IMPROVE

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

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Abstract

This report describes the progress made on establishing a state-of-the-art Knowledge Warehouse regarding the use of various types of Patient Generated Health Data (PGHD) in healthcare delivery, specifically concerning PGHD in several disease areas throughout the patient journey. The ultimate goal is to obtain state-of-the-art scientific evidence on the integration of in-clinic and out-of-clinic PGHD and experiences to harness value-based healthcare (VBHC) through improving the quality, reliability and use of Patient-Reported Outcome Measures (PROMs), Patient Preference Information (PPI), Patient-Reported Experience Measures (PREMs) to enhance healthcare enabling accelerated innovation of cost-effective and personalized patient journeys, based on accurate insight in health condition and treatment options in relation to foreseeable outcomes, patient experiences and preferences which are integrated for informed decision making by the patient, family members, and healthcare professionals. In the present deliverable the finalization of the initial umbrella literature originally reported in D2.1 is explained. Additionally, related developments of the literature screening software and the use of Large Language Models (LLMs) to better understand PGHD are discussed. Further, the updates made to the Knowledge Warehouse over the preceding year, including adding relevant systematic reviews and meta-analyses published between April 2024 and April 2025, are showcased. The records obtained via a systematic search were screened by both use-case experts and other trained consortium members, and relevant data was extracted and added to the Knowledge Warehouse. We used an adapted Screenathon Review procedure to deal with the high number of records, again crowdsourcing the title-abstract (TA) screening. The adaptations to the procedure were developed based on experiences with the initial Screenathon Review conducted to establish the original database, implementing crowdscreening and thus enabling consortium members present at the plenary meeting in Lecce to help conduct the update. The resulting updated Knowledge Warehouse with extracted data from the relevant systematic reviews continues to be used to develop the **IMPROVE** lab in Work Package 3 (WP3), as well as supporting the development and execution of the data collection in WP4 and WP5, and for the guidelines and best next practices in WP7. Additionally, we present the final results of the gap analysis, which is intended to align the scientific evidence base with the practical objectives of the IMPROVE project. The deliverable is concluded with an overview of next steps.

Keywords: Systematic Review, Patient Generated Health Data; Knowledge Warehouse

Abbreviations and Acronyms

AI	Artificial Intelligence
EC	European Commission
EHDS	European Health Data Space
EHR	Electronic Health Record
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
FT	Full-Text
HE	Horizon Europe
HTA	Health Technology Assessment
KPI	Key Performance Indicator
LLM	Large Language Model
MA	Meta-Analysis
ML	Machine Learning
PM	Project month
MS	Milestone
NLF	Noisy Label Filter
NLP	Natural Language Processing
OMOP	Observational Medical Outcomes Partnership
PGHD	Patient Generated Health Data
PROMs	Patient-Reported Outcome Measures
PPI	Patient Preference Information
PREMs	Patient-Reported Experience Measures
RCT	Randomized Controlled Trial
RWD	Real World Data
SR	Systematic Review
TA	Title-Abstract
VBHC	Value-Based Healthcare
WP	Work Package

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1. Introduction

Patient Generated Health Data (PGHD) and knowledge-sharing across the European Union (EU) will make healthcare provision 'smarter' and will accelerate the development of (cost-)effective and patient-preference based new treatments and medical devices and reduce the operational costs of integrated healthcare solutions by making the patient more central in the healthcare process (Tian et al., 2019). The main aim of IMPROVE is to create an accessible, functional, transferable and (cost-)effective platform that is capable of automatically enabling and integrating the added value of PGHD integrated healthcare solutions using patient-reported outcome measures (PROMs), patient preference information (PPI), and patient-reported experience measures (PREMs) and other people-generated information, accompanied by a management structure that can meet regulatory (e.g., AI Act, Data Act), ethical, legal, statistical and data requirements to support decision makers, patients, researchers, and healthcare professionals. IMPROVE will develop an evidence-based and real-time framework to effectively leverage integrated added value of people-centred integrated healthcare solutions. This information will be established in first instance by scientific evidence.

1.1. The Goals of Deliverable 2.3

In this report we first summarize how the initial database of evidence, termed the "Knowledge Warehouse", was created and its state prior to the updating process. We also describe and evaluate the implementation of the "next steps" formulated in IMPROVE deliverable 2.1 (D2.1). Subsequently, we describe the updating process in detail. The goal of the update is to supplement the existing database (Monschau et al., 2025) with those relevant systematic reviews and meta-analyses published between the establishment of that initial Knowledge Warehouse in 2024 and the time of the IMPROVE plenary meeting in June 2025. The records obtained via an updated systematic search were screened by experts via an adapted version of the Screenathon Review procedure (Monschau et al., 2024; Peschke et al., 2025), which we describe in detail in section 3. To ensure high data quality, we only include systematic reviews and meta-analyses published in scientific journals. During the data extraction, the reported risk of bias assessment was extracted, when available, from each selected systematic review or study and will be considered for the evaluation of the quality of the selected systematic review or study. Relevant data from the included systematic reviews was extracted and added to the existing data warehouse, which is utilized in the IMPROVE lab in work package 3 (WP3), as well as the development and execution of the data collection in WP4 and WP5, and for the guidelines and best next practices in WP7. Finally, we provide an overview of results and consider the next steps for WP2.

1.2. Nomenclature

The nomenclature that informed the inclusion criteria are listed in Table 1 below.

Table 1 Nomenclature Used to Develop Inclusion Criteria

Nomenclature	
HTA	**Health Technology Assessment**: Health Technology Assessment (HTA; *Health Technology*, n.d.) informs reimbursement and coverage decisions on how to allocate healthcare resources to different health technologies by carefully assessing the costs and benefits of health interventions, using cost-effectiveness and impact assessment as instruments.
PC	**Patient centricity**: Putting the patient first in an open and sustained engagement throughout the full process, to respectfully and compassionately achieve the best experience and outcome for that person and their family, committed to hearing, understanding and integrating patients' perspective in regulatory decision making as appropriate, considering '*valid scientific evidence*' when conducting benefit-risk assessment, including nonclinical and clinical investigations and patient information (such as PGHD).
PGHD	**Patient Generated Health Data**: Patient-generated health data (PGHD), created and captured from patients via wearable devices and mobile apps, are proliferating outside of clinical settings. Examples include sleep trackers, fitness trackers, continuous glucose monitors, and RFID-enabled implants, with many additional biometric (*Biometrics*, n.d.) or health surveillance applications in development or envisioned. These data are included in growing stockpiles of personal health information (PHI) being mined for insight by health economists, policy analysts, researchers, and health system organizations (Winter & Davidson, 2022).
PROMs	**Patient-Reported Outcome Measures**: Patient-reported outcome measures are questionnaires that collect health outcomes directly from the people or patients who experience the health outcomes themselves (Williams et al., 2016).
PPI	**Patient Preference Information**: Qualitative or quantitative assessments of the relative desirability or acceptability to patients, of features that differ among alternative health states, health interventions, or health services. Desirability: preferences for positive outcomes or features – Acceptability: aversion to negative outcomes (Russo et al., 2019).
PREMs	**Patient-Reported Experience Measures**: Patient-reported experience measures are psychometrically validated tools (e.g. questionnaires) used to capture patients' interactions with healthcare systems and the degree to which their needs are being met. Patient-reported experience measures are designed to determine whether patients have experienced certain care processes rather than their satisfaction with the care received (which may be subject to bias). A Patient-reported experience measure may, for instance, be used to collect information on the patient experience of hospital admission. Data derived from this could be used to inform service development and configuration (*Patient-Reported Experience Measure*, n.d.).
VBHC	**Value-Based Healthcare** (Koehring, 2015; Porter, 2010)**:** Value in healthcare is the measured improvement in a patient's health outcomes for the cost of achieving that improvement (Winter & Davidson, 2022). The goal of value-based care transformation is to enable the healthcare system to create more value for patients. Because value is

	created only when a person's health outcomes improve, descriptions of value-based healthcare that focus on cost reduction are incomplete (Teisberg et al., 2020).

