Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Supporting clinicians in the decision of including or excluding PGHD for the clinical decision process.

A THESIS SUBMITTED TO
TRINITY COLLEGE, THE
UNIVERSITY OF DUBLIN
IN FULFILLMENT OF THE REQUIREMENTS OF THE DEGREE OF
DOCTOR OF PHILOSOPHY

Alfredo Ormazabal

17th of January 2025

Supervised by Lucy Hederman and Damon Berry

Declaration

I declare that this thesis has not been submitted as an exercise for a degree at this or any other university and it is entirely my own work.

I agree to deposit this thesis in the University's open access institutional repository or allow the library to do so on my behalf, subject to Irish Copyright Legislation and Trinity College Library conditions of use and acknowledgement.

I consent to the examiner retaining a copy of the thesis beyond the examining period, should so they wish (EU GDPR May 2018).

Signed:  Date: ___27/09/2024_____

Summary

This thesis addresses clinician trust in Patient-Generated Health Data (PGHD) and its impact on clinical decision-making. Despite its potential, PGHD adoption is limited due to concerns about data quality, governance, and reliability. To support clinicians, this research developed the PGHD Trust Canvas, a decision-support tool that guides the evaluation of PGHD based on factors like quality and risk. Validation shows the tool is most effective in non-urgent care settings. The thesis offers a practical solution to enhance the integration of PGHD in healthcare and informs future policy and standards development.

Abstract

The integration of Patient-Generated Health Data (PGHD) into clinical decision-making holds immense potential for enhancing personalized healthcare. However, trust remains a critical barrier to its widespread adoption by clinicians. This thesis addresses the fundamental question of how clinicians can be assisted in deciding whether to trust or distrust PGHD in clinical workflows. Through a multi-phased approach, which includes a comprehensive literature review, interviews with clinicians, and a co-development process, this research investigates the factors that influence clinician trust in PGHD and presents a solution in the form of a decision-support tool: the PGHD Trust Canvas.

The study begins by reviewing the state of the art on clinician trust in PGHD, examining the complexities of PGHD data, such as its variability in quality and provenance, and the inherent challenges clinicians face when interpreting this data. The review highlights the lack of standardized frameworks for evaluating PGHD, which contributes to clinician skepticism about its reliability and actionability. Factors such as governance, data quality, and the potential risks associated with clinical decision-making based on PGHD are analyzed in-depth, leading to the identification of key issues that need to be addressed.

Through a series of qualitative interviews with clinicians, this research identifies the core factors that shape clinician trust in PGHD. These include the source and quality of the data, the context in which the data is used, and the level of risk involved in clinical decisions. The findings reveal that while PGHD can provide valuable insights, its integration into clinical workflows is hindered by concerns over governance, liability, and the lack of clear standards for data validation. Clinicians are particularly wary of relying on PGHD in high-risk clinical scenarios due to the variability and potential inaccuracies of the data.

In response to these challenges, the PGHD Trust Canvas was developed in close collaboration with clinicians. This decision-support tool provides a structured framework that guides healthcare professionals through the process of evaluating PGHD across multiple dimensions, including data quality, provenance, risk, and governance. Inspired by models such as the Business Model Canvas, the Ethics Canvas, and the Trust Canvas, the PGHD Trust Canvas offers a practical solution to help clinicians make informed decisions about whether to trust or distrust PGHD in their clinical practice.

The validation of the PGHD Trust Canvas was conducted through qualitative interviews with a new group of clinicians, who evaluated its usability and usefulness in clinical settings. The results of this validation study demonstrate that the tool is particularly valuable in non-urgent care settings, such as nursing homes, where clinicians have more time to assess data. In these environments, the PGHD Trust Canvas provides clarity and confidence in decision-making, helping to improve patient outcomes by reducing the risk of relying on untrustworthy data. However, the tool's effectiveness is limited in high-pressure environments, where quick decision-making is required. The research also highlights the tool’s potential as an educational resource, supporting the training of clinicians in the use of PGHD.

This thesis describes a significant contribution to the field of digital health by providing a structured, practical tool to assist clinicians in the decision-making process regarding PGHD. The PGHD Trust Canvas addresses the critical trust issues that currently hinder the integration of PGHD into clinical practice and offers a solution that can improve patient safety and clinical outcomes. Additionally, the study provides valuable insights into the governance, policy, and

training implications of PGHD, paving the way for future research and the development of standardized frameworks for its use in healthcare.

