseline visual acuity (ETDRS)	Disease severity	Visual acuity at treatment initiation, providing the principal baseline measure of disease severity and an important predictor of treatment response.	Mean ETDRS
Baseline disease activity	Disease severity	Presence of active macular neovascularisation and/or retinal fluid before treatment initiation.	% patients
Time from diagnosis to treatment initiation	Care process	Time between confirmed diagnosis and first anti-VEGF injection. Reflects timeliness of care delivery.	Days
Treatment intensity	Treatment	Number of anti-VEGF injections administered during follow-up, reflecting treatment exposure.	Mean number of injections
Treatment adherence	Care process	Proportion of scheduled treatment visits completed according to the planned treatment regimen.	% completed visits
PROM completion rate	Data quality	Proportion of patients completing the scheduled PROM assessments at baseline and follow-up.	% completed questionnaires

Table 11. Key Performance Indicators for Age-related macular degeneration: independent target variables

3.3 Cardiovascular

Use Case 6: VBHC framework for patients with chronic heart failure and coronary artery disease

Study

The objective of this case study is to establish a Value-Based Healthcare (VBHC) framework for cardiovascular patients in Slovenia, with a specific focus on two diagnosis groups: heart failure (HF) and coronary artery disease (CAD). The use case aims to integrate patient-reported outcomes, socio and demographic variables, and routinely collected clinical data into a common analytical framework that supports patient-centred follow-up, longitudinal outcome monitoring, and evaluation of value in routine cardiology practice.

Led by IER, the study builds on the broader IMPROVE framework and leverages inputs from WP2, WP3 and WP4 to define relevant value domains, support data compatibility and interoperability, and address data protection and governance requirements. The use case will test how disease-specific

PROMs and a generic quality-of-life instrument can be linked with clinical and administrative hospital data to better understand symptom burden, healthcare utilisation, complications and outcome indicators in cardiovascular care.

The study is organised as a cardiovascular use case with two diagnosis-specific observational cohorts: (1) chronic heart failure patients followed in cardiology outpatient care, and (2) patients with documented coronary artery disease managed in outpatient cardiology follow-up. Atrial fibrillation is no longer included in the Slovenian implementation of this use case due to inavailability of the recommended questionnaires in Slovenian language

The overall ambition is creating a structured dataset that allows the consortium to follow the treatment outcomes that matter most to patients and consequently enable the adaptation of treatment process in order to reach best possible outcomes. This is expected to generate practical evidence for future VBHC implementation in Slovenian cardiology.

Methodological Design

The cardiovascular use case is designed as an observational, real-world implementation study with an emphasis on digital PROM collection, linkage with routinely collected hospital data, and longitudinal follow-up of patients in outpatient cardiology care. Patients are included according to diagnosis and routine clinical follow-up.

PROMs are expected to be collected through the IMPROVE digital environment or an equivalent digital data collection workflow. Clinical, treatment, utilisation and mortality data are extracted from the hospital information system and related electronic health record infrastructure. PREMs might be added to the dataset if collected in routine care. The key methodological feature is therefore the creation of a diagnosis-specific PROM plus EHR dataset, linked through a unique study identifier. At the time of reporting, the status of the ethics application for the Slovenian cardiovascular use case is “pending”.

- Technology Used:

Digital tools and platforms that allow structured PROM capture, symptom monitoring and linkage with hospital clinical data. The final local implementation will depend on the operational workflow established at the participating site.

- Intervention Details:

The intervention is the implementation of a VBHC-oriented digital data collection model in routine cardiology care. It introduces systematic PROM capture, linkage with clinical outcomes and exploratory use of PROMs in follow-up planning.

- Recruitment Period:

Recruitment will cover the implementation phase of the Slovenian cardiovascular pilot and will start once the local digital PROM workflow, data capture procedure and ethics approval are in place.

- Follow-up Period:

A 12-month follow-up is planned for both HF and CAD cohorts, with longer-term analyses possible where routine clinical data remain available.

- Time Horizon for Analysis:

The analysis combines baseline and retrospective clinical information with prospective PROM and outcome follow-up after inclusion.

- Number of Participants:

The final sample size will depend on implementation timing and the number of eligible patients completing PROMs. The aim is to include a sufficiently large real-world cohort for exploratory analyses in both diagnosis groups (100 – 150 patients per group).

No randomization will be conducted, as this is an observational study focusing on real-world data collection. The study will not have a control group. Instead, all participants will be included in a single group for the collection of both clinical and patient-reported outcomes.

Questionnaires Used in Cardiovascular Use Cases

The cardiovascular use case uses a deliberately compact PROM set. Disease-specific instruments are used to capture symptoms and functional limitations, while EQ-5D-5L provides a generic measure of health-related quality of life that is common to both diagnosis groups. PHQ-2 is included as a brief screener for depressive symptoms, which are clinically relevant in chronic cardiovascular disease.

Instrument	Diagnosis group	Main construct
KCCQ-12	Heart failure	HF-specific health status, including symptoms, physical limitation, social limitation and quality of life.
SAQ-7	Coronary artery disease	CAD-specific health status, including angina-related symptoms, physical limitation, treatment satisfaction and quality of life.
Rose Dyspnoea Scale	Coronary artery disease	Functional breathlessness and exertional dyspnoea.
PHQ-2	Heart failure and coronary artery disease	Depressive symptom screening.
EQ-5D-5L	Heart failure and coronary artery disease	Generic health-related quality of life and utility measurement.

Table 12. Questionnaires Used in Cardiovascular Use Cases

Objectives

Primary Objectives

1. To evaluate longitudinal changes in patient-reported outcomes in patients with heart failure and coronary artery disease.
2. To assess the treatment outcomes in order to adapt and improve treatment process to achieve best possible outcomes for the patients.
3. To evaluate the feasibility and added value of integrating PROM collection into routine cardiology follow-up as part of a VBHC-oriented cardiovascular care model.

Secondary Objectives

4. To describe patient characteristics, treatment patterns and healthcare utilisation in the CAD and HF cohorts using linked PROM and EHR data.
5. To analyse patient engagement and completion of digital PROM collection over time.
6. To explore whether PROM results can support more structured monitoring, clinical decision-making and follow-up planning in routine cardiology care.
7. To generate a scalable indicator framework for future VBHC implementation in cardiovascular care in Slovenia.

Patient Pathway

The cardiovascular use case follows a shared care pathway for coronary artery disease (CAD) and heart failure (HF), structured around five broad phases: prevention and screening, diagnosis, therapy decision, therapy, and follow-up. The pathway is intentionally organised at a level that is common to both diagnosis groups, while still allowing for diagnosis-specific PROM collection and some differences in treatment intensity, clinical monitoring and event-driven reassessment. The purpose of the pathway is to show where patients typically enter care, how diagnosis and treatment planning are established, and at which points patient-reported outcomes can be collected and linked to routine clinical data (Figure 8).

