IMPROVE

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

D3.7: Scientific, policies and practices development V2

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This deliverable contains original unpublished work except where clearly indicated otherwise.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

EC	European Commission
GPDR	General Data Protection Regulation
KPI	Key Performance Indicator
PGHD	Patient Generated Health Data
PPI	Patient Preference Information
PREMs	Patient-Reported Experience Measures
PROMs	Patient-Reported Outcome Measures
VBHC	Value-Based Health Care
WP	Work Package
UCD	User Centred Design

Table of Content

Executive Summary

This deliverable is the second version on the development, execution and creation of the scientific, policies and practices tracker (T3.2). In the future deliverables of this series of deliverable we will provide more details on the technological aspects of the trackers and how the work can and will be automated, using Artificial Intelligence and Machine Learning methodologies, based on Language Learning Models, to trace updated state-of-the-art scientific methodologies, outcomes, and policies across the world and select the most important outcome on the predetermined Key Performance Indicators (KPIs) to feed WP4 and WP5. In order to train the Large Language Models first analyses need to be conducted in order to establish the correct framework and train the models subsequently. Specifically, the development of the tracker will be based on the data collected in T2.1, T2.2, T2.3 and T2.4. as well as following the integration principles and requirements defined. This beta version will be refined based on users' feedback following the UCD iterative cycles, during the update and maintenance process.

Keywords: Scientific; Policy; Practices; Tracker; Artificial Intelligence; Machine Learning

1. Introduction

1.1. Science, Practice and Policy tracker

The **Science, Practice and Policy Tracker** will be an important and innovative element of the IMPROVE platform designed to address the critical need for a unified system that monitors, analyses, and disseminates information on scientific practices and policies globally. As science becomes increasingly central to solving society's most pressing challenges—such as the global health crises and technological innovation—it is vital to have a resource that connects the dots between research advancements, best practices, and the policies that shape them. This tracker will become **an essential tool** for researchers, policymakers, healthcare professionals, industry leaders, and educators seeking to understand and influence the evolving relationship between science and policy.

The Science Practice and Policy Tracker is a **centralized hub** on the **IMPROVE platform** that combines data, insights, and tools to provide a comprehensive overview of global trends in scientific research and policy. The tracker enables users to:

- **Follow the evolution of scientific practices**:
    - Explore changes in how research is conducted, published, and shared.
    - Stay updated on new methodologies, technologies, and interdisciplinary approaches.
- **Monitor the impact of policies on science and society**:
    - Understand how legislation and regulations influence scientific progress.
    - Track the downstream effects of policies on public health, technological innovation, and societal well-being.
- **Connect stakeholders in science and policy**:
    - Provide a bridge between researchers, governments, and the private sector.
    - Facilitate dialogue and collaboration to ensure evidence-based policymaking and ethical scientific practices as well as sharing of best practices

Key Pillars of the Tracker

The key pillars of the tracker are all established and will be the fundament of the tracker. Subsequently, all elements will be incorporated into the tracker.

1. **Practice Evolution Monitoring**

The tracker focuses on **documenting and analysing changes in how scientific research influences the practice of utilizing patient-generated health data**, including:

- **Reproducibility Initiatives**: Highlighting efforts to improve the reliability and transparency of research focused on the integration of Patient Generated Health Data
- **Open Science Movement**: Tracking policies and practices aimed at making data, methodologies, and findings accessible to the public.
- **Emerging Technologies**: Monitoring the integration of cutting-edge technologies like AI, ML, and PGHD into scientific research.

2. **Policy Tracking and Analysis**

Policy decisions profoundly influence the trajectory of scientific research and its societal applications. The tracker includes:

- **Global Policy Mapping**: A visual database of science-related policies worldwide, categorized by region, discipline, and focus area (e.g., healthcare, data, AI).
- **Policy Impact Assessments**: Quantitative and qualitative analyses of how specific policies affect research funding, priorities, and outcomes.
- **Legislative Watchlist**: Notifications about upcoming or recently passed policies that could reshape the scientific and practice landscape, especially in the field of data and health.

