IMPROVE

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

D6.4: Stakeholder identification, categorization and prioritization

Version 0.3

Linwei He (TiU),
Emiel Krahmer (TiU),
Nadine Bol (TiU),
Sanne Nauts (PMSN)

Co-funded by the European Union

Document Control Sheet

Deliverable Number	D6.4
Deliverable Responsible	TiU
Work Package	WP6
Lead Editor	Linwei He
International Reviewer(s)	Aron Szpisjak (CIFS), Manuel Ottaviano (UPM)

History of Changes

Date	Version/Page	Change
20-11-2024	0.1	ToC of the deliverable
28-11-2024	0.2	Contribution to content sections
06-12-2024	0.3	Incorporate reviewers' comments
10-12-2024	0.3	Final version to submit

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This deliverable contains original unpublished work except where clearly indicated otherwise.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.

Legal Disclaimer

The information in this document is provided "as is" and as it has been collected according to the inputs provided by the different partners. The above referenced consortium members shall have no liability to third parties for damage of any kind including without limitation direct, special, indirect, or consequential damages that may result from the use of these materials subject to any liability which is mandatory due to applicable law. This data management plan is a living document and will evolve with the advancement of the project.

Abbreviations and Acronyms

DoA	Description of Action
EC	European Commission
WP	Work package
PROMs	Patient-reported outcome measures
PREMs	Patient-reported experience measures
PPI	Patient preference information
VBHC	Value-based healthcare
PGHD	Patient-generated health data

Table of Content

1. Objectives of WP6

The overarching goal of the IMPROVE project is to enhance healthcare systems by leveraging patient-generated health data (PGHD) to create integrated, patient-centered solutions. Central to this is the concept of value-based healthcare (VBHC), which focuses on improving patient health outcomes relative to the resources used. VBHC emphasizes the importance of aligning healthcare delivery with patient needs and preferences, to ensure the most efficient and effective use of healthcare resources. IMPROVE aims to use technological innovations to enhance the integration of key measures such as Patient-Reported Outcome Measures (PROMs), Patient-Reported Experience Measures (PREMs), and Patient Preference Information (PPI). These measures capture critical insights into health outcomes, patient experiences, and preferences, and by improving their integration, IMPROVE seeks to drive advancements in VBHC.

Work Package 6 (WP6) focuses on stakeholder identification, categorization, and prioritization to ensure that the IMPROVE framework is developed with a comprehensive understanding of the diverse needs of all stakeholders. Patients are central to VBHC, but other stakeholders—such as healthcare professionals, public authorities, researchers, and policymakers—play equally critical roles in implementing and benefiting from the IMPROVE platform. Understanding and involving these groups ensure that the platform aligns with real-world challenges, and facilitates its successful adoption. To achieve this, WP6 identifies relevant stakeholders, then analyzes their needs and requirements to ensure their perspectives are incorporated into the development process. By closely involving stakeholders throughout the design process, WP6 contributes to the creation of a robust, inclusive platform that supports VBHC and accelerates the adoption of patient-centered healthcare solutions.

This specific deliverable presents activities linked to Task 6.1 (Assessment of Gathered Stakeholder Requirements) and Task 6.2 (Co-creation with Stakeholders to Establish Needs and Functionality of the IMPROVE framework). These tasks aim to provide insights to the ongoing development of the IMPROVE framework, ensuring that it is in line with the diverse needs and preferences of key stakeholders. Task 6.1 focuses on identifying and categorizing stakeholder requirements, while Task 6.2 involves co-creating with stakeholders to define the functionalities of the IMPROVE platform. In the following sections we describe in detail how we approach these tasks and how they shape the upcoming activities in WP6.