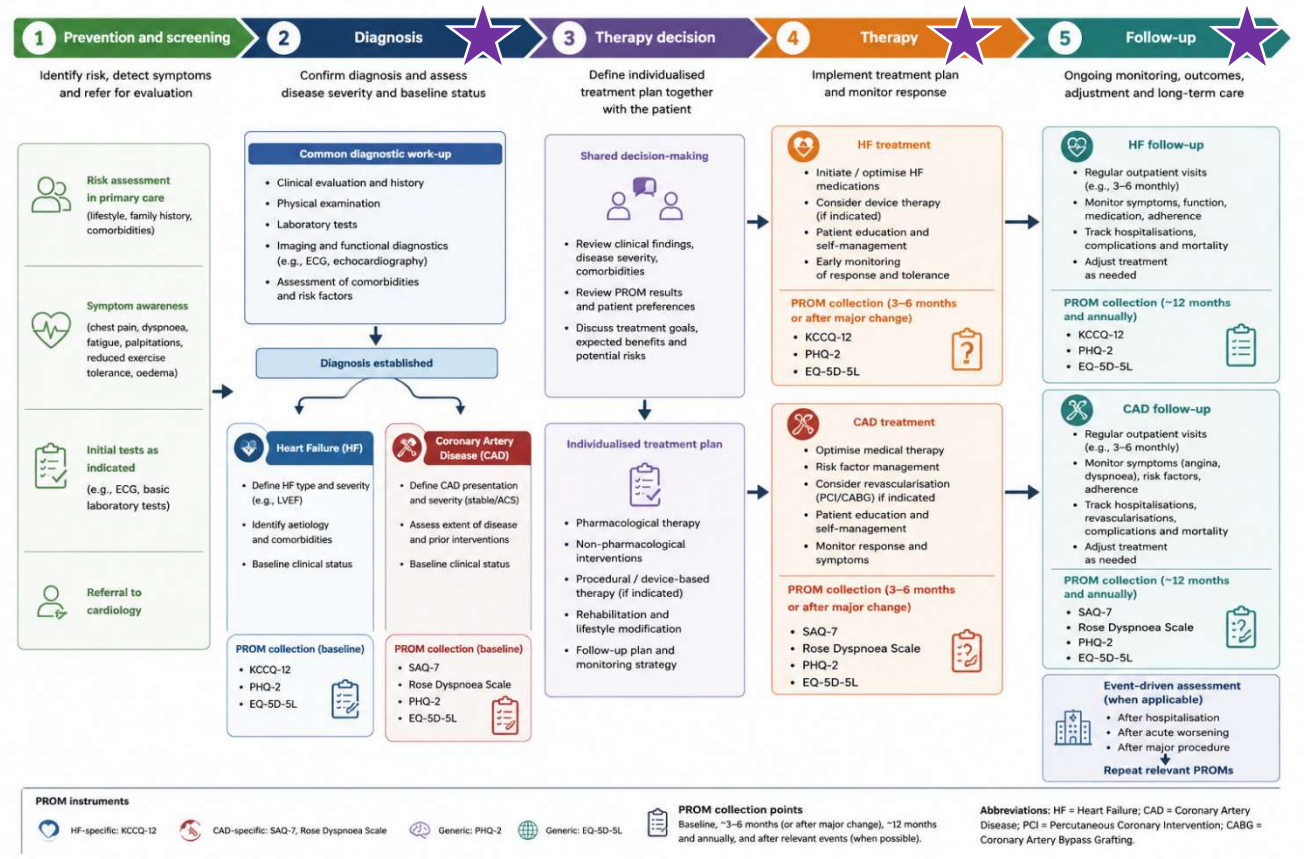


Figure 8: Cardiology patient pathway

The pathway begins with prevention and screening. In this phase, individuals with cardiovascular risk factors or symptoms suggestive of CAD or HF are identified either in primary care or in other parts of the health system. This may include patients presenting with chest pain, dyspnoea, reduced exercise tolerance, fatigue, oedema, or other symptoms that trigger further cardiology work-up. The main purpose of this phase is to recognise patients who require specialist assessment and to ensure referral into the cardiology pathway. PROM collection is not essential at this stage, but where operationally feasible, a generic baseline measure such as EQ-5D-5L could be collected to capture an early patient-reported assessment of overall health status before full diagnostic work-up.

The second phase is diagnosis. Here, the patient undergoes cardiology assessment aimed at confirming the diagnosis, defining disease severity, and establishing the baseline clinical profile. This phase includes specialist consultation, review of medical history and comorbidities, clinical examination, and relevant laboratory, imaging, or functional investigations. For heart failure, this phase includes diagnostic clarification and assessment of cardiac function, including the role of imaging and LVEF. For coronary artery disease, it includes confirmation of CAD status and relevant clinical history, including prior procedures where applicable. This is the key baseline measurement point for the use case, and PROM collection should be initiated here. For HF, the recommended baseline PROM set is KCCQ-12, PHQ-2 and EQ-5D-5L. For CAD, the recommended baseline PROM set is SAQ-7, Rose Dyspnoea Scale, PHQ-2 and EQ-5D-5L.

The third phase is therapy decision. Once the diagnosis and baseline clinical profile are established, the treating team defines the most appropriate management plan. This decision is based on clinical findings, disease severity, prior procedures, comorbidities, and the patient's functional status, but it should also take into account patient preferences and the PROM results collected at baseline. In practical terms, this phase determines whether the patient will primarily receive pharmacological management, intensified outpatient monitoring, rehabilitation-oriented support, device-based treatment, procedural treatment, or a combination of these approaches. PROM results are particularly relevant at this stage because they provide structured information on symptom burden, functional limitation and health-related quality of life, which can help refine treatment priorities and follow-up intensity.

The fourth phase is therapy. This includes initiation of treatment, optimisation of medication, implementation of non-pharmacological measures, and where relevant procedural or device-based interventions. Although the overall structure is common, the content of this phase differs somewhat between the two diagnosis groups. In HF, treatment may involve optimisation of heart failure medication, monitoring of symptoms and tolerance, and management of device-related or advanced treatment pathways where applicable. In CAD, treatment may include optimisation of antianginal and secondary prevention therapy, risk-factor management, and follow-up after revascularisation or other CAD-related interventions. A second PROM collection point is recommended during this phase, ideally after initial treatment optimisation or at an early follow-up interval of approximately 3–6 months. For HF, this intermediate assessment should include KCCQ-12, PHQ-2 and EQ-5D-5L; for CAD, SAQ-7, Rose Dyspnoea Scale, PHQ-2 and EQ-5D-5L should be repeated.

The final phase is follow-up. This phase covers routine outpatient monitoring, annual reassessment, and event-triggered review after clinically relevant deterioration, hospitalisation, or urgent procedures. It is in this phase that the VBHC logic of the use case becomes most visible, because repeated PROM collection can be directly linked to healthcare utilisation, complications, and mortality outcomes. During follow-up, clinicians assess whether symptoms are stable or worsening, whether treatment needs to be adjusted, and whether patients are experiencing a meaningful improvement or decline in quality of life and functional status. At a minimum, a major reassessment around 12 months is recommended for both diagnosis groups. At this follow-up point, the same PROM set used at baseline should be repeated: KCCQ-12, PHQ-2 and EQ-5D-5L for HF; SAQ-7, Rose Dyspnoea Scale, PHQ-2 and EQ-5D-5L for CAD. Additional event-triggered PROM collection can be considered after hospitalisation, acute worsening, urgent revascularisation, or other major clinical events, where this is operationally feasible.

Key Performance Indicators

The use case KPI framework is intentionally concise and focuses on indicators that are clinically meaningful, feasible to operationalise from the available CAD and HF data dictionaries (provided by GH Celje), and aligned with the overall IMPROVE evaluation logic. The KPIs therefore prioritise three dimensions: patient-reported health status, clinically relevant outcomes and feasibility of PROM-based data collection.

The tables below distinguish dependent target variables from independent variables. Dependent target variables represent the main outcomes of interest. Independent variables represent patient,

disease, treatment and process characteristics that can be used to describe the cohorts, explain variation in outcomes and support adjusted analyses.