3. **Cross-Sector Collaboration**

Recognizing that the challenges of the 21st century require collaboration across sectors, the tracker:

- **Connects Stakeholders**: Offers a platform for dialogue between scientists, policymakers, educators, and industry leaders.
- **Supports Interdisciplinary Research**: Identifies opportunities for collaboration across fields like medicines, psychology, sociology, behavioural science, biology, computer science, and economics.

4. **Visualization and Accessibility**

To make complex information digestible, the tracker provides:

- **Interactive Dashboards**: Real-time data visualizations that track trends and metrics.
- **Timelines**: Detailed chronologies of major policy shifts and their effects on science and society.
- **Custom Reports**: Users can generate reports tailored to specific needs, such as funding trends in renewable energy or global health initiatives.

5. **Educational and Advocacy Tools**

To empower educators, advocacy groups and patients themselves, the tracker includes:

- **Resource Library**: Access to policy briefs, research summaries, and toolkits for teaching and lobbying.
- **Case Studies**: Real-world examples of how science and policy have successfully intersected to address challenges.

Target Audience

The Science, Practice and Policy Tracker serves a wide range of users, each with specific needs, focused on the IMPROVE stakeholders. Several target groups will be also engaged during the stakeholder engagement sessions.

- **Patients**:
  - **Understanding data impact**: By increasing awareness of how patient-generated health data is used to shape healthcare decisions and research advancements.
  - **Recognizing patient contributions**: By highlighting the critical role of patient input in improving treatments and driving medical innovations.
- **Healthcare professionals**
  - **Enhancing treatment selection**: By advancing the role of patient preferences and experiences in choosing treatments, thereby personalizing healthcare to meet individual needs more effectively.
  - **Medical device design improvement**: By incorporating patient feedback directly into the design process, ensuring that new medical devices are more aligned with user expectations and experiences.
- **Researchers:**
  - Access information on how policies influence funding and ethical guidelines.
  - Stay informed about best practices and emerging research trends.
- **Policymakers**:
  - Use data-driven insights to craft and evaluate science-related policies.
  - Monitor the societal impacts of their decisions in real-time.
- **Industry Leaders**:
  - Align corporate strategies with emerging trends in science and regulation.
  - Identify opportunities for collaboration with academic and government partners.
- **Educators and Students**:
  - Equip students with the tools to understand the dynamic interplay between science, practices and policy.
  - Use the tracker as a teaching aid to explain global scientific challenges and solutions.
- **Patient associations**
  - Support campaigns with evidence-based insights and case studies.
  - Monitor the effectiveness of advocacy efforts and refine strategies accordingly.

Why It Matters

In today's interconnected world, science does not operate in a vacuum. Policy shapes the direction of research, while scientific discoveries often inform legislation. However, gaps between these domains can lead to missed opportunities or unintended consequences. The Science, Practice and Policy Tracker addresses these gaps by providing:

- **Clarity**: Making complex trends and relationships understandable for all stakeholders.
- **Proactivity**: Allowing users to anticipate and prepare for changes in science and policy.
- **Impact**: Ensuring that science is aligned with societal needs and that policies support ethical, equitable innovation.

2. Methodology

2.1 Science Tracker

Within *Task 2.1 – Systematic search and creating a database* we have developed a search strategy to support an analytical framework and methodology to assess the scientific evidence on patient reported inputs and health delivery services in an iterative process to balance recall and precision. We included as many potentially relevant studies as possible, while at the same time limiting the total number of search results. As a result, we have established the **Knowledge Warehouse** with several **Chambers**, completed with a database of potentially relevant documents from the scientific literature. A tested pre-trained deep learning model with a multi-language feature extractor has been utilized to allocate included studies into different chambers (1: Oncology - 1.1: Prostate cancer, 1.2: Cervical cancer, 1.3: Neck and neck cancer, 1.4: Breast cancer; 2. Ophthalmology - 2.1: Macular degeneration; 3: Cardiovascular, 3.1: Heart failure, 3.2: Coronary artery diseases, 3.3: Atrial fibrillation, 3.4: Severe aortic stenosis; 4: Neurology, 4.1: Multiple sclerosis and 5: Chronic inflammation - 5.1: Chronic rhinosinusitis). In this process, regular expressions were also used to improve the recall of the chamber allocations. The results will be used to inform the development of the methodologies (e.g., Use cases) in the other WPs (4,5), and to build guidelines and recommendations (WP7).