Table of contents

Table of figures

Table of tables

Acknowledgement

SFI's D-real:

This work was conducted with the financial support of the Science Foundation Ireland Centre for Research Training in Digitally-Enhanced Reality (d-real) under Grant No. 18/CRT/6224. For the purpose of Open Access, the author has applied a CC BY public copyright licence to any Author Accepted Manuscript version arising from this submission.

ADAPT centre:

This research was conducted with the financial support of Science Foundation Ireland under Grant Agreement No. 18/CRT/6224 at the ADAPT SFI Research Centre at Trinity College Dublin. The ADAPT SFI Centre for Digital Media Technology is funded by Science Foundation Ireland through the SFI Research Centres Programme and is co-funded under the European Regional Development Fund (ERDF) through Grant No. 13/RC/2106.

First and foremost, I would like to express my deepest gratitude to my supervisors, Lucy Hederman and Damon Berry, whose unwavering support and guidance made this thesis possible. Their invaluable insights and vast experience carried me through even the most challenging moments, both personally and academically, and for that, I am eternally grateful.
I extend my sincere thanks to the clinicians who generously shared their time and expertise. Their willingness to teach me what seemed second nature to them made this research achievable, and without their contributions, this thesis would not have been possible.
To my immediate and extended family—especially Elena and Ivan—I owe endless thanks for their patience and understanding. There were many moments when my attention was elsewhere, and your love and support carried me through.
Finally, I want to acknowledge my friend James, whose steadfast presence proved invaluable when I needed it most, and to Magally, who reminded me of my true worth, far beyond what I give to others. Thank you all.

Chapter 1. Introduction

As the healthcare landscape undergoes a transformative shift, driven by technological innovation and the emergence of Patient-Generated Health Data (PGHD), this introductory chapter sets the stage for the thesis. It begins with an Overview in Section 1.1, where the potential and challenges of integrating PGHD into healthcare practices are explored. Following this, Section 1.2 presents the Research Question, articulating the central inquiry of the thesis.

Section 1.3, introduces the hypothesis, suggesting that a decision-support tool will assist clinicians in making more informed decisions regarding the trustworthiness of PGHD. The Objectives of the thesis are outlined in Section 1.4, detailing the goals of reviewing the state of the art, identifying key factors affecting clinician trust in PGHD, developing a decision-support tool, and validating its usefulness.

Section 1.5 presents the approach taken, which includes a comprehensive literature review, qualitative interviews with clinicians, and a co-development process for creating and validating the PGHD Trust Canvas—a tool designed to help clinicians assess the trustworthiness of PGHD.

In Section 1.6, the thesis contributions are highlighted. The major contribution is the development of the PGHD trust canvas, a structured tool for assisting clinicians in evaluating PGHD across key dimensions such as data quality, provenance, and risk. The minor contribution includes the knowledge gained from the qualitative study on clinician perspectives, particularly the factors influencing trust and the barriers to PGHD adoption.

Section 1.7 lists the Publications arising from this thesis, which include papers presented at 2023 and 2024 IEEE international symposiums on computer-based medical systems. These publications focus on the clinician perspective on PGHD and the development of the PGHD Trust Canvas. Finally, Section 1.8 provides an overview of the thesis, summarizing the structure of the research.

1.1 Overview

Patient-Generated Health Data refers to health-related information created, recorded, gathered, or inferred by patients or their designees -such as family members or caregivers- outside of the traditional clinical environment (Shapiro *et al.*, 2012). This data can include a wide range of information such as:

- Biometric data: Measurements like blood pressure, glucose levels, heart rate, and weight.
- Symptoms tracking: Details about symptoms experienced over time.
- Treatment history: Information on medications taken, therapy sessions, and other treatments.
- Lifestyle data: Inputs on daily activities, dietary habits, exercise, sleep patterns, and other behaviors that impact health.
- Wellness data: Information that reflects the patient's mental and emotional health, such as mood logs and stress levels.

The above list is by no means exhaustive and serves as a synthesis from general knowledge. Chapter 2 delves deeper into these concepts, along with the difficulties in scope and definition. Furthermore, the boundaries between these classifications are not well defined, particularly when vendors self-define the type of data their technologies claim to gather. For example, Google’s Pixel smartwatches include features like 'Stress management,' where they

commercially claim that users can 'check for signs of stress' by identifying 'possible signs of stress' and 'look back on your day or week to discover patterns.' These claims appear deliberately vague, potentially due to the weak evidence behind them. Although not clarified on their website—which contributes to clinicians' skepticism—these technologies use Heart Rate Variability (HRV) to infer stress levels. However, some studies highlight the limitations and complexities of using HRV as a reliable standalone measure of stress (Billman, 2011). This ambiguity and variability in data quality underscore the complexity of PGHD, influenced by the heterogeneous sources and methods of data collection.