Category	KPIs	Definition
PROM / health status	Change in KCCQ-12 score	Mean change in KCCQ-12 summary score between baseline and follow-up, reflecting HF-specific symptoms, limitations and quality of life.
PROM / health status	Change in EQ-5D-5L	Mean change in EQ-5D-5L index and/or EQ VAS between baseline and follow-up.
PROM / mental health	Change in PHQ-2	Change in depressive symptom burden over time.
Healthcare utilisation	HF-related hospital admission	Occurrence or rate of hospital admission related to heart failure worsening or decompensation during follow-up.
Safety / complications	HF care-related complication	Occurrence of documented device-related, medication-related or healthcare-associated complications.
Mortality	All-cause mortality	Vital status during follow-up; where possible, time from baseline/index event to death.

Table 13. Key Performance Indicators for Heart Failure: dependent target variables

Category	KPIs	Definition
Demographics	Age and sex	Age at baseline and recorded biological sex.
Baseline health status	Comorbidity and lifestyle profile	Cardiovascular comorbidities, smoking status, alcohol use, height/weight and derived BMI where feasible.
Disease severity	LVEF and diagnostic category	Left ventricular ejection fraction, imaging performed and HF diagnostic category.
Treatment	HF treatment profile	Pharmacological treatment, procedural treatment, device therapy and cardiac rehabilitation.

Table 14. Key Performance Indicators for Heart Failure: independent regular variables

Category	KPIs	Definition
PROM / health status	Change in SAQ-7 score	Mean change in SAQ-7 score between baseline and follow-up, reflecting CAD-specific symptoms, limitations and quality of life.
PROM / symptoms	Change in Rose Dyspnoea score	Change in exertional dyspnoea and functional breathlessness over time.
PROM / health status	Change in EQ-5D-5L	Mean change in EQ-5D-5L index and/or EQ VAS between baseline and follow-up.
PROM / mental health	Change in PHQ-2	Change in depressive symptom burden over time.
Clinical outcome / utilisation	Major cardiovascular event or admission	Occurrence of acute myocardial infarction, stroke, heart-failure admission or other cardiovascular hospitalisation during follow-up, where identifiable in the linked dataset.
Procedure / mortality	Revascularisation or death	Occurrence of PCI/CABG during follow-up and all-cause mortality/vital status.

Table 15. Key Performance Indicators for Coronary Artery Disease: dependent target variables

Category	KPIs	Definition
Demographics	Age and sex	Age at baseline and recorded biological sex
Baseline health status	Comorbidity and renal profile	Cardiovascular comorbidities, diabetes/insulin dependence, creatinine and dialysis dependence where available.
Physiology / severity	Initial clinical status	Heart rate, systolic blood pressure, discharge diagnosis, cardiogenic shock/cardiac arrest where relevant, left main disease and number of diseased vessels where available.
Treatment history	Prior revascularisation	History and timing of prior PCI and/or CABG.

Table 16. Key Performance Indicators for Coronary Artery Disease: independent regular variables

Use Case 7: Severe aortic stenosis / TAVI

Study

This use case focuses on patients with severe aortic stenosis undergoing TAVI in the Interventional Cardiology Department at Vall d'Hebron University Hospital in Barcelona.

It aims to advance the care pathway digitalization through the implementation and validation of a remote patient monitoring platform that improves the continuity of care, supports clinical decision-making, and empowers patients before and after the intervention.

The proposed approach includes the deployment and validation of the Get Ready® digital solution to optimize the aortic stenosis care pathway, enable early identification of potential risks, facilitate coordination among healthcare professionals across different levels of care and empower patients throughout their care process. It also includes the digitalization of the pathway through validated protocols, educational materials, questionnaires, and the collection of Patient-Generated Health Data (PGHD).

Methodological Design

This is a prospective, randomized, open-label, single-center study with event evaluation, designed to assess a 24-hour early discharge strategy combined with non-invasive remote electrocardiographic monitoring in patients undergoing TAVI.

In addition to the assessment of clinical safety and arrhythmic events, the use case will include the collection of Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs), together with other clinical and remote follow-up variables, in order to generate a more comprehensive dataset focused on outcomes that are relevant to patients through the digital platform.

- Technology Used:

The main technology used in this use case will be the Get Ready® platform, which will support structured data collection and serve as the basis for the digitalization of the care pathway. The solution will contribute to optimizing the TAVI programme, improving continuity of care through remote patient monitoring, facilitating more coordinated care, and reinforcing the active role of patients in the management of their condition.

In addition, the platform will be used to collect PREMs and PROMs. The patient application will allow the recording of health status data in both study groups throughout follow-up, while the non-invasive remote electrocardiographic monitoring system will be used in the intervention group for ambulatory ECG monitoring during the first month after discharge.

- Intervention details:

The intervention will combine the collection of clinical data, the administration of PROMs and PREMs, and the implementation of remote follow-up tools in patients undergoing TAVI.

- Control group (standard management):

Patients will receive the hospital standard post-TAVI management, which may include conventional in-hospital monitoring, serial ECGs, discharge according to clinical decision and pacemaker implantation if clinically indicated. In this group, health status data will also be collected through the patient App, together with questionnaires focused on patient outcomes and experience.

- Intervention group (early discharge + remote monitoring):

Patients will be discharged 24 hours after the TAVI procedure and will be provided with an ECG device monitoring system, enabling intermittent 2-lead ECG recording for one month that they will take home. The system will allow remote transmission of arrhythmic events and the detection of conduction disturbances.

Detected events will be reviewed by the clinical staff involved in the study, who will determine whether in-person or remote assessment is required. In addition, health status data, as well as PROMs and PREMs, will also be collected through the digital tool.

- Recruitment period:

Recruitment period is planned from April 2026 to July 2027.

- Follow-up period:

Each participant will be followed for 12 months. In person hospital follow-up visits will take place after 30 days (±3 days) and after 12 months (±30 days) from the intervention. During these 12 months, clinical variables, adverse events, health status information will be collected through the digital platform, and patient-reported outcome questionnaires will be completed.

- Time Horizon for Analysis:

The overall study timeline will run from April 2026 to July 2028, followed by an additional 3-month period for data analysis and study conclusions.

- Number of participants:

Approximately 100 participants are expected to be included.

- Randomization procedure:

A simple 1:1 randomisation procedure will be applied, and the study will be open label.

- Groups:

The study will have two groups:

1. Control (N≈50): standard post-TAVI management, including collection of health status data through the patient application and patient-reported questionnaires.
2. Intervention (N≈50): 24-hour early discharge plus non-invasive remote electrocardiographic monitoring, together with collection of health status data and patient-reported questionnaires.

Objectives

- **Primary Objectives / Primary Endpoints**
  1. 30-day incidence of the composite clinical endpoint:
     - all-cause death,
     - unplanned hospital readmission for any cause.
  2. 30-day incidence of clinically relevant arrhythmic events leading to therapeutic change:
     - relevant conduction disturbances,
     - permanent pacemaker implantation,
     - relevant adjustment of pharmacological treatment,

- new-onset or recurrent atrial fibrillation with therapeutic impact,
- other sustained supraventricular or ventricular tachyarrhythmias requiring intervention.