2.2 Policy Tracker

For the Policy tracker we have started to analyse the policies that have been collected by the Bruegel organization to see how they fit into the IMPROVE framework. In addition, we started with collecting more local, regional and national policies that might be affecting the project. This will be done during the 2nd and 3rd years and will be reported in the next versions of this report. PGHD in healthcare encompasses information directly provided by individuals regarding their health status, symptoms, treatment outcomes, quality of life, and healthcare experiences. This type of data has become increasingly important in shaping patient-centered care models, improving clinical outcomes, and informing healthcare policy. As healthcare systems worldwide embrace digital transformation, tracking policies related to PGHD is critical to understanding regulatory, ethical, and operational frameworks that influence its use and integration.

Objectives of the Policy Tracker

The **Policy Tracker on Patient-Reported Data in Healthcare** aims to:

1. **Map Existing Policies**: Identify and document national, regional, and international policies governing the collection, use, sharing, and storage of PGHD.
2. **Monitor Emerging Regulations**: Track ongoing policy developments at various levels, including EU directives, member state initiatives, and global guidelines.
3. **Assess Implementation**: Evaluate the adoption and operationalization of policies to determine their impact on healthcare outcomes and patient empowerment.
4. **Identify Best Practices**: Highlight successful strategies and frameworks that promote the ethical and effective use of PGHD.

5. **Flag Policy Gaps**: Recognize areas where further regulatory or policy intervention is required to address challenges related to data privacy, interoperability, and equitable access.

Key Areas of Focus

The policy tracker will cover the following key dimensions:

1. **Data Privacy and Security**:
    - Policies such as the EU's General Data Protection Regulation (GDPR) and specific healthcare-focused data protection measures.
    - National laws addressing the confidentiality and security of PGHD, particularly in digital health applications.
2. **Data Collection and Standardization**:
    - Standards for PGHD collection, ensuring accuracy, reliability, and comparability across different healthcare systems.
    - Policies promoting the use of interoperable platforms to facilitate seamless integration of PGHD into electronic health records (EHRs).
3. **Ethical and Legal Considerations**:
    - Guidelines on obtaining informed consent for the use of PGHD in research, clinical care, and policy development.
    - Policies ensuring that PGHD usage aligns with ethical principles, avoiding exploitation or misuse.
4. **Integration with Clinical Workflows**:
    - Legislative measures supporting the inclusion of PGHD in clinical decision-making processes.
    - Policies encouraging healthcare providers to leverage PGHD for personalized treatment plans and improved patient engagement.
5. **Governance and Oversight**:
    - EU-level initiatives, such as the European Health Data Space (EHDS), aimed at fostering cross-border health data sharing while safeguarding individual rights.
    - National governance mechanisms to oversee the implementation of PGHD-related policies.
6. **Research and Innovation**:
    - Policies incentivizing the use of PGHD in clinical research and health technology innovation.

- Funding mechanisms and frameworks supporting patient-generated health data projects.

Monitoring Methodology

The policy tracker employs a systematic approach, which includes:

- **Regular Monitoring**: Frequent updates on legislative changes, regulatory announcements, and new policy introductions.
- **Stakeholder Engagement**: Collaboration with patient association groups, healthcare providers, policymakers, and technology developers to gather diverse perspectives.
- **Data Analysis**: Evaluating the effectiveness and impact of PGHD policies through the 10 use case studies

Potential Benefits

A comprehensive policy tracker in IMPROVE will:

- Facilitate informed decision-making for policymakers and healthcare leaders.
- Encourage harmonization of policies across jurisdictions to promote equitable access and use of PGHD.
- Enhance public trust by ensuring transparency and accountability in the management of sensitive patient data.