2. Finalization Knowledge Warehouse "V1"

D2.1 reported on the establishment of the initial Knowledge Warehouse, which, as summarized above, used the Screenathon Review procedure to conduct TA screening. However, not all the post-processing steps, particularly the data extraction from the relevant records, had been completed when this deliverable was published. Accordingly, we report a summary of the completed database here, before explaining how it is currently being updated.

Of the 12,473 records that were TA screened during the first Screenathon, 4,286 were classified as relevant. Of these, 447 unique records were screened on full-text (FT). Of these, 266 unique records were ultimately included in the Knowledge Warehouse. Consult Figure 1 for an overview of this process.

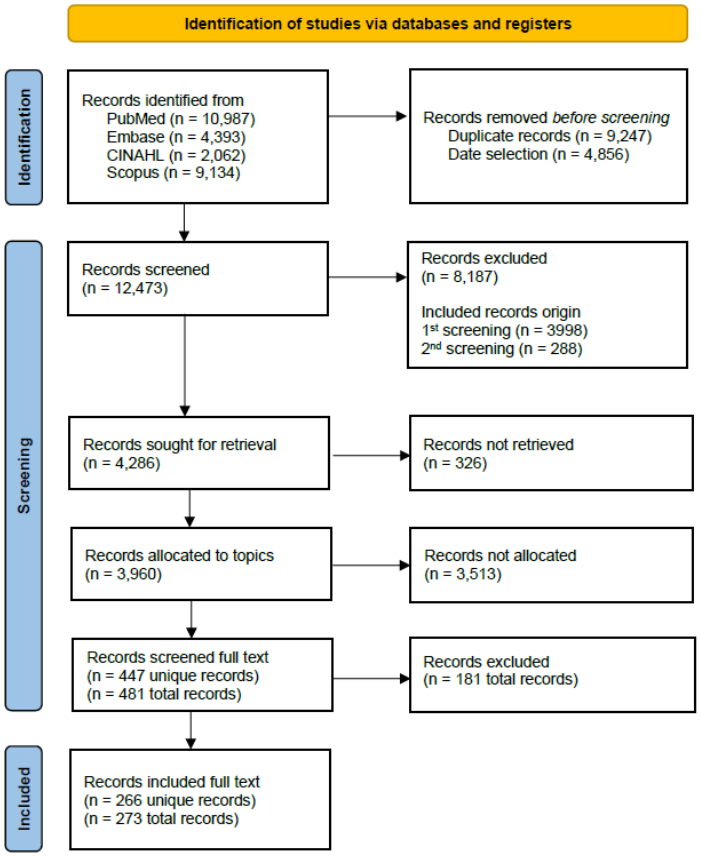


Figure 1 PRISMA Flow Diagram of Initial Database.

In Table 2, which is the updated version of a table already presented in D2.1, we show the total number of full manuscripts that were analysed, the included articles that were selected, and the number of

individual studies that were included in these literature reviews. This has been divided by each of the disease areas for the use cases to inform them and WP5 in more detail about the state-of-the-art in scientific research.

Table 2 Labelling Decision Frequencies for the 12,473 Records Screened (per Disease Topic).

Therapeutic Area	Disease Topic	TA Inclusions After Topic-Allocation	Included Systematic Reviews	Nr. Individual studies in Reviews
Oncology	Breast	118	72	2382
Oncology	Cervical	14	3	101
Oncology	Neck and Head	56	34	777
Oncology	Prostate	55	42	1118
Ophthalmology	Macular Degeneration	13	10	296
Neurology	Multiple Sclerosis	32	24	855
Cardiovascular	Atrial Fibrillation	24	9	895
Cardiovascular	Coronary Artery	31	13	813
Cardiovascular	Heart Failure	67	43	1464
Cardiovascular	Aortic Stenosis	32	5	386
Chronic Inflammation	Chronic Rhinosinusitis	28	18	355
TOTAL		470	273	9 442

For a more extensive report on the initial state of the Knowledge Warehouse initial database please consult the datapaper (Monschau et al., 2025) that was published about this topic. The data is available on DataverseNL and is accessible via the following DOI: https://doi.org/10.34894/EVYU9X.

Following FT screening, data was extracted from the included reviews. Examples of the data extracted were the disease covered by the review, which timeframe it covered, the number of primary studies included, the risk of bias, the kind of PGHD covered and whether effect sizes were available, amongst others. This data is utilized in the IMPROVE lab in WP3, as well as the development and execution of the data collection in WP4 and WP5, and for the guidelines and best next practices in WP7.

Finally, in Table 3, which is the updated version of a table already presented in D2.1, we analyse the scientific outputs from the systematic literature review to see if the state-of-the-art provides IMPROVE with a better understanding of the implementation of PGHD including PROMs, PREMs or PPIs in different moments of the clinical pathway, pre, during or post-hospital stay.

Table 3 Scientific Outputs from the Systematic Literature Review.

Therapeutic Area	Disease Topic	PREMs	PROMs	PPIs	Pre	During	Post
Cancer	Breast	1	68	0	14	19	64
Cancer	Cervical	0	3	1	3	3	3

Cancer	Neck and head	2	31	2	20	21	31
Cancer	Prostate	1	29	7	15	6	23
Ophthalmology	Macular Degeneration	1	9	0	5	3	10
Neurology	Multiple Sclerosis	3	17	7	3	10	7
Cardiovascular	Atrial Fibrillation	2	8	0	4	7	5
Cardiovascular	Coronary Artery	3	13	1	7	9	11
Cardiovascular	Heart Failure	11	38	3	14	37	31
Cardiovascular	Aortic Stenosis	1	1	2	1	0	1
Chronic Inflammation	Chronic Rhinosinusitis	0	18	0	6	1	15

3. Methods: Updating the Knowledge Warehouse

3.1. Database Search

To fit the requirements of the Screenathon set up, the aim was to run a broad search in both more subject-specific as well as more general databases. The search queries used were based on a description of the main terminology in the field of interest: Patient-Generated-Health-Data. Four databases (PubMed, Embase.com, CINAHL, and Scopus - search date: 13.05.2025) were searched using a date limit of publication between April 2024 and April 2025 . The initial pool of records found was supplemented using a broader search in the OpenAlex database (Priem et al., 2022). The search was focused on systematic literature reviews and meta-analyses on the use of PGHD. We excluded conference abstracts, letters to the editor, theses, and pre-prints. The eligible studies should be written in English, should contain a persistent object identifier (e.g., DOI, PubMed ID) and the title plus abstract should be available.

An example of part of the search in PubMed is described in Table 4. The queries used were updated versions of those used in the establishment of the evidence base. Details on that original search (Weijdema et al., 2024), including the exact searches, the nomenclature document, full search details, and the database output (.ris files) can be found on the Open Science Framework: www.osf.io/bh7fy.

Table 4 Example Query (PubMed).

Pubmed (Main version (US), 13 May 2025,):
((("patient centri"[Title/Abstract] OR "Patient centered"[Title/Abstract] OR "patient focus*"[Title/Abstract] OR "Patient-Centered Care"[MeSH Terms] OR "Patient Reported Outcome Measures"[MeSH Terms] OR "patient reported outcome*"[Title/Abstract] OR "patient assessed outcome*"[Title/Abstract] OR "PROMs"[Title/Abstract] OR "PROM"[Title/Abstract] OR "Patient Preference"[MeSH Terms] OR "patient preference info*"[Title/Abstract] OR "PPI"[Title/Abstract] OR "PPIs"[Title/Abstract] OR "HTA"[Title/Abstract] OR "health technology assess*"[Title/Abstract] OR "biomedical technology assess*"[Title/Abstract] OR "technology assessment, biomedical"[MeSH Terms] OR "patient generated health data"[MeSH Terms] OR "PGHD"[Title/Abstract] OR "patient generated health data"[Title/Abstract] OR "Patient generated data"[Title/Abstract] OR "Patient reported health data"[Title/Abstract] OR "Patient reported data"[Title/Abstract] OR "Self-assessed health data"[Title/Abstract] OR "PREM"[Title/Abstract] OR "PREMs"[Title/Abstract] OR "patient reported experience measur*"[Title/Abstract] OR "value based health care"[MeSH Terms] OR "VBHC"[Title/Abstract] OR "value based health care"[Title/Abstract] OR "Value health care"[Title/Abstract]) AND ("systematic review*"[Title/Abstract] OR "meta analys*"[All Fields] OR "systematized review*"[Title/Abstract] OR "scoping review*"[Title/Abstract] OR "literature review*"[Title/Abstract] OR "umbrella review*"[Title/Abstract] OR "Systematic Review"[Publication Type]) AND*

2024/04/08:2025/04/08[Date - Entry]) NOT ("letter"[Publication Type] OR "comment"[Publication Type] OR "editorial"[Publication Type] OR "preprint"[Publication Type])) AND "english"[Language]*

The data was managed using Endnote stored in Microsoft's SharePoint for easy access. The search hits (including publication title, authors, abstract and DOI) were downloaded in RIS file format. A file containing all the hits for each search was stored in Microsoft's SharePoint for easy access were merged and duplications were removed. This removal occurred while importing the database output using EndNote X20 (default settings). The combined deduplicated results of the search were the starting point for creating the Screenathon dataset. In the result section we provide all the details about how many records were included, and how many participants participated in the Screenathon event, amongst other details.