The idea of patients generating their own data has been mostly welcomed by the healthcare community. The incorporation of PGHD into the patient's electronic healthcare record (EHR) promises benefits to quality of care by allowing providers access to the patients' preferences and goals (Berry, 2011), by allowing clinicians to use their time more efficiently through a relationship of partnership with the patient (Ferguson, 2000), by allowing doctors access to better reports of quality of life (Slevin *et al.*, 1988), and many more ways. Research in areas of medicine like in the self-management of diabetes, clearly supports the incorporation of PGHD solutions (Greenwood *et al.*, 2017) to their practice. The advent of mobile health applications, wearable devices with possible medical capabilities and an obvious interest on behalf of tech companies to disrupt healthcare, make PGHD increasingly available. It is imperative that the uses, benefits, barriers, risks, etc. of PGHD in clinical decision making is researched.

However, adoption into clinical decision making continues to be an issue (Demiris *et al.*, 2019) . Although practitioners of various disciplines manifest themselves interested in their patients to actively generate their data, they are concerned about the way it is presented and the impact it may have in their workflow (Huba and Zhang, 2012). Further concerns include the limited knowledge of whether the information that the patient is willing to generate aligns with the purposes of the clinical process (Jacobs, Clawson and Mynatt, 2015) and whether the needs and expectations of patients and physicians diverge, particularly in the timing and actionability of PGHD by providers.

Another reason why the inclusion of PGHD is met with resistance is related to workflow (Nundy *et al.*, 2014). A typical clinician can only avail of a short period of time to see the patient and can only take in a limited amount of information. Adding irrelevant or unreliable information to their computer screens could potentially distract them from seeing what they should see. Ideally, the only information presented to the clinician at the time of making decisions should meet a minimum level of quality as stipulated by, for example in Ireland, the Health Information Quality Authority (HIQA)'s dimensions of data quality: relevance, accuracy, reliability, timeliness, punctuality, coherence, comparability, accessibility, and clarity (European Statistical System, 2011; Canadian Institute for Health Information, 2017; HIQA, 2018).

Despite the proliferation of devices that generate PGHD (Carroll *et al.*, 2017; Lai *et al.*, 2017; O'Rourke, 2017), the desire of many patients to include their data into their health records (Reading and Merrill, 2018), and the achievements some companies have made in mobile health apps (Miyaji *et al.*, 2020; Wattanapisit *et al.*, 2020), a veil of scepticism, or at least caution, seems to linger among healthcare providers (Tarassenko and Greenhalgh, 2020). This can be expected, since the quality and provenance of the information coming from these technologies seems impossible to verify and control PGHD (Magrabi *et al.*, 2019), and making clinical decisions heavily based on under such uncertainties would introduce an unacceptable level of risk to the patient safety.

The caution on behalf of clinicians is further justified by PGHD's variability and inconsistencies in the very nature of the data itself. When the PGHD patterns don't clearly correlate with disease mechanisms, clinicians find it difficult to confidently use it in clinical decisions. According to Adozo et al. (2020), when encountering these situations, experts consistently made the distinction between clinical, health and wellbeing data. When considering data like step counters, or sleep patterns, the variability between different sources in data was aceptable for the purposes of individual empowerment and wellbeing. The same variability of data became problematic when dealing with measurements of a more clinical nature, like blood glucose levels. Acting on these data is viewed as inconsistent with patient safety due to the risk of harm of an intervention such as the use of insulin.

A major difficulty in the decision making process is that real world decisions, particularly in healthcare, are limited by bounded rationality (Simon, 1979; Bate *et al.*, 2012) , where decisions are taken under the acknowledgement that the information used to make them is incomplete and imperfect. This puts the topic of trust in a prominent place for the clinician. Furthermore, there seems to be a correlation between usability of a system and trustworthiness. According to Acemyan and P. Kortum (2012), more usable systems are also more trusted systems. In terms of trusting data, much of the literature surrounds trust in data for research purposes (Wallis *et al.*, 2007), rather than in decision-making. The medical field understands the trust-usability correlation in the context of adoption of technologies on behalf of the patient (Or and Tao, 2012; Gagnon *et al.*, 2016; Cresswell *et al.*, 2017), yet clinicians have been found to often resist technology.