2.3 Practice Tracker

Considering the developments in the Science tracker, for IMPROVE, this means that we can achieve a higher quality and accuracy than traditional approaches and immediately prioritize findings as well as incorporate new evidence, without too much manual analytical work, which we will do during the upcoming years. This process will allow us to identify and assess the available models, methods and their potential biases in scientific research and how we can IMPROVE them. This can then subsequently also be done for practices outside the scientific research community, for example the FDA guidance for Patient Focused Drug Development[1]and Medical Device Development[2], several IMI projects such as PREFER[3], SISAQOL[4], and PARADIGM[5] that also have been evaluated and analysed manually, see for more details *Deliverable 2.2: Practice reports and updates*. During the 2nd and 3rd year of the project we will develop a pipeline to automate the process of the Science Tracker, which consists of identifying new literature for a given disease use case (even the specific chamber) and extracting relevant data and information to inform users. This pipeline will involve the use of web scrawlers (to identify newly published studies), machine learning classifiers (to identify relevant ones among the found studies) and Large Language Models (to extract useful information and data). We will test and validate this pipeline across the different practices in the Science Tracker that we have come across that are relevant for the project. Furthermore, we will conduct consultations with relevant and significant

[1] https://www.fda.gov/drugs/developmentapproval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporationpatients-voice-medical
2 Patient Preference Information (PPI) in Medical Device Decision-Making | FDA
[3] https://www.imi.europa.eu/projects-results/project-factsheets/prefer
[4] https://www.imi.europa.eu/projects-results/project-factsheets/sisaqol-imi
[5] https://imi-paradigm.eu/

stakeholders (e.g., patients, support network of formal and informal caregivers, associations, researchers, healthcare professionals, healthcare system regulators, ministries of health, and industry) in a co-creation and living lab approach (WP6-WP7), in order to create consensus about these findings during the next year, including the relevance of the current models and definitions, and factors driving effective and efficient use of PGHD, to elicit stakeholder needs and capabilities in situations, contexts of use, etc. For now, we have established the evaluation framework below that we have used for the first 5 practices that we have selected as relevant for the IMPROVE framework.

Analysis of Practice Template

1. Project Overview

- **Title**: The formal title of the research project.
- **Principal Investigator(s)**: Name(s) of the lead researcher(s).
- **Consortium partner(s)**: Organization(s) or institution(s) involved.
- **Funding Source(s)**: Identify funding agencies or sponsors.
- **Project Duration**: Start and end dates of the project.

2. Methodology

- **Summary of the project**: Short summary of the project
    - **Research Problem**: Clearly state the central problem or issue being addressed.
    - **Objectives**: Specific goals of the project.
- **Population, Disease Area and Sample**: Population, sample size, disease area(s).
- **PGHD used**: What kind of PGHD is mainly analysed in the project
- **Data Collection Methods**: Tools and techniques for data collection (e.g., surveys, interviews, experiments, archival research, etc.).

3. Results & Findings

- **Key Findings**: A summary of the main findings (if available).
- **Data Representation**: Any charts, graphs, or tables that represent the data (if available).
- **Patterns/Trends**: Noteworthy patterns or trends observed from the data.

4. Discussion & Conclusion

- **Interpretation of Findings**: Discuss the meaning and implications of the results in relation to the IMPROVE project
- **Gap analyses and Implications for Future Research related to IMPROVE**: Discuss any limitations or constraints exhibited by the project as well as recommendations for future studies or areas for further investigation.

3. Results

3.1 Science Tracker

As described in the methodology, within WP2 we have conducted several systematic reviews and desk research to collect the necessary information and establish the state of the art. The outcomes of the first extensive systematic umbrella review are published in D2.1 Systematic reviews and updates V1. In order to prevent redundancy, we will only summarize the main outcomes here. During this first Screenathon where >12,000 titles and abstracts were screened, we started to build the **Knowledge Warehouse** and started to extract the most relevant data for building the data dashboard (WP3) and conducted a gap analyses. Based on this Knowledge Warehouse, we have trained artificial intelligence models to identify relevant publications and builded the first versions to analyze the data and text automatically, a crucial step towards changes in healthcare. This is part of the Science tracker that will be built with Large Language Models that will automatically analyse the scientific articles that will be included in the Knowledge Warehouse and its chambers. The next steps will be to evaluate the outputs and insights from these scientific papers to establish the needs for more detailed systematic reviews (e.g., focusing on randomized clinical trials, clinical trials) to define the use case studies in more detail. Subsequently, the Large Language Models that have been developed will automatically update the most relevant outcomes to support the project.