3.2. Eligibility Criteria

The inclusion and exclusion criteria for the studies eligible for this review were identical to those utilized for the establishment of the evidence base (see below). The sole addition was the "disease topic check", which required screeners to ensure that the title-abstract combination they were assessing indeed belonged to the disease topic that particular screener had been assigned to. Note that criterion six is only relevant for the laterFT screening phase.

0. *Disease-topic Check: Does this title-abstract combination fit the disease topic I was assigned to?*
1. Study Type: Literature reviews (e.g., systematic, narrative, scoping) or meta-analyses.
2. Content: It should contain (PGHD). PGHD Is defined as data created and captured from patients via wearable devices, mobile apps or surveys, which are proliferating outside of clinical settings. Examples include sleep trackers, fitness trackers, continuous glucose monitors, and RFID-enabled implants, with many additional biometric or health surveillance applications in development or envisioned.
3. Population: The population of interest of the studies under review is restricted to adult human patients that are, have been or will be under treatment for a certain condition. For this search, the interventions considered are the studies assessing factors influencing treatment adherence, with the identification of the effect on adherence of one or more factors as an outcome of these studies. Studies considering adult human subjects (≥ 16 years old). For reviews and overviews, only those including ≥ 80% of included studies analysing adult population.
4. Condition Type: Both chronic and acute physical conditions.
5. Treatment: The studies eligible for this review are those that analyse PGHD to any kind of treatment or medical recommendation, meaning not only medication taking, but also other health behaviours such as attending follow-up appointments, implementing lifestyle changes (e.g., avoiding certain foods, engaging in specific exercise), using medical devices, among others

6. *Data (for the FT): Studies that for the factors analysed report at least the direction of the effect accompanied by its statistical significance and its uncertainty estimates.*

3.3. Title-Abstract Selection Process

The TA screening procedure was an adapted version of the Screenathon Review (Monschau et al., 2024; Peschke et al., 2025), with the main change being the utilization of the active learning feature of ASReview (ASReview LAB developers, 2024; van de Schoot et al., 2021), which dynamically ordered records based on relevance. The procedure began with a training where members collectively assessed a predetermined set of records to increase their understanding of the inclusion criteria. These records and their labels were discussed in a group setting, enhancing the prospective reviewers' understanding of both the criteria and the screening process. To counteract screening fatigue, attendees were free to flexibly decide how many records they would like to screen. See Figure 2 for a representative example of the screening view.

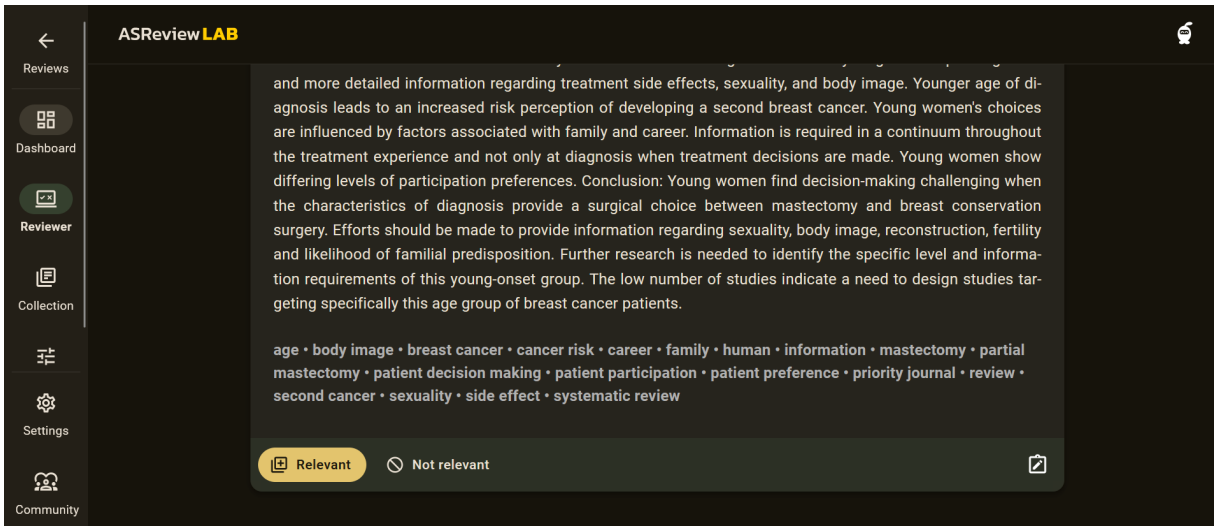
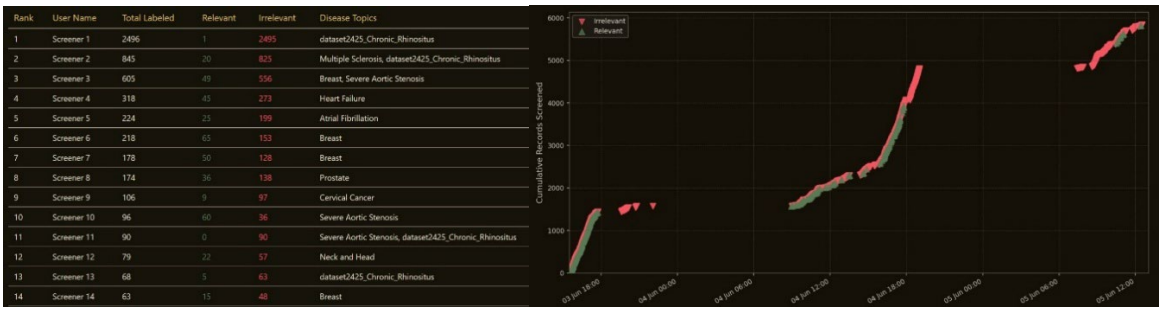


Figure 2 Screenshot of the review screen for one of the papers screened during the second Screenathon.

The actual screening was carried out over three days, both during structured sessions and at attendee's leisure. The organization team was on-site to facilitate the screening and give attendees insights into the process. See Figure 3 for examples. Why is this figure important at this point?



Rank	User Name	Total Labeled	Relevant	Irrelevant	Disease Topics
1	Screener 1	2496	1	2495	dataset2425_Chronic_Rhinositus
2	Screener 2	845	20	825	Multiple Sclerosis, dataset2425_Chronic_Rhinositus
3	Screener 3	605	49	556	Breast, Severe Aortic Stenosis
4	Screener 4	318	45	273	Heart Failure
5	Screener 5	224	25	199	Atrial Fibrillation
6	Screener 6	218	65	153	Breast
7	Screener 7	178	50	128	Breast
8	Screener 8	174	36	138	Prostate
9	Screener 9	106	9	97	Cervical Cancer
10	Screener 10	96	60	36	Severe Aortic Stenosis
11	Screener 11	90	0	90	Severe Aortic Stenosis, dataset2425_Chronic_Rhinositus
12	Screener 12	79	22	57	Neck and Head
13	Screener 13	68	5	63	dataset2425_Chronic_Rhinositus
14	Screener 14	63	15	48	Breast

Figure 3 Example statistics shown to attendees to give insight into screening progress.