- **Secondary Objectives / Secondary Endpoints**
  1. All-cause mortality at 30 days and 1 year.
  2. Unplanned hospital readmission for any cause at 30 days and 1 year.
  3. Cardiovascular mortality at 30 days and 1 year.
  4. Cardiovascular hospital readmissions at 30 days and 1 year.
  5. Permanent pacemaker implantation rate at 30 days and 1 year.
  6. Incidence of high-grade atrioventricular block.
  7. Incidence of new-onset or recurrent atrial fibrillation requiring therapeutic change.
  8. Time to pacemaker implantation or therapeutic change due to arrhythmia.
  9. Evolution of conduction disturbances detected within the first 72 hours after TAVI.
  10. Evolution of QRS duration.
  11. Adherence to remote monitoring.
  12. Length of hospital stay.
  13. Direct costs associated with the index of hospitalization and readmissions.
  14. Health-related quality of life assessed through a validated questionnaire.
  15. Collection and analysis of PROMs and PREMs to evaluate patient-perceived outcomes and care experience within the digitalized care pathway.

Patient Pathway

The patient pathway for a severe aortic stenosis patient is provided in Figure 9.

Figure 9: Severe aortic stenosis pathway. PREMs will be collected during follow up, PROMs at the diagnosis and staging and follow up stages. Concept: PMS/MDT, Design. ius

Key performance indicators

Independent variables:

Category	KPIs	Definition
Activity	Procedure volume	Total number of procedures performed of TAVI in CL, in a certain period of time (week/month/year)
Efficiency	Length of stay	The average length of stay post- procedure defined as date of discharge - date of admission for the specific procedure. To be measured in hours and then reported in days (e.g. 2,4 days).
	Fast track discharge rate	Ratio of stays with less than 2 days spent in the hospital over total stays for the intervention
	In-person visits	Reduction of in-person visits for patient follow-up
	Prioritization on the waiting list	Number of patients prioritized on the waiting list at the date of the procedure or in follow-up in a certain period of time (week/month/year)

Quality	30-day readmission rate	The % of patients with new admission with the same speciality as previous procedure within 30 days after procedure date. Matched on patient id and speciality
	Complications	The % of complications in patients with TAVI procedures in a certain period of time (week/month/year)
	Mortality	The % of mortality in patients with TAVI procedures in a certain period of time (week/month/year)
	QoL	The QoL in patients with TAVI procedures in a certain period of time (week/month/year). The following validated questionnaires will be used to measure quality of life: KCCQ-12 (Kansas City), TASQ-Q
	Frailty	It measures the index of multidimensional frailty of the patient, integrating clinical, functional, cognitive and social deficits. The validated Fragile Index-VIG (IF-VIG) questionnaire will be used
Patient experience	Patient NPS	Net Promotor Score for patients with respect to the use of the platform
	PREM PPE-15	Patient-Reported Experience Measure - Picker Patient Experience Questionnaire. Questions on the hospitalization process experience.
HCP experience	HCP NPS	Net Promotor Score for health care professionals respect to the use of the platform
Adherence	Total of calls	Total number of calls to patients from the support centre and the hospital
	Type of calls	Total number of calls classified by type
	Program adherence by phase	Percentage of patients with adherence to the program greater than 50%

Dependent variables:

Category	KPIs	Definition
Sustainability	CO2 footprint	Reduction in CO2e as a result of project interventions (e.g. Reduced traveling by patients (remote consultations), reduced length of stay, reduced material usage)

Table 17. Key Performance Indicators for severe aortic stenosis use case

3.4 Neurology

Use Case 8: VBHC framework for Multiple Sclerosis (MS) rehabilitation

Study

The objective of this case study is to create the VBHC framework for multiple sclerosis subjects, in particular focused on a target population of young patients (≤ 40 years old) with a relapsing remitting disease course or progressive disease course. PROMs will be collected through national MS Care Unit(s) focused on neurorehabilitation treatments and used together with PREMs and PPI to determine whether a virtuous national MS Care Unit in term of PROMs and/or PREMs and/or PPI generates an impact on direct or indirect health care cost. The PROMs outcomes, identified from the already existing PROMOPRO-MS dataset, will be collected as active and passive measurements (digitally). We will engage different stakeholders (healthcare professionals, patients, caregivers, industry and academics) to adopt a framework for meaningful patient and public involvement in improving access to neurorehabilitation treatments and service design.

Methodological Design

The study adopts an experimental, prospective, interventional design aimed at evaluating the added value of integrating patient-reported dimensions into the standard multidisciplinary neurorehabilitation pathway for people with Multiple Sclerosis (MS), within a Value-Based Health Care (VBHC) framework. The methodological approach is based on a two-arm parallel-group design, in which participants are allocated to either a control condition receiving standard care (multidisciplinary rehabilitation) or an intervention condition receiving an “enhanced support” (in parallel with the multidisciplinary rehabilitation defined by the individual rehabilitation plan). We will use a block randomization method to randomize participants

- Technology Used:

The present Use Case does not rely on any specific technology, as the aim is to assess a method (i.e., a multi-disciplinary approach to rehabilitation including PROMS, PREMS and PPI) rather than a specific tool (e.g., health technology). The results will also provide insights at the process level, such as the impact of this integrated approach on direct or indirect health service costs. However, it is important to note that the Use Case may benefit from the use of technological tools for data collection. A subgroup of the experimental group may receive, based on the results of the PPI survey a device for monitoring physical activity (number of steps), sleep (time spent sleeping) and basic physiological functions (heart rate) to be used the week before the baseline assessment and the week after the follow-up assessment. In this way, it will be possible to assess the impact of rehabilitation and integrative intervention on daily life.

The study ultimately aims to enhance neurorehabilitation treatment for patients with multiple sclerosis (MS) by incorporating PREMS and PPI into the standard evaluation and treatment prescription process. The main aims are:

1) Create the VBHC framework for multiple sclerosis subjects
2) Evaluate the impact of the MS Care Unit approach by integrating the patient reported dimension into the standard evaluation. PROMs/PREMS/PPI will be collected through national MS Care Unit(s) focused on neurorehabilitation treatments (multidisciplinary rehabilitation) to determine

whether the use of PROMs and/or PREMS and/or PPI generates an impact on intangible and indirect cost.

- Intervention details:

The study will involve two groups: the intervention group, which will undergo this enhanced support incorporating PREMS and PPI, and the control group, which will follow the standard evaluation and rehabilitation process.

- Participants

50 people with MS will be randomized into one of two groups: Control Group (25 participants) or Intervention Group (25 participants).

Inclusion criteria for participation in the study are as follows:

- Having the diagnosis of MS with a relapsing remitting or progressive disease course
- 18-40 years old
- Having accepted to participate in the study and provided written informed consent
- Having the availability to participate on all study activities
- Patients with a prescription of multidisciplinary rehabilitation plan: at least 2 rehabilitation activities among physical therapy, pelvic rehabilitation, psychological support, speech therapy and occupational therapy.

Individuals that do not fulfil ALL the inclusion criteria will be excluded from participating.

Both groups will be assessed at baseline (T0) and after multidisciplinary rehabilitation (T1).