2. Methods of WP6

WP6 adopts a co-creation approach, emphasizing the inclusion of diverse stakeholders throughout the development process of the IMPROVE platform. This inclusive approach ensures that all relevant stakeholders—patients, healthcare professionals, public authorities, researchers, and policymakers—are closely involved in shaping a framework that meets their needs and expectations. By actively engaging stakeholders, WP6 aims to enable the smart use of PGHD, ultimately facilitating patient-centric and (cost-)effective advanced integrated healthcare solutions.

For this specific deliverable, WP6 focuses on stakeholder identification, categorization, and prioritization. The methods employed include:

- **Literature review**: Relevant literature in domains such as healthcare delivery, patient-centered care, and value-based healthcare is reviewed to map potential users of the IMPROVE platform. This step contributes to the initial identification of stakeholders.
- **Collaborating with WP3 and WP5**: By working closely with these work packages, WP6 identifies unique and universal stakeholders across different disease areas. This collaboration also helps determine both direct and indirect users of the platform, contributing to the identification and categorization of stakeholders.
- **Conducting interviews with selected stakeholders**: Interviews with the initially identified stakeholders provide deeper insights into their practices regarding PROMs, PREMs, and PPI, as well as their perspectives on the IMPROVE platform. These insights inform the prioritization of stakeholders, ensuring that their needs are systematically addressed during platform development.

This systematic and inclusive methodology ensures that WP6 identifies, understands, and prioritizes the most relevant stakeholders, laying a foundation for the IMPROVE platform that is user-centered, and that can effectively advance value-based healthcare.

3. Stakeholder identification, categorization, and prioritization

3.1. Stakeholder identification

Stakeholder analysis is a systematic approach to identifying and assessing the roles, interests, and potential influence of individuals or groups associated with a project. This process provides a clear understanding of who the stakeholders are, what their needs and concerns might be, and how they could affect or be affected by the project (Brugha & Varasovszky, 2020). By systematically analyzing these dynamics, strategies for meaningful engagement can be developed, ensuring the project's success.

To initiate this process for the IMPROVE platform, we first consulted literature from healthcare delivery, patient-centered care, and digital health innovation domains. Literature on healthcare delivery highlighted the critical involvement of healthcare professionals and public health entities as both implementers and beneficiaries of digital health platforms (Dansky & Gamm, 2004; Porter, 2006). Research on patient-centered care emphasized the importance of including patients and caregivers, as their lived experiences directly inform the value of integrated healthcare solutions (Fix et al., 2016). Additionally, insights from digital health innovation literature identified researchers, industry stakeholders, and financial entities as key drivers of technological advancement and resource allocation (Laurisz et al., 2023). These findings guided the development of an initial list of potential stakeholders, including **healthcare professionals, researchers, patients, caregivers, service providers, public health entities, and financial stakeholders**.

In May 2024, WP3 hosted a co-design workshop to explore these stakeholder groups further. This workshop involved brainstorming sessions with experts to identify practical, real-world stakeholders who could serve as end users or collaborators in the design and implementation of the IMPROVE platform. Findings from the workshop aligned with and expanded upon the literature, confirming the importance of including healthcare professionals, researchers, patients, and public health entities. In addition to confirming these stakeholders, the workshop also pointed at two new roles that are important to take into account, namely policymakers and industry innovators. Policymakers are relevant because they can utilize PREMs, PROMs, and PPI to inform policy decisions, as well as the adoption/implementation of platforms in healthcare systems. Industry innovators can use these metrics to design medical devices, products and services in such a way that they optimize patients' outcomes and experiences.

By integrating insights from both the literature and the co-design workshop, we refined the stakeholder list to include:

- **Healthcare professionals** (e.g., doctors, nurses, and medical staff).
- **Patients** (individuals and patient advocacy groups).
- **Researchers** (e.g., academics and innovators in medical and healthcare research).
- **Service providers** (e.g., IT developers for healthcare technology).

- **Public health entities** (e.g., government bodies, policymakers, and regulatory agencies).
- **Financial entities** (e.g., insurance companies and healthcare payers).
- **Industry stakeholders** (e.g., medical device manufacturers and pharmaceutical companies).