The total number of records screened, and the percentage included, can be found in the results section.

The final step of the Screenathon Review procedure is a quality check which includes routine noisy-label filtering (NLF) and the verification of record integrity. This check was conducted in the same manner as described in D2.1. The NLF (Neeleman et al., 2024) consists of the systematic screening of the excluded records using ASReview. In this process, a machine learning model was trained using the records included during the Screenathon as relevant examples and a subset of irrelevant records to distinguish between the two categories. This model predicts the likelihood of relevance for each excluded record. The screener then prioritized reviewing the records that the model predicted as most likely relevant but were initially excluded during the Screenathon. Additionally, it was ensured that the included records had complete meta-data available and could be retrieved.

For the adapted Screenathon Review, a post-processing step was added, which extends these efforts using four steps: (1) Topic correction: ensuring each record is assigned to the appropriate disease category. (2) Re-screening: conducting title/abstract and FT reviews to resolve any misclassifications and to detect any missed records following “topic correction”. (3) Focused screening: within each disease pool, performing a new round of screening guided by a predefined stopping rule. (4) Stringent NLF pass: applying a stricter NLB with a stopping threshold of 20, recording any additional inclusions to finalize the dataset. Deploying the post-Processing allows for an opportunity to “resweep” the pool for any previously missed records. Simultaneously, the four extended steps effectively utilize human-Artificial Intelligence (AI) collaboration by retraining the model, despite the possibility of previously wrong inclusions. This updated Phase 4 provides a structured endpoint to the Screenathon workflow, ensuring that the screened pool meets high standards of accuracy and completeness.

3.4. Full-text Review

After the TA screening and quality check phase and in parallel to the post-processing, the included papers were screened for FT eligibility by an independent screener for each of the five use cases, considering the eligibility criteria described above. This was decided to optimize the workflow of the FT procedure, TA screening, and quality check was combined. This allowed the reviewer to complete the full cycle for each publication per disease topic in one stretch, before applying the post-processing procedure. For each publication assigned, the reviewer checked each criterion and assessed the inclusion of only those publications meeting the full criteria.

The results from all screening phases were then added to the data warehouse. This file contains a row for every paper screened during the adapted Screenathon. There are binary columns to indicate inclusion in the screening steps, along with various metadata and more elaborate screening decision data. The outcome of this screening step is described in the results section.

3.5. Data Extraction

Data extraction is the process of systematically identifying relevant characteristics of (systematic) reviews based on the information available in the selected publications. It provides the basis for meta-analysis and is a necessary step that precedes the assessment of the risk of bias in authors' synthesis of their findings or in reviewers' interpretation. Data extraction mainly followed the PICO framework (i.e. focusing on questions regarding patient (problem or population), intervention, comparison (control or comparator), outcome), but other data like T (timing) and S (type of study) was extracted when available. Meta-data of the articles, such as DOI, authors, title, journal, publication year and open access availability were extracted via OpenAlex.

Reviewers, namely content experts from the relevant disease topics, extracted the fields listed below from the systematic reviews and the individual studies as reported in the reviews. For the extraction a custom template was used in Covidence, created for this project. This streamlined the extraction, making it easier and ensuring that the format was the same for all papers.

1. Record Title
2. Lead Author
3. Review Country
4. Type of Review (Systematic, Scoping etc.)
5. Search Period
6. Databases Searched
7. Number of Included Studies
8. Countries (of included studies)
9. Clinical Domain Scope (goal of review)
10. Reported Risk of Bias Assessment
11. Conclusions
12. Effect Sizes (availability and description)

13. PGHD (type and description)
14. Time of Data Collection

4. Results: State-of-the-art Evidence

4.1. Screening

In total, 27 attendees representing a wide range of IMPROVE partners took part in the second Screenathon event. By the afternoon of day three, i.e. the end of the Screenathon event, 5,842 records had been screened on title-abstract relevance. Of these records, 453 (7.8%) were labelled as relevant, while 5,390 (92.2%) were labelled as irrelevant. Screening rates varied across participants, ranging from 3 to 2,496 screened records per person, with an average of 216 records (mean = 216.4, SE = 95.19). At the end of day three, six disease-topics had reached their stopping rule (Macular Degeneration, Chronic Rhinosinusitis, Breast, Prostate, Severe Aortic Stenosis, and Fibrillation) and were therefore considered completed. The remaining five projects (Multiple Sclerosis, Cervical, Neck and Head, Coronary Artery Disease, and Heart Failure) were still in progress and proceeded to the post-processing stage for completion.

Post-processing yielded 221 additional inclusions (≈1.8% of the original 12,000 records). The largest gains came from Breast cancer (+80) and Heart failure (+42). Topic reallocation removed 54 misclassified records and FT corrections removed 211. Some additional inclusions were found through were found after the NLF quality-check (Neeleman et al., 2024), namely 1 for Breast Cancer, 2 for Multiple Sclerosis, 1 for Coronary Artery Disease and 13 for Heart failure, before the stopping rule of 20 irrelevant records was reached.

Table 5 shows the total number of records that have been analysed, the number of records included during both TA and FT inclusions (with the latter taking into account the post-processing changes), and the number of individual studies captured by the systematic literature reviews and meta-analyses analysed. This data is given per the disease area to better inform both the use cases and WP5 in more detail about the state-of-the-art in scientific research.

Table 5 Screening Decision Frequencies per Topic.

Disease area	Use case	*N* TA inclusions	*N* final inclusions[1]	*N* individual studies captured by SRs/MAs
Oncology	Breast	146	80	1597
Oncology	Cervical	8	5	55
Oncology	Neck and head	25	19	422
Oncology	Prostate	45	17	467
Ophthalmology	Macular Degeneration	8	1	0

Neurology	Multiple Sclerosis	71	28	728
Cardiovascular	Atrial Fibrillation	27	0	0
Cardiovascular	Coronary Artery	31	25	358
Cardiovascular	Heart Failure	45	42	985
Cardiovascular	Aortic Stenosis	69	1	21
Chronic Inflammation	chronic rhinosinusitis	12	3	35
TOTAL		487	221	4668

Note. SRs = Systematic reviews; MAs = Meta-analyses; [1]After FT screening and post-processing

4.2. Description of Extracted Data

Subsequently we analysed the number of studies that were included from each country in the studies that we have analysed. Most of the studies were conducted in Western countries, like the United States, Canada, Netherlands, Germany, the United Kingdom, France, Italy and others. For Asian countries, most studies were included for China, where we found that only 58 studies were reported, and for Taiwan, Japan, Korea, and India even fewer. This means that there were almost no studies included for African countries or Latin America, which creates a significant bias in the interpretation of the findings. The same is found for Eastern European countries, which are largely missing in the scientific databases. Consult the section on geographical bias in 5. Gap Analysis for more information. What about Oceania? Australia and New Zealand are quite active in collecting and analyzing PROMs, at least in orthopaedics.

Table 6 Number of Studies Included per Country per Use-case.

Countries	Total	Oncology	Chronic Inflammation	Cardiovascular disease	Ophthalmology[1]	Neurology
United States	101	61	0	29	0	11
Canada	51	32	0	15	0	4
Australia	59	37	0	15	0	7
United Kingdom	42	30	0	12	0	0
Netherlands	55	33	0	15	0	7
Germany	44	24	0	12	0	8
China	58	38	1	17	0	2
Sweden	36	21	0	13	0	2
Italy	42	22	0	10	0	10
Taiwan	17	13	0	4	0	0
France	25	19	0	2	0	4
Korea	22	16	0	4	0	2
Brazil	24	16	0	3	0	5

Denmark	31	23	0	5	0	3
Norway	18	14	0	4	0	0
Japan	21	14	0	6	0	1
Remaining	220	127	1	49	0	43

Note. The numbers in this table give estimates. Additionally, this is the number of reviews the country appeared in; it might be that within the review the distribution among countries is very uneven. [1]In the case of ophthalmology no country information was available.