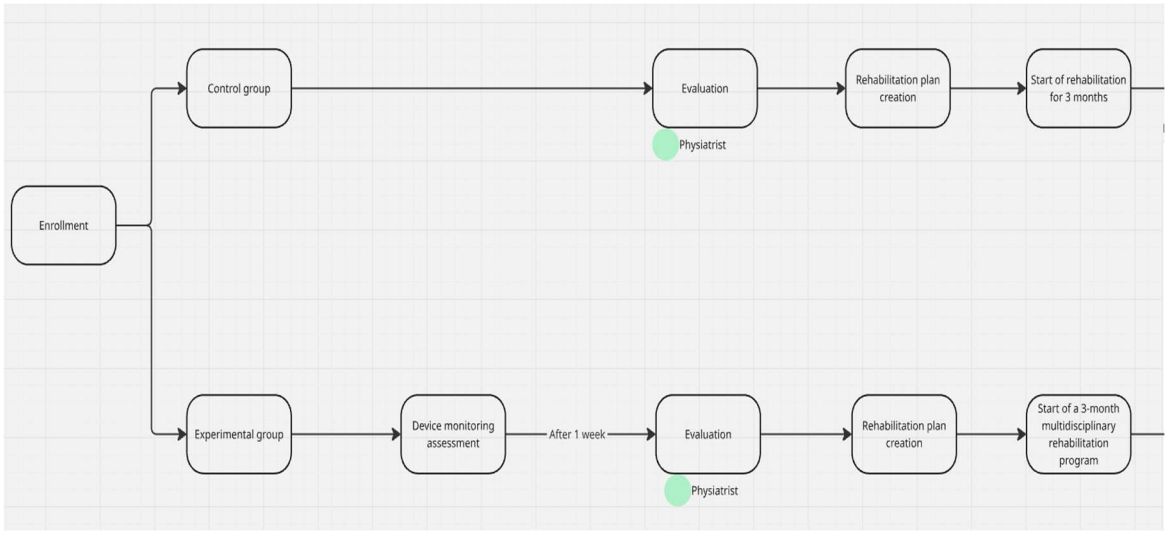
The assessment will include the Multiple Sclerosis Functional Composite score (MSFC), an index frequently used to monitor MS progression and treatment effects (Cutter et al., 1999; Fisher et al., 1999) composed by three tests: (i) Timed 25-Foot Walk Test (T25FW), quantitative measure of lower extremity function, requiring that the patient is directed to one end of a clearly marked 25-foot course and is instructed to walk 25 feet as quickly as possible, but safely. The task is immediately administered again by having the patient walk back the same distance. Patients may use assistive devices when doing this task. Average time is recorded; Nine Hole Peg Test (NHPT) is a quantitative measure of upper extremity (arm and hand) function, during this patients places and removes nine pegs; each hand tested twice and average time or reciprocal is used; (iii) Paced Auditoriy Serial Addition Test (PASAT) with 3 second-inter stimuli interval is a measure of cognitive function that specifically assesses auditory information processing speed and flexibility, as well as calculation ability. Single digits are presented either every 3 seconds and the patient must add each new digit to the one immediately prior to it. The test score is the number of correct sums given (out of 60 possible) in each trial.

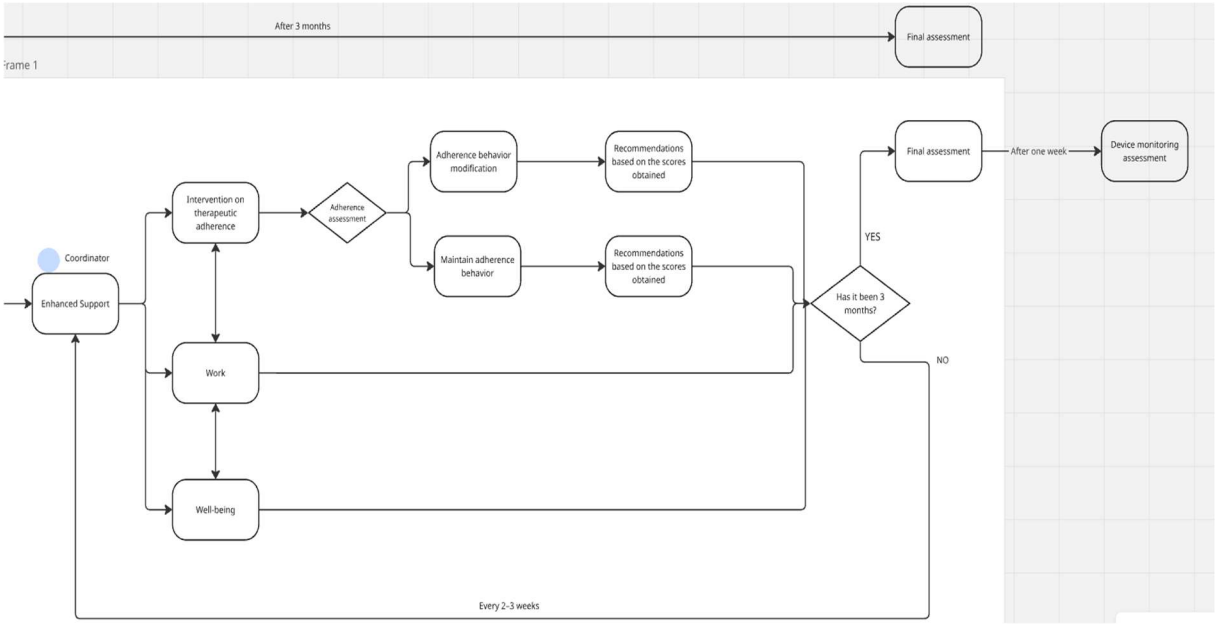
Perceived fatigue and mood status will also measured by the Modified Fatigue Impact Scale (MFIS) (Vollmer & Patrucco; 2009) and the Hospital Anxiety and Depression Scale (HADS) (Costantini, Musetti et al., 1999), respectively.

We will evaluate the Quality of Life (QoL) using the EuroQoL 5 dimensions-5 levels (EQ-5D-5L) to calculate QALY (see KPI section) and the World Health Organization Quality Of Life 100-item version (WHOQOL-100) to further detail QoL impacted domains (Bertoli, Mosconi et al., 2015).

Moreover, difficulties at work and caregiver burden will be assessed through the Work Productivity and Activity Impairment-Multiple Sclerosis (WPAI-MS; Rottoli, Lapucci et al., 2010) and the caregiver strain index (Bassi, De Cunto et al., 2006). All participants will also undergo standard assessment based on the individual rehabilitation plan.

Only the experimental group will be assessed using an in-depth battery of outcomes to capture the patient-reported dimension, which will also be used to tailor the enhanced support intervention.





In addition, a subgroup of the experimental group may receive, a device for monitoring physical activity (number of steps), sleep (time spent sleeping) and basic physiological functions (heart rate) to be used

the week before the T0 assessment and the week after the T1 assessment. In this way, it will be possible to assess the impact of rehabilitation and integrative intervention on daily life.

PROMs/PREMs/PPI	What it measures
HLS-EU-Q6 (European Health Literacy Survey Questionnaire – shortshort form)	Health Literacy
PROFFIT (Patient-Reported Outcome for Fighting Financial Toxicity)	Financial Cost and economic barriers
CIASS (Chronic Illness Anticipated Stigma Scale)	Social Stigma
PICS (Patient Information and Communication Satisfaction questionnaire)	Perceived Involvement
PTOPS (Physical Therapy Outpatient Satisfaction Survey)	Flexibility and availability of access to rehabilitation service
CSQ-8 (Client Satisfaction Questionnaire – 8 item version)	Treatment satisfaction
CARE (Consultation and Relational Empathy Measure)	Treatment satisfaction
HADS (Hospital Anxiety and Depression Scale)	Mental Health
MFIS (Modified Fatigue Impact Scale)	Fatigue
IPQ-R (Illness Perception Questionnaire – Revised)	Disease and treatment perception
Resilience Scale	Resilience
TSRQ (Treatment Self-Regulation Questionnaire)	Motivation
Participation Scale	Participation
PAM 13 (Patient Activation Measure – 13 item version)	Control
SEMCD (SelfEfficacy for Managing Chronic Disease scale)	Self-efficacy and self-management
WHOQOL-100 (WHO Quality of Life – 100 items)	Quality of life
EQ-5D-5L	Quality of life
WPAI-MS (Work Productivity and Activity Impairment Questionnaire – Multiple Sclerosis version)	Work impact
CSI (Caregiver Strain Index)	Caregiver Burden
PPI	Patient preferences

Table 18: PROMs, PREMs, and PPI Tools included in the neurology use case and their targeted Health-Related constructs that are evaluated

Enhanced support

The “Enhanced Support” will take place in parallel with the multidisciplinary rehabilitation defined by the individual rehabilitation plan (intervention group). This type of support is based on three different models, each focusing on specific dimensions: adherence, work and well-being.