3.2. Stakeholder categorization

Stakeholder categorization is a critical step in the stakeholder analysis process, aimed at organizing identified stakeholders based on their roles, influence, and involvement in the IMPROVE platform (Brugha & Varasovszky, 2020). Categorizing stakeholders ensures a structured approach to engagement and prioritization, aligning with the project's objectives to create an inclusive and patient-centered healthcare solution (Kapiriri & Razavi, 2021).

Based on insights collected in the previous section, we categorized the potential stakeholders into three primary groups:

1. **End users:**

   These are stakeholders who will directly interact with and benefit from the platform. End users include:

   - **Healthcare professionals**: Doctors, nurses, and other medical staff who will utilize the platform to enhance patient care.
   - **Patients and caregivers**: Individuals providing or receiving care, who will provide PROMs, PREMs, and PPI. Their experiences and preferences will shape the platform's usability and relevance.
   - **Service providers**: Hospitals, clinics, and other organizations (e.g., technology providers) responsible for delivering healthcare services, including the collection and usage of PROMs, PREMs, and PPI.

2. **Stakeholders involved:**

   This group consists of those who contribute to the design, development, or implementation of the platform. Their expertise and feedback are crucial for refining and validating the platform. Examples include:

   - **Researchers**: Developing evidence-based methodologies for integrated healthcare solutions.
   - **Industry stakeholders**: Innovators and suppliers of digital health technologies.
   - **Public health entities**: Collaborating to ensure the platform meets regulatory and public health standards.

3. **Stakeholders to be informed**:

   These stakeholders have a vested interest in the project but may not directly interact with the platform. They include:

   - **Policy makers and regulators**: Guiding the adoption of the platform within healthcare systems.

- **Financial entities**: Insurance companies and payers monitoring the platform's cost-effectiveness and return on investment.

The categorization process is guided by specific criteria:

Level of involvement: The degree to which the stakeholder engages with, utilizes, or contributes to the platform.

Impact on outcomes: The stakeholder's influence on the development and adoption of the IMPROVE platform.

Needs and expectations: The stakeholder's goals, concerns, and requirements.

3.3. Stakeholder prioritization

Stakeholder prioritization focuses on identifying which stakeholders across various categories and disease areas should receive focused attention during the development of the IMPROVE platform. To facilitate this, WP6 has developed an interview protocol designed to gather insights into stakeholders' current practices related to PROMs, PREMs, and PPI, the challenges they face, and their perspectives on the potential benefits of the IMPROVE platform. These interviews will help us understand which stakeholders are in the greatest need of improved healthcare solutions, who stands to benefit the most from the platform, and which requirements are most critical to shaping its development and implementation.

Interviews will be conducted across five key disease areas (use cases): Oncology, Ophthalmology, Cardiovascular, Neurology, and Chronic Inflammation. Participants will be drawn from the stakeholder categories identified in the previous step, including clinicians and nurses (healthcare professionals), patients and caregivers, technologists and service providers, as well as policymakers and public health entities. This ensures a diverse range of perspectives are included in the prioritization process. By exploring their perspectives, WP6 aims to refine its understanding of stakeholder priorities and align platform development with real-world needs.

To support this prioritization effort, WP6 created a stakeholder suggestion sheet. Partners from each use case are asked to propose stakeholders for interviews, providing details such as their organizations and roles (e.g., clinician, patient, policymaker). This ensures a comprehensive and collaborative approach to stakeholder identification and prioritization.

By combining insights from the stakeholder suggestion process and follow-up interviews, WP6 will prioritize stakeholders based on their relevance, influence, and needs, ensuring that the IMPROVE platform effectively addresses the most critical healthcare challenges and delivers maximum value to its users.