4.3. Categorization of PGHD

In Table 7 we analyse the distribution of crucial PGHD types, including PREMs, PROMs and PPIs, as well as the measurement moments in relation to treatment included in the systematic literature syntheses captured by the update. PREMs and PPIs are relevant dimensions because of their adjacency to the patient-centred approach, which is has not been investigated in previous studies.

Table 7 Scientific Outputs from the Systematic Literature Review.

Main topic	Subtopic	PREMs	PROMs	PPIs	Pre	During	Post
Oncology	Breast	7	70	4	49	39	68
Oncology	Cervical	0	4	0	1	3	4
Oncology	Neck and head	1	12	0	1	8	13
Oncology	Prostate	0	16	0	3	12	14
Ophthalmology	Macular Degeneration	1	1	0	1	0	1
Neurology	Multiple Sclerosis	7	26	0	22	23	24
Cardiovascular	Atrial Fibrillation	0	0	0	0	0	0
Cardiovascular	Coronary Artery	5	19	0	1	17	11
Cardiovascular	Heart Failure	8	27	0	0	30	16
Cardiovascular	Aortic Stenosis	1	1	0	0	1	0
Chronic Inflammation	Chronic Rhinosinusitis	0	3	0	3	3	3

Note. The numbers in this table give estimates. Data was not always provided.

5. Gap Analysis

5.1 Overview and Purpose

Following the synthesis of evidence from the systematic literature review and meta-analyses, a comprehensive gap analysis was undertaken to identify weaknesses, missing elements, and underrepresented aspects in the current use and exploitation of PGHD across the disease areas relevant to the IMPROVE project. This analysis represents a crucial step in the overall research continuum, bridging the knowledge gained in WP2 and WP3 with the operational and implementation activities planned in WP4 and WP5. Its primary aim is to ensure that the IMPROVE framework rests

upon a robust empirical foundation by highlighting where the existing scientific evidence is insufficient, inconsistent, or biased, and by delineating where new or complementary data collection is necessary.

The gap analysis goes beyond a simple quantitative evaluation of data availability; it provides a qualitative and contextual interpretation of the strengths and limitations of current PGHD research. It examines the degree to which different disease areas, patient populations, and data modalities have been explored in the literature, identifying structural imbalances that may affect the validity and generalizability of PGHD-based evidence. Furthermore, it considers methodological and geographical biases, variations in data quality, and the maturity of PGHD integration with other real-world data (RWD) sources.

In this sense, the analysis serves not only as a diagnostic exercise but also as a strategic planning tool for the subsequent phases of the project. By systematically mapping where the evidence is strong and where it is lacking, it enables the consortium to prioritize areas for targeted data enrichment, to refine the design of the IMPROVE data model, and to define requirements for interoperability and standardization. The findings also provide essential input for the development of disease-specific use cases under WP5, ensuring that these pilots are designed to validate the framework under conditions that reflect real-world diversity and data complexity.

Ultimately, the gap analysis is intended to align the scientific evidence base with the practical objectives of the IMPROVE project: to advance the use of patient-generated data as a cornerstone of patient-centered, data-driven healthcare innovation. By identifying the areas where existing research falls short and by translating these insights into actionable guidance for data collection and system design, this task lays the groundwork for a more comprehensive and inclusive understanding of how PGHD can contribute to improving clinical outcomes, healthcare delivery, and patient empowerment.

5.2 General Observations

Across the 4,668 individual studies identified, several **cross-cutting gaps** emerged that limit the full integration of PGHD in evidence-based healthcare and model development:

Geographical Bias:

The current evidence base is heavily skewed toward Western countries such as the United States, Canada, and several nations in Western Europe, including Germany, the Netherlands, France, Italy, and the United Kingdom. This is consistent with the reported contribution to authorship of countries for publishing in general (Brück, 2023). These countries dominate the published research landscape on the use of Patient-Generated Health Data (PGHD), reflecting well-established research infrastructures, widespread use of digital health technologies, and mature data governance frameworks. In contrast, only a small proportion of studies originate from Eastern Europe, Africa, or Latin America, and contributions from many low- and middle-income countries are almost entirely absent. This uneven geographical distribution introduces a significant bias in the scientific understanding of how PGHD can be implemented, interpreted, and used to improve healthcare delivery across different health systems.

The lack of representation from underexplored regions limits the generalizability of current findings and reduces the applicability of existing evidence to diverse sociocultural and economic contexts.

Healthcare systems in these regions often differ substantially in terms of digital infrastructure, clinical workflows, patient engagement practices, and regulatory environments (Ibeneme et al., 2022; Serge et al., 2024). Consequently, models and tools developed on the basis of data from Western populations may not translate effectively into settings with different disease prevalence patterns, healthcare access constraints, or patient behaviour dynamics. Moreover, disparities in digital literacy, data accessibility, and technological readiness exacerbate the risk of excluding vulnerable or underserved populations from the benefits of data-driven healthcare innovations. Our review is focused on digital-based PGHD, even though other means can be used, and paper-based reporting has been used for decades. However, we have focused the review on digital-based PGHD, since data digitalization can widen and boost its use, availability and usability, thus allowing transformation towards patient-centred models.

From a methodological perspective, this imbalance also affects the development of predictive algorithms and machine learning models trained on PGHD, which may inadvertently encode region-specific biases. Without data that reflect the heterogeneity of global healthcare experiences, there is a risk that PGHD-based insights will favour populations already well represented in the data while failing to capture the needs of others. In the context of the IMPROVE project, addressing this limitation is essential to achieve the overarching goal of building an inclusive, equitable, and generalizable framework for real-world data integration.

Uneven Disease Representation:

Some disease areas, such as Breast Cancer, Heart Failure, and Multiple Sclerosis, are relatively well represented in the current body of evidence, reflecting both their high research visibility and the long-standing integration of PROMs in these clinical fields. In oncology and neurology in particular, the use of PGHD has become increasingly common as part of comprehensive care models and clinical trials, often supported by well-established measurement tools and registries. These conditions benefit from active research communities, structured clinical networks, and mature patient advocacy infrastructures that facilitate systematic data collection and dissemination. As a result, a substantial number of studies include validated PROMs capturing dimensions such as quality of life, symptom burden, and functional capacity, providing a solid empirical foundation for understanding the patient's experience in these domains. In contrast, several other disease areas, most notably Atrial Fibrillation, Aortic Stenosis, Macular Degeneration, and Chronic Rhinosinusitis, show major gaps in available PGHD evidence. For these conditions, the number of identified studies is low, and even among those that exist, data are often fragmented, inconsistently collected, or limited to narrow clinical subgroups. In cardiology, for instance, while Heart Failure has received considerable attention due to its chronic and highly symptomatic nature, Atrial Fibrillation and Aortic Stenosis remain underexplored in terms of patient-reported data. These diseases are typically managed through procedural or pharmacological interventions, where clinical endpoints, such as survival, readmission, or rhythm control, have historically dominated the research focus (Lansac et al., 2025; Seligman et al., 2020; Zannad et al., 2013). As a result, the subjective dimensions of patient well-being, treatment adherence, and perceived quality of care have been insufficiently documented, despite their relevance for improving outcomes and supporting shared decision-making. The apparent gap suggested by the paucity of evidence may be due to our focus on digital-based reporting, but may be seen as opportunity to adapt

existing outcomes to digital platforms, so that these may enhance their uptake not only in research but also in clinical practice.

Similarly, in ophthalmology, Macular Degeneration research has only recently begun to incorporate patient-reported outcomes, and even then, studies often lack standardized instruments or validated measures for vision-related quality of life. The scarcity of data in this area poses challenges for integrating PGHD into disease monitoring and model calibration, as patient experiences of functional impairment, daily activity limitations, and treatment burden remain poorly quantified. The same applies to chronic inflammatory diseases such as Chronic Rhinosinusitis, where available studies are sparse and vary greatly in design and scope. This is particularly problematic given that such chronic, quality-of-life–dominated conditions could benefit significantly from systematic PGHD integration.

The imbalance in disease representation not only reflects differing levels of clinical and research uptake of PGHD but also reveals structural barriers to the routine capture of PGHD. These include the absence of standardized data capture tools, limited patient engagement strategies, and varying levels of clinical interest or awareness regarding the value of patient-reported data. Consequently, while some fields have successfully embedded PGHD collection into their research and care frameworks, others remain dependent on manual entry of data forms, often not transcribed to electronic health records, clinician-reported or administrative data, effectively leaving critical aspects of the patient experience undocumented.