1) Adherence intervention: We will focus on three main variables; awareness, disease control and acceptance, which are important elements that have an impact on adherence behaviors.
2) Vocational rehabilitation: In this case, the goal is to help patients develop strategies to improve well-being and productivity in the workplace
3) Goal assessment-driven intervention, based on individual day life goals: The purpose of this intervention is to help participants identify reliable objectives that can contribute to improve their quality of life in everyday activities. During the intervention, specific objectives will be identified and possible strategies to be applied in daily life to achieve them.

The person who will give this treatment to patients is the “Coordinator” that will work in collaboration with a multidisciplinary team (a group of mentors/HCP). This defined group will provide advice and guidance to the “Coordinator”. The "coordinator" will meet the patient for the “Enhanced support” approximately every 2-3 weeks for a total of 3 to 6 times, depending on the feedback of people affected by the disease engaged in the multi-stakeholder process.

MULTI-ACT Implementation

To ensure the engagement of all relevant stakeholders throughout the project, we will apply the MULTI-ACT framework (Zaratin, Bertorello et al., 2022).

An Engagement Coordination Team (ECT) will first be established to oversee and manage stakeholder involvement. Central members of the ECT will include people affected by MS (both patients and caregivers) and MULTI-ACT–trained representatives, who will support the team throughout all engagement processes. In addition, the ECT will include experts relevant to the project’s mission and priority areas (e.g., rehabilitation physicians, therapists, psychologists, and policy makers). All ECT members will be expected to ensure the representativeness of their respective communities.

The first task of the ECT will be to validate the study protocol and conduct a critical review of the proposed outcomes, including the potential to monitor physical activity, sleep, and basic physiological functions through a wearable device before and after the rehabilitative treatment to assess its impact on daily life. Overall suggestions to remove, add, or modify outcomes will be collected and integrated into a revised version of the protocol, which will then be submitted for ethics approval.

Next, we will administer to the ECT the Patient Preference Information questions focused on the intervention design. Feedback from this activity will help refine the study questions before extending them to a broader community, including the study participants. Based on this process, decisions regarding specific aspects of the intervention (e.g., the frequency of the enhanced support integrative intervention) will be finalized.

At the end of the study, the results will be presented to the ECT to evaluate the effectiveness of the engagement process and to discuss dissemination and implementation strategies.

The ECT will be involved through in-person or online meetings, as well as individual interviews or surveys. The total expected workload will not exceed four to five meetings, each lasting approximately two to three hours.

- Recruitment period:

Recruitment will last 12 months (from September 2026 to August 2027).

- Time Horizon for Analysis:

Analyses will be carried out in the last year of the project (M48-60, i.e., from November 2027 to October 2028).

- Number of participants:

50 people with MS

- Randomization procedure:

We will use a block randomization method to randomize participants into groups that result in equal sample sizes.

- Groups: Control (N=25), Intervention (N=25),

25 participants will be allocated to the intervention group (PREMS/PPI-enhanced assessment and treatment prescription process), whilst 25 participants will be allocated to the control group (standard assessment and treatment prescription).

Objectives

- **Primary Objectives**:
  1. Create the VBHC framework for multiple sclerosis subjects
  2. Evaluate the impact of the MS Care Unit approach by integrating the patient reported dimension into the standard evaluation. PROMs/PREMS/PPI will be collected through national MS Care Unit(s) focused on neurorehabilitation treatments (multidisciplinary rehabilitation) to determine whether the use of PROMs and/or PREMS and/or PPI generates an impact on intangible and indirect cost.

- **Secondary Objectives:**
  1. Improve of clinical outcomes and quality of life following the integrated support intervention (in addition to multidisciplinary rehabilitation therapy) that values and incorporates the patient's perspective (patient-reported dimension)
  2. Improve of patient experience and satisfaction throughout the care pathway
  3. Improve of patient adherence to the multidisciplinary rehabilitation plan
  4. Identify of factors (facilitators/barriers) influencing access to the MS Care Unit among young patients with multiple sclerosis

Patient Pathway

The patient pathway for multiple sclerosis is provided in Figure 10.

Figure 10: Neurology patient pathway. PREMS and PROMs will be collected during follow up. Concept: PMS/FISM, Design. ius

Key Performance Indicators

Dependent target variables:

Category	KPIs	Definition
Efficiency	Direct costs	Staff cost per pathway
	Indirect cost: (Informal care) hours of caregiver assistance	Hours of free time lost
	Productivity loss: Absenteeism	Hours of absence from work
	Intangible cost: QALY	A QALY (Quality-Adjusted Life Year) is a measure used in health economics that combines the length of life and the quality of health into a single value, where 1 QALY represents one year of life in perfect health.
	Value index (cost/QALY)	The Value Index (cost per QALY) expresses the cost required to gain one additional quality-adjusted life year (QALY) from a specific intervention. It is calculated by dividing the total cost of an

		intervention by the number of QALYs gained, and it is used to compare the economic value of different healthcare treatments (cost/QALY)
Quality	Clinical pathway deviation rate	Interruption of the rehabilitation cycle
Patient experience and clinical condition	Change in neurological symptoms	Assess whether, over time (T0-T1), patients' neurological symptoms change detectably (Multiple Sclerosis Functional Composite score)
	Patient satisfaction score and PREMs score	Assess patients' satisfaction and experience (PREMs score)
	Disease-specific clinical outcome (PROMs score)	Differences in patient-reported outcomes between the first and second visit.
Adherence	Adherence rate	Number of missed/cancelled rehabilitation sessions

Independent target variables:

Category	KPIs	Definition
Quality	Rehabilitation cycles since first visit	Number of rehabilitation cycles previously performed
	Adverse event rate	Clinical health events (e.g. breaking a limb, etc.) that cause a change/modification of the rehabilitation plan
	Clinical pathway deviation rate	Interruption of the rehabilitation cycle
Patient experience and clinical condition	Patient satisfaction score and PREMs score	Assess patients' satisfaction and experience at baseline (PREMs score)
	Disease-specific clinical outcome (PROMs score)	Patient-reported outcomes at baseline.
Adherence	PROMs/PREMs completion rate	Percentage of completion of questionnaires implicated in the study
	Patient retention	Number of patients remain in the study until the end of the observation period