Causing a compounding effect, the issues of liability and actionability (Fiore-Gartland and Neff, 2015; Schroeder *et al.*, 2017; Andersen *et al.*, 2018; Jim *et al.*, 2020) also present a problem to even consider incorporating PGHD into the clinical decision process. Clinicians are not necessarily trained to deal with the types of information that PGHD provides, and very little is known about clinicians' trust in PGHD, or their trust in the patient at all (Papautsky and Panganiban, 2018). Clinicians also find it unsettling that there are no ethical or medico-legal frameworks to guide them to deal with the deluge of data that potentially could come from their patients (Tiase, 2017). They simply don't know their liability when using PGHD for clinical decisions, nor do they know their liability should they ignore it.

Another major difficulty encountered is the lack of standardization and guidelines when designing PGHD-generating technologies. Risk-based guidelines like the ones that regulate medical devices (HPRA, 2017) seem insufficient when trying to decide whether PGHD data is trustworthy or if it should be trusted. In their white paper, Emmott et al. (Emmott *et al.*, 2024) argue that while existing medical device regulations frameworks are foundational, they may not adequately address the specific needs of PGHD. The paper emphasizes the importance of developing a "fit-for-purpose" framework that evolves with technological advancements and ensures the relevance, reliability, and quality of PGHD.

Lack of guidance not only limits what clinicians should do with PGHD. Vendors of technologies that create PGHD are also lacking sufficient standards, tools, and frameworks to design technologies that create trustworthy PGHD. Cresswell et al. (Cresswell *et al.*, 2018) recommend that priority is given to "collaboration across stakeholder groups to create tools that work for all" among their 5 priorities. We believe that part of having a "tool" that works for clinicians is to have a tool that can be trusted.

Comparable barriers to the introduction of a digital technology into the medical field have been encountered before; a particularly contentious example is that of the introduction the introduction of Electronic Health Records (EHR) to healthcare systems. Proponents of the use of PGHD in clinical care can learn from these experiences in the past, where efforts were placed in understanding provider trust in the technology to be implemented. In 2011, when efforts were placed in understanding acceptance of EHR systems by healthcare providers, Ortega Egea and Román Gonzáles (2010) extended Davis's Technology Acceptance Model (Davis, 1989) to include trust and risk related factors like institutional trust, perceived risk and information integrity.

Trust as a construct, is considered by many as natural and necessary for human cooperation across many disciplines and fields (Gambetta and Badcock, 1990). In enterprise modelling and knowledge management (Goranson *et al.*, 2003), in participative decision making (Kearney and Hays, 2019), etc. Particularly interesting have been the observations of Lawler (1995) where trust is cited as important for the implementation of self-managed work teams. Lawler emphasizes that trust is essential for enabling autonomy and collaboration within teams, as it fosters the confidence necessary for decentralized decision-making. Just as Lawler's high-involvement organizations depend on trust to empower individuals to manage tasks effectively, clinicians must trust the accuracy and relevance of PGHD to integrate it meaningfully into patient care.

The fact that the trust construct is used by so many, in so many contexts, with so many purposes rather than making it an established concept, it turns it in an almost organic concept with many mutations and strains. Diego Gambetta and Badcock's book (1990), perhaps the most common citation in the literature, almost comically titles his conclusion chapter "Can we Trust Trust?", revealing our linguistic dependency on the word to communicate its meaning.

In their proposal of an integrative model of trust, Mayer, Davis and David Schoorman (1995) concentrate on the concept from an interpersonal perspective, highlighting the characteristics of the trustee as a way to understand why the trustor may have a greater or lesser amount of trust on the trustee. The authors point out three characteristics of a trustee appearing in the literature at the time that affect trustworthiness: ability, benevolence, and integrity. Analysing person to person and organization to organization interactions, these characteristics of the trustee are easy to understand, since ability, benevolence and integrity are easily attributed to entities liable to culture like people and organizations. When analysing these dynamics from a person to organization or person to system, perhaps it requires some reconcilement with the concepts of quality and provenance.