3.2 Policy Tracker

For the Policy tracker we have not found any new EU-policies that needs to be incorporated. In the - A dataset on EU legislation for the digital world (bruegel.org)) – we provide a comprehensive overview of mandated (by May 2024) and detailed examination of the key legislative developments and policy initiatives shaping digitalization within the European Union. This includes an analysis of:

1. **Legislative Measures Relevant to Digitalization**:
    - **Historical Context**: Legislative measures enacted prior to the current legislative session, providing a foundation for understanding the evolution of digital policies.
    - **Current Legislative Session (2019–2024)**: Measures enacted during this period, focusing on their objectives, scope, and potential impact on the digital landscape.
2. **Ongoing EU Policy Initiatives**:
    - These initiatives are actively under development and could lead to the introduction of new legislative measures in the near future.

Looking ahead, our analysis will also expand to assess whether complementary policies are being established at national, regional, or local levels to enhance or support the frameworks developed by the European Commission. These additional layers of policy could provide valuable insights into the broader integration of digitalization strategies across different governance tiers. By monitoring these developments, we aim to offer a clearer picture of how digital policy is evolving within the EU, identifying synergies and gaps that may inform future legislative and governance efforts. This will be reported in upcoming versions of this deliverable. By continuously tracking and analyzing policies related to patient-reported data, this initiative will provide a valuable resource for advancing patient-centered care and fostering innovation in digital healthcare ecosystems.

3.3 Practice Tracker

For the practice tracker we have identified and starting to analyse several practices across countries and regions, in order to develop a knowledge base of the existing practices that are conducted to develop methods or frameworks for collecting and using patient reported outcomes. Subsequently, data gathering will be done in existing repositories of good practices in different fields and with direct contacts with a wide range of leading regional and national ecosystems.

More specifically, in D2.2 Practice report and updates V1 the first steps in establishing the analysis of practices relevant to the IMPROVE project have been reported. In particular, a methodology was outlined with the establishment of an Analysis of Practice Template to be used for analysing the existing relevant projects and to be able and extract the relevant practices. Subsequently, five key projects were analysed: PREFER, BEAMER, Gravitate-Health, SISAQOL-IMI, and PARADIGM. There is quite some heterogeneity in how the projects incorporate Patient-Generated Health data in their work and their ultimate goals for their usage. Therefore, the insights generated for IMPROVE are rich and provide an initial but broad picture. Specific emphasis can be put on the SISAQOL project which aims to provide recommendations for how to analyse and interpret PROMs data. These insights can be incorporated into the IMPROVE project and platform if deemed desirable.

The current deliverable is the first in a series of deliverables mapping practices relevant to IMPROVE. Subsequently, the proposed methodology will be validated with stakeholders and fine-tuned to meet the specific needs of IMPROVE and the practice tracker. Furthermore, many of the projects analysed are ongoing and therefore updates of the information gathered will be provided. Many additional projects have been identified as potentially relevant to IMPROVE and these projects will also be analysed to create a comprehensive overview of relevant practices to be implemented in the practice tracker. This will also allow for extensive engagement between IMPROVE and other projects.

4 Conclusion

This deliverable summarizes the second step in the process of establishing and building the Scientific, Policies and Practices tracker and shows the development, execution and creation of the three trackers to collect the necessary insights for the successful execution of the project, to support WP4 and WP5. First, the scientific data that has been collected as a result of the systematic literature reviews and desk research have been stored in the **Knowledge Warehouse** and will feed the development of the Use cases in more detail. For the Policies tracker we have established European legislation, initiatives and actions that are relevant for IMPROVE. As it will take some years before new will be developed, for the policy tracker we will analyze existing developments in EU-member states. During the next years we will start collecting local, regional and national initiatives that need to be incorporated in the analyses. Subsequently, for the Practice tracker we have established a methodology to be used for analysing the existing relevant projects and to be able and extract the relevant practices. Subsequently, five key projects were analysed and reported in D2.2: Policy tracker. During the next months, the proposed methodology will be validated with relevant stakeholders and fine-tuned to meet the specific needs of IMPROVE and the practice tracker. We will also use the Large Language Models developed for the Science tracker to start analysing the outcomes of the practices and projects that we have collected in order to be able to summarize their main inputs for the IMPROVE project.

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.

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