For the IMPROVE project, this uneven distribution has direct implications for the design of both the data framework (WP4) and the disease-specific use cases (WP5). Addressing this imbalance will require targeted efforts to expand PGHD collection in underrepresented conditions, particularly by developing and validating disease-specific PROMs and PREMs, harmonizing data structures, and encouraging systematic data capture in clinical practice. Through this approach, the IMPROVE framework can ensure that its model development and validation processes reflect a balanced representation of diseases, ultimately improving the robustness, generalizability, and patient relevance of its outcomes.

Incomplete PGHD Dimensions:

While PROMs are relatively well captured in certain disciplines, particularly oncology and neurology, the presence of PREMs and data on PPI remains limited or altogether absent in most of the analysed literature. This imbalance reveals a persistent focus within healthcare research on quantifiable clinical outcomes and symptom-based metrics, often at the expense of the broader experiential and participatory dimensions of patient care. PROMs have become well-established tools in clinical research, primarily due to their standardized formats and validated psychometric properties, which facilitate their inclusion in trials and observational studies. As a result, outcomes such as pain, fatigue, mobility, or health-related quality of life are relatively well represented, particularly in diseases where patient functioning and symptom burden are central to treatment evaluation.

In contrast, PREMs, which focus on the patient's perception, satisfaction and experience of healthcare processes, communication, accessibility, coordination of care, and the interpersonal aspects of treatment, have received far less attention in scientific literature. When such data is collected, they are often limited to small-scale institutional surveys or quality improvement initiatives rather than systematically integrated into research designs. This lack of standardization and the absence of

validated instruments across disease areas limit the comparability of findings and hinder the use of PREM data for model development or policy evaluation. Moreover, the underrepresentation of PREMs restricts understanding of how care delivery models, technological interfaces, or patient–provider relationships influence clinical outcomes and adherence.

Similarly, information regarding PPI in healthcare research remains extremely sparse. Only a limited number of studies explicitly report involving patients or citizens in study design, data interpretation, or decision-making processes. This omission reflects a broader structural issue in biomedical research, where patients are often treated as data providers rather than as active contributors to knowledge generation. The lack of PPI data creates a gap not only in empirical evidence but also in the participatory ethos that underpins modern person-centered healthcare. When patients are not engaged in shaping research priorities or evaluating care processes, opportunities to identify barriers, contextual nuances, and meaningful outcomes are lost.

The combined absence of PREMs and PPI data therefore represents a critical shortcoming in the current PGHD landscape. It limits the multidimensional understanding of health that is necessary for effective patient-centered care and hinders the development of models that account for subjective experiences, preferences, and trust in healthcare interactions. Furthermore, this omission perpetuates a one-directional flow of information, where data are extracted from patients without systematically capturing how patients themselves perceive or influence their healthcare journeys. Incorporating these experiential and participatory dimensions into data frameworks is essential for bridging the gap between clinical performance and perceived quality of care, and for fostering a more holistic evidence base capable of supporting sustainable and inclusive innovation in healthcare.

Temporal Gaps in Measurement:

A recurring limitation observed across the analysed studies concerns the temporal scope of PGHD collection, mostly PROMs. In most cases, data are gathered retrospectively or at single points in time, often after the completion of treatment. This post-treatment focus provides useful insights into recovery, satisfaction, or long-term quality of life but fails to capture the full trajectory of the patient's journey. Very few studies report longitudinal PGHD encompassing pre-treatment baselines, intra-treatment dynamics, and post-treatment follow-up, which are crucial for understanding how health outcomes evolve over time and how patients experience the different stages of care. Underutilization of continuous monitoring data represents missing opportunities to detect early warning symptom fluctuations or behavioural adaptations that could inform proactive and personalized interventions resulting into improved health outcomes.

This fragmented temporal coverage may stem from the logistical and methodological challenges associated with repeated data collection, including patient adherence, technological constraints, and limited integration with care workflows. However, the lack of temporal granularity represents a missed opportunity to leverage PGHD as a dynamic source of information capable of capturing subtle transitions in health status. For diseases characterized by fluctuating symptoms, such as heart failure or multiple sclerosis, this shortcoming significantly undermines the potential of PGHD to enhance predictive analytics or early intervention models. Future research should therefore focus on establishing continuous or periodic data collection mechanisms, integrating digital health tools and remote monitoring systems that enable real-time reporting. Such approaches would not only provide

a more comprehensive depiction of disease progression but also strengthen the analytical capacity of model-based frameworks to learn from patient trajectories across the entire continuum of care.

Data Quality and Standardization Issues:

Another critical gap relates to the lack of methodological consistency and standardization in PGHD collection and reporting – PROMs are mostly standardized and validated, but for PREMs and PPIs this is still lacking. The studies examined demonstrate a wide variety of data capture instruments, differing in structure, scale, and validation status. Even when similar constructs are measured-for instance, pain, fatigue, or physical functioning-the underlying tools, response formats, and scoring methods are often incompatible, making it difficult to compare results across studies or to synthesize data in meta-analyses. In addition, many studies do not provide sufficient metadata to contextualize the data, such as details about timing, collection mode, population characteristics, or instrument calibration. This inconsistency introduces variability and uncertainty that undermine the reliability and reproducibility of PGHD-based evidence.

While initiatives to provide standards and guide PREM use are ongoing (see for example Committee for Medicinal Products for Human Use (CHMP), 2022; International Conference on Harmonization, 2021; Pharmacovigilance Risk Assessment Committee (PRAC), 2025), the absence of harmonized standards also poses challenges for data reuse and integration within larger data infrastructures. Without agreed-upon definitions of data elements, terminologies, and quality criteria, the interoperability of PGHD across platforms, institutions, and countries remains limited. This situation contrasts sharply with the growing expectations for FAIR data management in health research, which emphasizes the importance of findability, accessibility, interoperability, and reusability. The heterogeneity observed in the literature suggests that PGHD collection has evolved in a fragmented manner, often driven by local initiatives, disease-specific studies, or proprietary technologies, rather than by coordinated methodological frameworks. Establishing a shared set of common data elements, validated instruments, and quality control protocols is therefore a fundamental prerequisite for ensuring that PGHD can be systematically integrated into the broader ecosystem of real-world data and used to support large-scale analytics, policy evaluation, and clinical decision support.

Limited Integration with Clinical and RWD Sources:

A further major limitation identified through the analysis concerns the insufficient integration of PGHD with clinical and other real-world data sources. The majority of studies treat PGHD as stand-alone datasets, collected independently from electronic health records, imaging data, laboratory results, or administrative registries. As a result, the potential value of PGHD in providing contextualized, multidimensional insights into patient health is largely underutilized. When patient-reported information is not linked with objective clinical parameters, it becomes difficult to interpret whether subjective improvements correspond to measurable clinical outcomes, or how self-reported symptoms relate to disease progression and treatment response. This isolation limits the scope of analysis and constrains the capacity to develop predictive models or comprehensive health profiles that combine biological, clinical, and experiential dimensions.

The lack of integration stems from both technical and organizational barriers. On the technical side, data heterogeneity, incompatible formats, and the absence of shared interoperability standards

impede seamless linkage between PGHD and institutional datasets. Organizationally, siloed data governance structures, differing consent procedures, and unclear data ownership often restrict the possibility of data sharing across systems. Moreover, many PGHD sources-particularly those generated through mobile apps or wearable devices-are hosted by private vendors, raising additional concerns regarding data accessibility and long-term preservation. Overcoming these challenges will require the establishment of interoperable infrastructures and governance frameworks that promote safe and meaningful data exchange. Integrating PGHD with clinical and RWD sources will not only enhance the analytical power of the IMPROVE framework but also facilitate more holistic and person-centered healthcare research, where clinical outcomes can be evaluated alongside patient experiences and behaviours captured in real time.