Table 19: KPIs for the neurology use case

3.5 Chronic inflammation

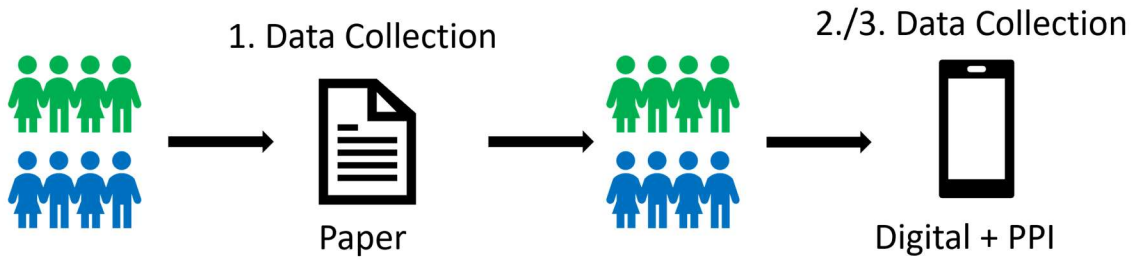
Use Case 9: Chronic Rhinosinusitis (CRS)

Study

The topic of Chronic Inflammation IHI IMPROVE Case Study focuses on Chronic Rhinosinusitis (CRS). CRS is a very widespread disease affecting more than 10 % of the population in Europe. Although chronic inflammation and malignancies differ in many aspects of the disease, the assessment of QoL and patient reported outcomes for value-based treatment share a lot of issues and barriers. Recently, new treatment options became available for patients with severe uncontrolled CRS with nasal polyps. Several biologics aimed toward specific molecular mediators of inflammation were approved for this patient group. The treatment solutions are expensive and have to be continuously injected. To evaluate treatment response the clinical use of PGHD is recommended by guidelines and position papers. Interestingly, PROMs and PREMs only poorly correlate with objective measurements in CRS. This is unsatisfactory for clinicians but underlines their relevance to obtain a holistic understanding of our patients. The combination of both – clinical investigations and PROMs/PREMs are required to assess patient´s disease in relation to his/her subjective disease experience. Broad evaluation should be performed not only in study situations but in real world patient treatment. Applying this use case faces the whole spectrum of CRS patients as well as different kinds of stakeholders.

Methodological Design

The study is designed as a longitudinal observational study aimed at collecting Patient-Reported Outcome Measures (PROMs) in combination with clinical data to get a better impression of how far QoL and disease related QoL as well as distress impact patients with CRS. All patients complete the existing questionnaires for the CRS use case on paper. The second and third data collections, which are scheduled as part of routine patient appointments, will be conducted digitally using iPads available at the clinic. The digital questionnaires are designed so that there is a playful variation of one or two questionnaires, while the others are identical to the existing questionnaires. Additionally, the option to complete questionnaires with digital assistance may be provided. As a second focus we will investigate the patient's and healthcare provider's view on the impact and usability of PROMs within the clinical setting and therefore implement additional questionnaires that address these points. To determine which type of PROM (Patient-Reported Outcome Measure) integration patients prefer (paper vs. digital; playful vs. traditional), a so-called Patient Preference information (PPI) questionnaire is being designed/planned, which each patient will complete at the end of the second or third data collection. Additionally, heath care providers will be asked to answer a questionnaire regarding their preferred method of evaluation of the questionnaire, the implementation of the automated scoring, and longitudinal presentation of the scores.



- Technology Used:

Data collection within the clinical setting. Pre-studies are performed on paper, integration of ePROMs is established within the project together with BETTER and will be implemented as soon as possible.

- Intervention details:

The intervention includes the use of PROMs and the evaluation of their impact on clinical decisions, disease perception, perception on the usability, integration, and added value of PROMs determined by patients and healthcare providers.

- Recruitment period:

The recruitment phase will last approximately 10-12 months, targeting 80-250 patients for primary implementation.

- Follow-up period:

The follow-up period will be between 3 to 24 months to further monitor the patients´s further course of disease as well as potential changes within. Limits are relative since the study will be performed in "running cohorts" of UDUS.

- Time Horizon for Analysis:

The analysis will cover a period of 36 months defined by the project timeline.

- Number of participants:

Patients are recruited during clinical routine primarily and follow-up. Therefore, we aim to integrate 80-250 patients.

- Randomization procedure: N/A

Groups: N/A

Objectives

With the project we would like to integrate PGHD in the routine consultation. The comparison to mPROMs, ePROMs and an automatized evaluation process is aimed to exploit the opportunities for health care improvement. The timely visualization could additionally be used to discuss specific changes of symptoms or quality of life aspects with the patient and support the joint efforts to live up to the patient´s true needs. In addition, we would like to support the patient´s access and joint patient-orientated path through improved design and interactive tools.

- **Primary Objectives:**
  1. To evaluate the QoL and disease related QoI and distress in relation to the disease.
  2. To evaluate added value of PROMs from the patient´s perspective.
  3. To evaluate added value of PROMs from the health care providers' perspective.
- **Secondary Objectives:**

1. To evaluate the usability and feasibility of PROMs within the clinical setting in two forms: A) Paper work and B) ePROMS designed by BETTER and the use of tablet computers.
2. To evaluate the relative effort of PROMs within the clinical setting
3. To evaluate the change within PROM rating in relation to the course of disease and treatment

Patient Pathway

The patient pathway for a chronic rhinosinusitis patient is provided in Figure 11.

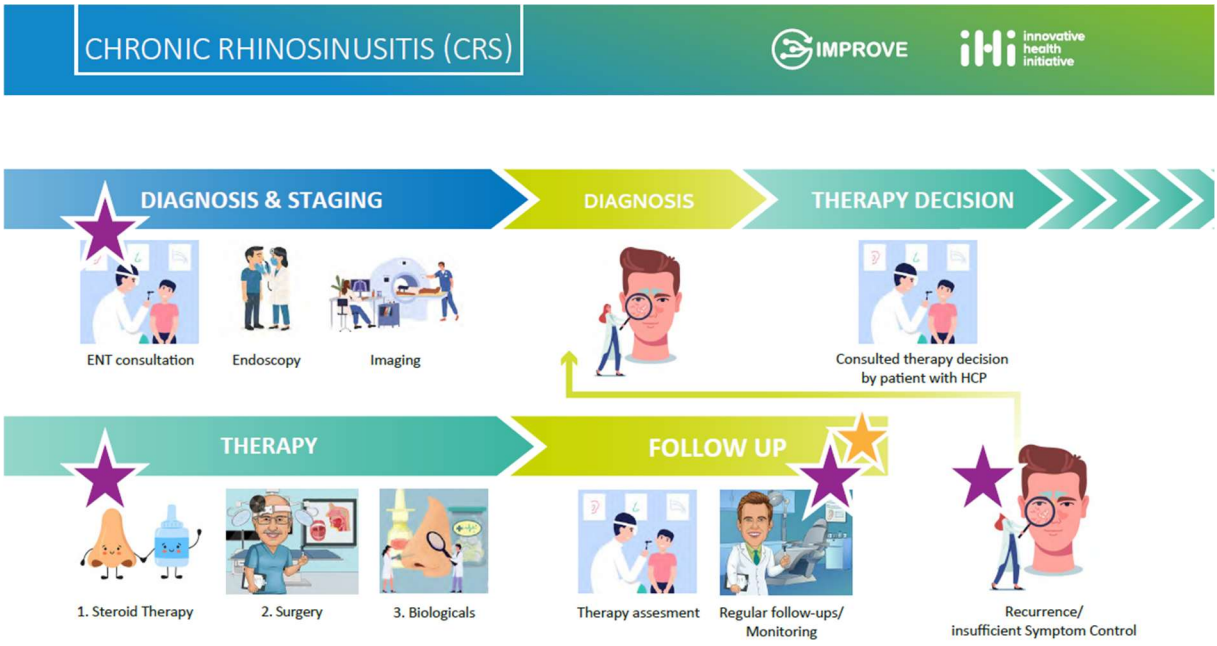


Figure 11: Chronic rhinosinusitis patient pathway. PREMs and PROMs are collected during follow up. Concept: PMS/UDUS, Design. ius