Rather than advocating for the adoption of PGHD in the clinical decision-making process, research efforts are probably best made in the search for the right contextual conditions where PGHD is appropriate for clinical decisions, as well as the aspects that make PGHD trustworthy. Professor of philosophy, Baroness Onora O'Neill, questions whether more trust is positive (O'Neill, 2018). Even though she focuses on interpersonal trust, she argues that the rational decision would be to trust the trustworthy and distrust the untrustworthy. It is therefore the aim of this research to provide the tools for clinicians to achieve well directed trust on PGHD and also well directed distrust of it.

1.2 Research question

It has been widely accepted that PGHD holds untapped potential in clinical decision-making by providing real-time, continuous insights into a patient's health outside traditional clinical settings (Nazi, Newton and Armstrong, 2024). However, for PGHD to be effectively integrated into clinical

workflows, trust in the data becomes a crucial factor (Papautsky and Panganiban, 2018). Clinicians must feel confident in the quality, reliability, and relevance of the data before including it in their decision-making processes. Determining whether to trust or distrust PGHD involves evaluating several elements, such as the accuracy of the data, its source, and how it aligns with other clinical information. Since PGHD comes from a variety of digital devices and self-reported methods, which can vary widely in nature quality and form, providing clinicians with tools to guide their decision on whether to trust this data is essential. This research seeks to explore how clinicians can be assisted in this process, ensuring that PGHD is utilized effectively while safeguarding patient outcomes and supporting evidence-based care.

1.2.1 Research Question (RQ)

How can clinicians be assisted with the decision whether to trust or distrust PGHD in the context of clinical decision-making?

To answer the RQ, the following sub-research questions (SRQs) need to be addressed:

- SRQ1 What is the current state of the art (SOA) on clinician trust in PGHD ?
- SRQ2 How can healthcare providers evaluate the various sources and context of PGHD for its use in the clinical decision-making process?
- SRQ3 What type of decision support tool can be developed to support healthcare providers facing the decision whether to trust PGHD for its use in clinical decision-making process?
- SRQ4 Do clinicians find the tool developed useful to make the decision whether to trust or distrust PGHD?

1.3 Hypothesis

Central to this thesis is the hypothesis that a specialized tool has significant potential benefits for clinicians to assist in determining and deciding upon the trustworthiness of PGHD. This hypothesis stems from the recognition that PGHD, while being a valuable asset in healthcare, presents unique challenges in terms of its reliability and trustworthiness. The premise under investigation is:

"A decision-support tool will be useful for clinicians to make more informed decisions whether to trust or distrust PGHD for its use in the clinical decision-making process."

This hypothesis acknowledges the nuances of the challenging decisions clinicians face when considering PGHD in the clinical decision process and proposes a practical solution to address the trust challenges associated with its use. By introducing a tool that aids in the assessment of PGHD, the hypothesis suggests that clinicians can make more informed decisions about whether to trust or distrust PGHD, thereby enhancing the quality of patient care and improving clinical outcomes. The subsequent chapters of this thesis will explore the nature and trust challenges of PGHD from the clinicians' perspective, describe the development of a tool to help clinicians with these trust challenges, and provide a qualitative validation for such tool.

1.4 Objectives

The objectives of this thesis are tailored to address the sub-research questions and encompass a comprehensive review of existing literature, interviews with clinicians, the development of a relevant decision tool, and the validation of such tool from the clinicians' perspective. The below listed objectives directly address the sub-research questions in section 1.2.

O1. Review the state of the art on the topics of clinician trust in data focusing on:

a Understanding of PGHD and clinician trust, including quantification or trust.
b Identification within the literature and understanding of the main factors that affect clinician trust in PGHD.

O2. Identify and classify the key factors that, from the clinician's perspective affect the decision whether to include or exclude PGHD from their clinical decision process.

O3. To develop a tool to help clinicians with the decision whether to include or exclude PGHD from their clinical decision process.

O4. To establish the validity of the tool developed in the fulfilment of O3 for clinicians deciding whether to use PGHD as part of specific clinical decisions.

1.5 Approach

The approach taken to this research includes a rigorous literature review, semi-structured interviews with healthcare providers, co-development studies, and further interviews to assess the validity of the developed artifact. Each of these steps is crucial in building a comprehensive understanding of the role of PGHD in clinical decision-making and developing tools to aid clinicians in this process. See Figure 1.