4. Conclusions and next activities

We are now in contact with the use case leaders from the five disease areas—Oncology, Ophthalmology, Cardiovascular, Neurology, and Chronic Inflammation—and aim to schedule interviews with relevant stakeholders in the upcoming period. To support these activities, WP6 is finalizing a central ethics application, which will be submitted to the research ethics and data management committee at Tilburg University. This application will serve as a template for all partners conducting interviews. While the use of this template is optional, it is provided to streamline the ethics approval process and ensure compliance with ethical and data protection standards. Partners will have the flexibility to adjust the interview protocol and procedures to best suit their organizational needs and contexts.

In the upcoming year, WP6 will focus on the following steps to ensure successful completion of the tasks:

1. We will finalize the categorization and prioritization of the identified stakeholder requirements, in collaboration with the use case leaders. The interview data will be analyzed, and the requirements will be summarized to inform the development of the IMPROVE platform.
2. Based on initial stakeholder feedback from the interviews, we will work with the IMPROVE project team and stakeholders to map out the desired functionalities of the platform, ensuring it is designed in a feasible, user-centered manner.

In summary, WP6 will focus on conducting interviews, analyzing the collected data, and integrating the findings into a comprehensive overview of stakeholder needs and requirement framework. This will guide the development of the IMPROVE platform, ensuring that the needs of the most critical stakeholders are effectively addressed.

5. References

Brugha, R., & Varvasovszky, Z. (2000). Stakeholder analysis: a review. *Health Policy and Planning, 15*(3), 239-246.

Dansky, K. H., & Gamm, L. S. (2004). Accountability framework for managing stakeholders of health programs. *Journal of Health Organization and Management, 18*(4), 290-304.

Fix, G. M., Hogan, T. P., Amante, D. J., McInnes, D. K., Nazi, K. M., & Simon, S. R. (2016). Encouraging patient portal use in the patient-centered medical home: three stakeholder perspectives. *Journal of Medical Internet Research, 18*(11), e308.

Kapiriri, L., & Razavi, S. D. (2021). Salient stakeholders: Using the salience stakeholder model to assess stakeholders' influence in healthcare priority setting. *Health Policy OPEN, 2*, 100048.

Laurisz, N., Ćwiklicki, M., Żabiński, M., Canestrino, R., & Magliocca, P. (2023). The stakeholders' involvement in healthcare 4.0 services provision: The perspective of co-creation. *International Journal of Environmental Research and Public Health, 20*(3), 2416.

Porter, M. E. (2006). *Redefining health care: creating value-based competition on results.* Harvard Business Press.

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 behaviors. 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.

Funding Acknowledgement

This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No. 101132847. The JU receives support from the European Union's Horizon Europe research and innovation program and COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe, and the contributing partners Universidad Politecnica de Madrid (UPM), PredictBy (PBY), Danish Medicine Agency (DKMA), Roche (ROCHE), Institute for Economic Research (IER), Copenhagen Institute for Futures Studies (CIFS), Fundació Institut d'Investigació Biomèdica de Bellvitge (IDIBELL), Philips Medical System Nederland BV (PMSN), Heinrich-Heine-Universitaet Duesseldorf (UDUS), Tilburg University (TiU), Dedalus (DEDA), Fondazione Italiana Sclerosi Multipla Fism Onlus (FISM), AReSS Puglia (ARSS), MultiMed (MM), iserundschmidt GmbH (ius), Better (BET), The Netherlands Cancer Institute (NKI), University of Applied Sciences St. Pölten (STPUAS), Eye Hospital, University Medical Centre Ljubljana (EYE), Utrecht University (UU), UDG Alliance (UDGA), Medtronic Iberica SA (MDT), Fundacio Hospital Universitari Vall D'Hebron – Institut de Recerca (VHIR), Splosna Bolnisnica Celje (SBC), ORTOPEDSKA BOLNIŠNICA VALDOLTRA (OBV), ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS (CERTH).

www.ihi.europa.eu

Supporters of the Innovative Health Initiative Joint Undertaking:

Project partners:

Coordinator

Associated Partner