Key performance indicators

Independent regular variables:

Category	KPIs	Definition
Adherence	Completion rate	PROM completion rate (paper vs. ePROMs)
	QoL change	Change in QoL and distress scores
Quality	Tool usability	Usability of PROM tools
	Preference clarity	Patient preference clarity (paper vs digital)
Efficiency	Complete time	Time burden for PROM completion

Table 20: KPIs for the chronic inflammation use case

4. Summary and conclusion

This deliverable establishes the methodological foundation for the IMPROVE pilot studies by defining the study designs, patient pathways, objectives and KPI frameworks across all use cases, hence, participating disease areas. A harmonised approach has been adopted to enable the systematic collection and evaluation of PROMs, PREMs, PPI and other patient-generated health data within diverse clinical settings. The resulting framework provides a common structure for assessing patient-centred outcomes, care experiences and value-based healthcare indicators across the project use cases.

The work performed in this deliverable demonstrates a high level of maturity and readiness of the pilot studies. For all use cases, the methodological design, intervention approach, data collection strategy, recruitment and follow-up plans, and evaluation KPIs have been defined. In addition, the patient pathway approach has enabled alignment of data collection points across disease areas, creating the basis for future cross-use-case analyses and comparison of outcomes. On top of that, it provides an overall view on the IMPROVE data collection.

The next phase of IMPROVE will focus on the implementation and execution of the defined studies, including patient recruitment, collection of clinical and patient-reported data, and validation of the proposed KPI frameworks. The evidence generated through the pilot studies will be used to evaluate the feasibility, effectiveness and scalability of integrating patient-reported information into routine care pathways and value-based healthcare models. The results will further support refinement of the IMPROVE framework and contribute to recommendations for broader adoption of patient-centred outcome measurement practices across healthcare systems and disease areas.

Use case maturity level overview

	Methodological Design defined	Technology defined	Intervention details defined	Recruitment period	Follow-up period	KPIs & Objectives defined
UC1: Systems for automated radiotherapy trial QA applied to prostate cancer	X	X	X	X	X	X
UC2: Multicentre quantitative imaging biomarkers to harness outcome parameters relevant for cervical cancer patients	X	X	X	X	X	X
UC3: Head and Neck Cancer	X	X	X	X	X	X
UC4: Breast Cancer	X	X	X	X	X	X

UC5: Age-related Macular Degeneration (AMD)	X	X	X	X	X	X
UC6: VBHC framework for patients with chronic heart failure and coronary artery disease	X	X	X	X	X	X
UC7: Severe aortic stenosis / TAVI	X	X	X	X	X	X
UC8: VBHC framework for Multiple Sclerosis (MS) rehabilitation	X	X	x	X		X
UC9: Chronic Rhinosinusitis (CRS)	X	X	X	X	X	X

Table 21: Use case maturity level overview

Pathway indicator

As illustrated in Figure 12, PROMs, PREMs and PPIs are collected at different points along the patient pathway across all IMPROVE use cases, with the greatest concentration during therapy and follow-up phases. PROMs constitute the core longitudinal outcome layer, complemented by targeted PREM and PPI collections at key decision points to capture patient experience and preferences throughout the care journey.

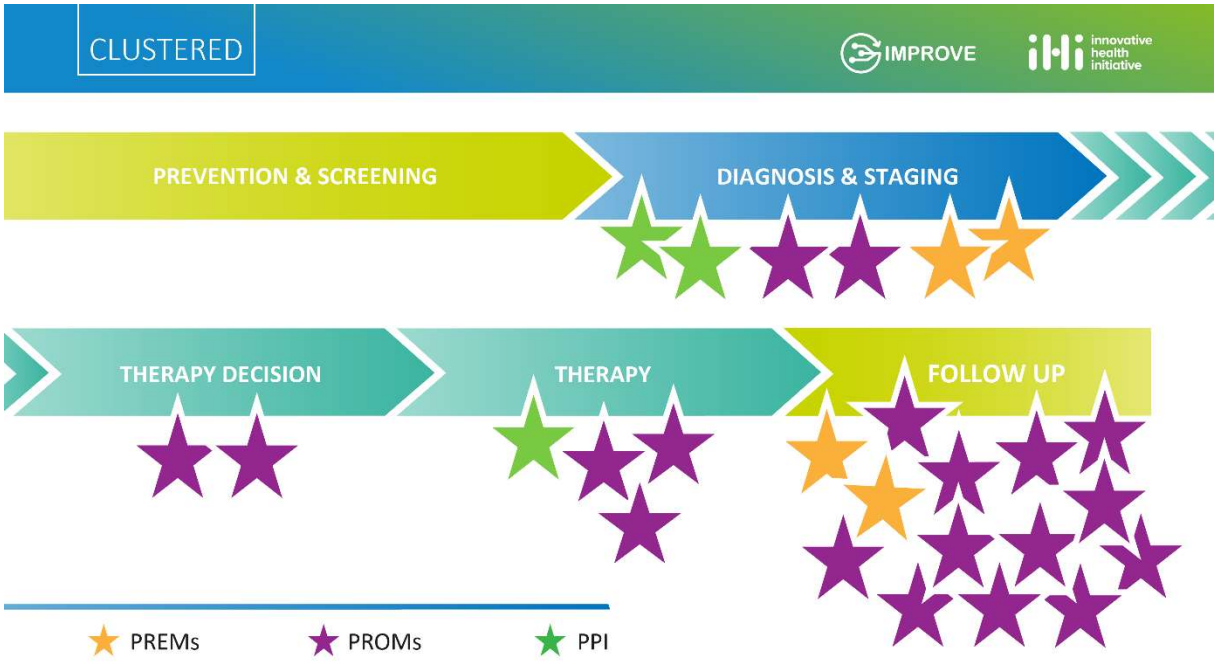


Figure 12: Overview of PROMs, PREMs and PPI collection within the IMPROVE project over all use cases
Concept: PMS, Design. ius

About IMPROVE

IMPROVE aims to be a dynamic, ready-to-use framework for seamlessly integrating patient-reported information. This adaptable system constantly evolves with the latest evidence, using PGHD and health system data to provide cost-effective solutions for diverse treatment conditions in real settings. The project follows Ontology, Epistemology, and Methodology principles. Ontology defines structures in patient-reported outcomes; Epistemology ensures valid knowledge; Methodology links techniques to outcomes, systematically addressed in its work.

IMPROVE optimizes patient-reported information in real settings, offering a deep understanding of patient behaviour. The project sets up ontology, epistemology, and methodology to minimize the burden on stakeholders cost-effectively. It adopts a scalable, data-driven approach with NLP-driven knowledge extraction. Real World Data is integrated into the Federated Causal Evidence module for comprehensive understanding. Evidence collected enables visualizing attributes affecting patient-reported outcomes through IMPROVE Engagement Factors and Indicators Knowledge Graphs.

IMPROVE's toolkit includes resources for decision-makers, featuring plausible scenarios via the Copenhagen Method. Patient engagement via the MULTI-ACT model ensures sustainable healthcare aligned with patient priorities. This project delivers a modular, open access strategy, providing a trustworthy ecosystem of evidence-based applications. Patient engagement and co-creation scenarios solidify its role in transforming healthcare research and care.

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