5.3 Disease-Specific Gaps

Table 8 provides a concise overview of the main gaps identified in the use and availability of PGHD across the disease areas studied in the IMPROVE project, together with corresponding implications for ongoing and future work in WP4 and WP5. It shows that while some conditions such as Breast Cancer, Heart Failure, and Multiple Sclerosis already have a substantial evidence base, the data are often uneven in scope, typically strong in PROMs but weak in PREMs, PPIs, or longitudinal coverage. Other areas, including Atrial Fibrillation, Aortic Stenosis, Macular Degeneration, and Chronic Rhinosinusitis, demonstrate clear data scarcity, with few studies and limited standardization.

The implications column translates these findings into actionable priorities for WP4 and WP5. These include expanding data collection to underrepresented diseases and regions, developing standardized PROM and PREM instruments, improving linkage with EHR systems, and establishing new RWD pipelines through partner networks. Overall, the table highlights where targeted data enrichment and methodological harmonization will be required to strengthen the IMPROVE framework and ensure balanced representation across disease areas.

Table 8 Overview of Main Gaps and their Implications for WP4/5

DISEASE AREA	MAIN GAPS IDENTIFIED	IMPLICATIONS FOR WP4 / WP5
BREAST CANCER	High PROM coverage, limited PREMs/PPIs; limited non-Western data	Expand experience-focused instruments; incorporate data from EU cohorts
CERVICAL CANCER	Very low number of studies; missing longitudinal PGHD	Develop new data collection protocol and partner registry inclusion
HEAD & NECK CANCER	Fragmented PROMs; missing standardization	Harmonize PROM tools and align with EHR outcomes
PROSTATE CANCER	Poor PREM representation; minimal PPIs	Integrate patient experience data into future use cases

MULTIPLE SCLEROSIS	Strong PROM base; lack of continuous PGHD over treatment	Design longitudinal PGHD pipelines via digital tools
HEART FAILURE	Large evidence base, but poor pre-treatment data capture	Enhance early-stage PGHD and symptom monitoring integration
ATRIAL FIBRILLATION / AORTIC STENOSIS	Severe lack of PGHD data	Collect new RWD through partner networks (e.g., ARSS, UDUS)
MACULAR DEGENERATION	Minimal data and missing country information	Targeted data extraction and validation needed
CHRONIC RHINOSINUSITIS	Sparse PGHD; minimal standardization	Develop core data collection framework and PROM validation

5.4 Methodological and Structural Gaps

A number of methodological and structural challenges were identified during the analysis, each of which poses significant constraints on the efficient use, interoperability, and scalability of Patient-Generated Health Data (PGHD) within real-world healthcare and research settings.

Data Fragmentation:

One of the most persistent obstacles is the high degree of fragmentation across existing PGHD sources. Data is often collected within individual projects, institutions, or proprietary digital platforms without mechanisms for long-term preservation, standardization, or interoperability. This isolation makes it difficult to integrate datasets across diseases, populations, or healthcare systems, thus preventing large-scale analyses and comparative studies. The lack of centralized repositories or FAIR-compliant infrastructures severely restricts data discoverability and reuse. Moreover, differences in data models, variable definitions, and formats create inconsistencies that undermine the capacity to perform cross-disease comparisons or longitudinal assessments. Without unified data management frameworks, valuable information risks remain siloed within local contexts, reducing its impact on evidence generation and health system learning.

Ethical and Governance Barriers:

Beyond technical issues, ethical and governance challenges remain a significant limitation for the wider adoption and secondary use of PGHD. Variability in national and institutional consent procedures, differences in data ownership interpretations, and inconsistent application of data protection regulations (such as GDPR) often hinder the sharing and integration of patient-contributed information. Many existing PGHD initiatives operate within closed systems that lack clear governance mechanisms for cross-border or multi-institutional collaboration. This creates uncertainty regarding the legal and ethical responsibilities of data controllers, particularly when combining patient-reported information with clinical or administrative datasets. Furthermore, the absence of transparent communication and feedback mechanisms can erode trust among patients, discouraging sustained participation in PGHD collection. Addressing these governance issues is therefore critical to ensuring

ethical integrity, regulatory compliance, and societal acceptance of data-driven healthcare frameworks.

Technical Limitations:

Technical barriers further constrain the potential of PGHD to contribute meaningfully to real-world data ecosystems. A lack of interoperability between patient-facing applications, clinical information systems, and research databases limits seamless data exchange and contextual integration. Many PGHD sources rely on proprietary technologies or non-standard data formats that are incompatible with common data models such as Observational Medical Outcomes Partnership (OMOP) or interoperability standards such as Fast Healthcare Interoperability Resources (FHIR). This heterogeneity not only increases the burden of data cleaning and transformation but also introduces risks of information loss or distortion during integration. Additionally, disparities in data quality, device calibration, and data transmission protocols further complicate harmonization efforts. Overcoming these limitations will require the adoption of common technical standards, open interfaces, and modular architectures that allow PGHD to flow securely and efficiently between systems, ensuring that patient-generated information can be used alongside clinical and administrative data to produce more comprehensive insights into health outcomes.

5.5 Recommendations and Next Steps

Building upon the insights derived from the gap analysis, a series of targeted recommendations has been formulated to guide the next phase of the IMPROVE project and to ensure the development of a sustainable, interoperable, and scientifically rigorous data ecosystem.

The first priority is to establish a comprehensive data harmonization framework under WP4, defining a unified set of principles and technical specifications for integrating PGHD with other forms of RWD. This framework should include the definition of common data elements, controlled vocabularies, and standardized metadata structures that enable consistent data capture and facilitate interoperability across sites and disease areas. In parallel, it should address data governance and access policies to ensure that all data processing activities remain compliant with ethical and legal standards while promoting data reusability and transparency.

Secondly, it is essential to prioritize new data collection efforts in underrepresented diseases and regions, particularly those identified in this analysis as having scarce or fragmented evidence. Expanding the geographical and clinical diversity of PGHD will improve the generalizability and inclusiveness of the IMPROVE framework. Collaboration with partner institutions, registries, and regional health systems should be encouraged to ensure that data collection reflects a wide spectrum of healthcare realities, technological capacities, and patient experiences.

A further key action involves the implementation of robust quality assurance procedures for PGHD integration, including mechanisms to assess data provenance, completeness, and reliability. Metadata documentation must be systematically embedded within all datasets to ensure transparency in data lineage and to support reproducibility of analytical processes. Establishing these procedures early in

the project will allow for ongoing monitoring of data quality and facilitate future updates or validation exercises.

In addition, future use case designs under WP5 should be strategically aligned with the findings of the gap analysis. Each use case should explicitly address one or more of the identified weaknesses, whether related to temporal data gaps, missing experiential dimensions, or lack of integration with clinical data, and test how different PGHD inclusion mechanisms can fill these voids in practice. This approach will ensure that the IMPROVE framework is iteratively validated and refined under real-world conditions, bridging the gap between theoretical modelling and clinical application.

Finally, the continuous analysis and iterative updating of the screening database remain critical to maintaining an up-to-date overview of the evolving PGHD evidence base. As additional studies are processed and new data become available, these updates will be reflected in Deliverable V2 and subsequent project outputs. This living approach will allow the consortium to dynamically adjust its priorities and strategies, ensuring that the IMPROVE project remains responsive to scientific progress, technological innovations, and the changing landscape of data-driven healthcare research.

6. Discussion

The Knowledge Warehouse updated described above serves as a pivotal resource for bridging existing evidence gaps, refining the relevance and precision of insights, and accelerating the development of actionable use cases. This comprehensive approach underscores the critical importance of methodical and evidence-based strategies in fostering innovation and addressing the multifaceted challenges inherent in healthcare delivery, especially considering only a very limited number of studies have focused on PREMs and PROMs. By systematically identifying and analysing recently published systematic reviews and meta-analyses, we have been able to construct a detailed and holistic overview of the current evidence regarding the use of various types of PGHD. This spans their integration across multiple disease areas, the stages of the patient journey, and their implications for value-based healthcare. These findings lay the groundwork for subsequent steps, including the development of the IMPROVE lab, coordination of data collection in WP4 and WP5, and the creation of guidelines and best practices in WP7. In what follows we discuss how the “Next Steps” laid out in D2.1 have been implemented and summarize the future systematic-review related tasks in WP2.

6.1. Finalization of Next Steps Laid Out in D2.1

Below we summarize the progress made on the five points that constituted the roadmap in D2.1. We have already discussed one of the five “next steps” originally laid out in D2.1, namely “*AI Model Testing*”, which is covered in section 2.2. We thus turn to the remaining steps, namely “*Screening Software Enhancement*”, “*Individual Study Screening*”, “*PGHD Definition*”, and “*Data Extraction*”.

Screening Software Enhancement: Based on the insights gained from the initial Screenathon Review conducted for IMPROVE, crowdscreening has been added as a functionality to ASReview V2 in the form of a multiagent, multiexpert architecture (de Bruin et al., 2025). As planned, this system automates

database management, strategically distributing records across screeners withing an active-learning framework. In this implementation, a central task server assigns the highest-ranked unlabeled records to available screeners. Each screener acts as an oracle, providing labels that are continuously integrated into the shared AI model. Because the system retains and re-ranks records asynchronously whenever new labelling decisions are made, updates occur in real time and without interrupting the screening workflow. Thus, ASReview V2 enables collaborative model training across screeners whilst maintaining consistency in labeling decisions and reducing manual oversight in managing the screening pool – two key improvements in comparison with the initial iteration of the Screenathon Review where active learning was not used and record-batches were assigned to screeners manually. Additionally, for the update we used the new default ML model (u4), which ships with ASReview V2 and has demonstrated a 24.1% reduction in loss over the previous default model (de Bruin et al., 2025) on the SYNERGY dataset (De Bruin et al., 2023), a widely used benchmark for machine learning-assisted systematic review software. This dataset covers a wide range of systematic reviews, including the ones from the health domain. However, to test whether the model also works for the IMPROVE data, we tested its performance using the data from the first version of the **K**nowledge **W**arehouse. This analysis is based on the dataset manually screened during the first Screenathon Review (Westerbeek & van de Schoot, 2025). It shows that on average, screeners using u4, as opposed to the previous default model (u3), would only have had to screen less than half the number of papers until all the relevant papers have been identified (Monschau et al., 2025). The new features and careful model choice enable a more scalable, transparent and efficient version of crowdsourced screening, which is expected to substantially reduce review time whilst preserving accuracy and reproducibility in the yearly update process.

Individual Study Screening: The current, as well as future Knowledge Warehouse updates will take systematic reviews into account.

PGHD Definition: A detailed research plan has been developed regarding this step which is explained in detail in section 6.1.1. below.

Data Extraction: The data extraction of relevant systematic reviews identified in WP2 has been finalized. Data from the records identified during the first Screenathon Review have been extracted and form the basis of the Knowledge Warehouse. The records identified in the second, adapted Screenathon Review have undergone data extraction with the help of content experts, ensuring that empirical evidence and use case development continue to be aligned. Table 9 summarizes the progress made on the five "next steps" from D2.1.

Table 9 Overview of Progress on "Next Steps" from D2.1.

"Next Step" from D2.1	Description	Progress
AI Model Testing	Run simulations to see which ASReview model is best for screening of IMPROVE papers	U4 model from ASReview V2 best compromise of speed and accuracy based on simulations

Screening Software Enhancement	Improve ASReview based on feedback from Screenathon and enable crowdscreening	Crowdescreening implemented in ASReview V2; administrator dashboard simplifies paper assignment
PGHD Definition	Use LLMs to understand how PGHD is defined and used in the literature	Developed research plan which leverages NLP and LLMs to automate parts of the analysis
Individual Study Screening	Identify and screen individual studies	Knowledge Warehouse comprised of individual systematic reviews and meta-analyses
Data Extraction	Extract detailed data for further analysis and synthesis	Extraction reported in D2.1 finished; extraction based on Screenahton 2 in progress

6.2. Next Steps

There are three concrete next steps which will be carried out in the context of WP2 that will ensure that the project continues to be based in state-of-the-art research and using a clear conceptualization of PGHD. These include 1) the yearly updating of the Knowledge Warehouse, 2) the execution of the outlined research plan for better understanding of what constitutes PGHD in the literature and 3) organizing a feedback moment for use-case leaders to give input on the Knowledge Warehouse from the perspective of particular pathologies. Below we describe a detailed research plan for achieving 2). Regarding 3), interviews will be conducted with use-case leaders to ensure that the reviews contained in the Knowledge Warehouse cover relevant aspects of the implementation of PGHD in their area of expertise. Together with the gap analyses, these measures will provide a better answer on how PGHD can inform enhancing treatment selection (advancing the role of patient preferences and experiences in choosing treatments, thereby personalizing healthcare to meet individual needs more effectively), the 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) and accelerating market entry (by speeding up the introduction of patient-centric and cost-effective advanced integrated care solutions, thus enhancing the accessibility of innovative treatments), especially in the disease areas that are central to IMPROVE.

6.2.1 Understanding PGHD

While the importance of PGHD in advancing healthcare is increasingly acknowledged, there remains no clear agreement on what constitutes PGHD or how it should be used. To address this gap, we aim to examine how PGHD is defined and applied across the papers included in our evidence database. However, given the large volume of literature, manual inspection of all papers would be both time-consuming and error-prone. To overcome these challenges, we will leverage recent advances in natural language processing (NLP) and generative AI-particularly large language models (LLMs)-to automate

parts of the analysis. We have outlined the following research plan to be carried out over the coming months, specifically it is projected to be finished by April 2026.

Part 1. Understanding how PGHD is defined

Our first goal is to investigate how PGHD is defined and discussed in academic literature. Starting from a position of minimal prior assumptions, we will focus on papers that explicitly mention the term "PGHD" and extract their definitions. This will allow us to synthesize a comprehensive, up-to-date understanding of how PGHD is conceptualized across studies.

Part 2. Mapping the facets of PGHD

Building on the synthesized definition, we will explore how fine-grained facets of PGHD-such as actors, contexts, data types, purposes, and quality-are represented across disease areas. To give a hypothetical example, in cardiovascular research, PGHD may primarily involve wearable or sensor-based data, whereas in oncology it may largely refer to self-reported measures such as life satisfaction questionnaires.

General Analysis Framework

To carry out both parts of the research plan, we will follow the following analysis framework:

1. **Corpus extraction.**
   Academic papers will be converted from PDF to Markdown format to facilitate text analysis using LLMs.
2. **LLM validation.**
   We will assess whether our chosen LLM can accurately extract information from papers by validating its outputs against manually curated metadata (e.g., sponsorship source, country, databases, number of studies analyzed, type of review, search scope, population, clinical domain, effect sizes, PGHD type, and phase of data collection). This step serves as a proxy for evaluating the model's suitability for understanding PGHD-related content.
3. **PGHD definition.**
   a. *Context retrieval:* We will use rule-based keyword filtering to identify paragraphs relevant to PGHD, supplemented by LLM-assisted refinement for improved precision.
   b. *LLM analysis:* Using the retrieved contexts, the LLM will extract and summarize definitions of PGHD, enabling us to derive an overarching, synthesized definition that captures the range of uses across the literature.
4. **PGHD facets extraction.**
   a. *Keyword updating:* Based on the synthesized PGHD definition, we will refine the list of relevant keywords.
   b. *Context retrieval:* We will again identify PGHD-relevant text segments using the updated keywords and LLM-based filtering.
   c. *Facet definition:* We will classify PGHD according to several analytical facets such as:
      i. **Actors** (e.g., patients, caregivers, devices, portals)
      ii. **Contexts** (e.g., home vs. clinical setting, continuous vs. episodic reporting)

iii. **Data types** (e.g., symptom diaries, PROMs, wearable/sensor data, photos, social media)
iv. **Integration** (e.g., EHR-linked, standalone, app-based)
v. **Purpose** (e.g., clinical care, self-management, research, quality improvement, engagement)
vi. **Governance and quality** (e.g., ownership, consent, interoperability, reliability)

d. *Analysis:* We will analyse how these facets vary across articles and disease domains.

5. **Data analysis and visualization.**
Finally, we will quantify and visualize the distribution of PGHD definitions and facets across disease areas, highlighting patterns and gaps in the literature.

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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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