A1 Literature review: A rigorous review of the literature established the state of the art of the topic of provider trust in PGHD. The review covered potential benefits, challenges and barriers to its use, the state of adoption of PGHD in clinical decision making, and the issues of trust for clinicians. Within the structure of this research, this approach is taken to accomplish O1 and SRQ1 and partially SRQ2 in section 1.2.

A2 First study: A series of semi-structured interviews with clinicians determined the requirements in terms of quality and provenance for PGHD to be used in the clinical decision-making process, based on the different levels of risk and uncertainty. Within the structure of this thesis, this approach is taken to accomplish O2 and SRQ2 in section 1.2.

A3 Second study: Based on the findings of A1 and A2, a co-development study created a tool to help clinicians reflect on the trustworthiness of PGHD. Within the structure of this thesis, this approach is taken to accomplish O3 and SRQ3 in section 1.2.

A4 Third study: A study to assess the usefulness and usability of the artifact developed in A3 was carried out using qualitative interview research. Within the structure of this thesis, this approach is taken to accomplish O4 and SRQ4 in section 1.2.

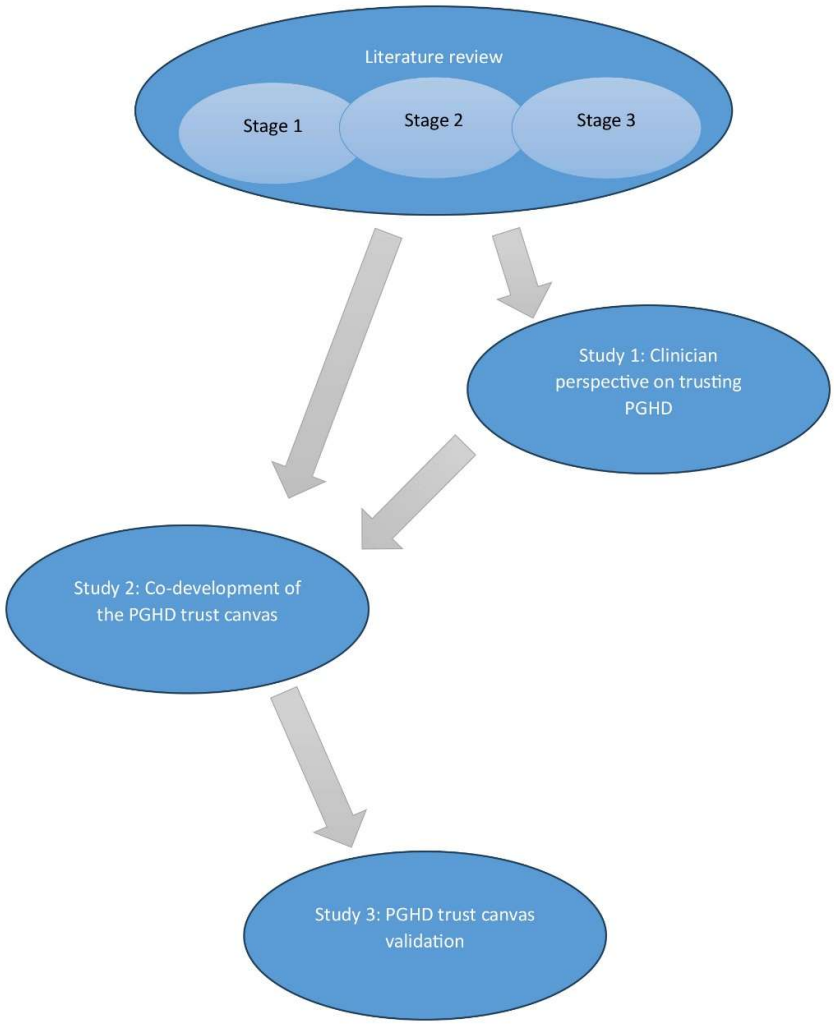


Figure 1 Graphical representation of the research studies

1.6 Thesis contributions

The major contribution of this thesis is the PGHD Trust Canvas, with its development described in Chapter 5 and its validation described in Chapter 6. A minor contribution is the in-depth knowledge gained from the study on the clinician perspective on trusting PGHD described in Chapter 4.

1.6.1 Major contribution

The PGHD Trust Canvas is a major contribution of this thesis, offering an innovative solution to the critical challenge of evaluating the trustworthiness of PGHD in clinical decision-making. Developed in close collaboration with clinicians, the tool provides a structured framework that helps healthcare professionals assess key factors such as data quality, source reliability, and clinical relevance. By guiding clinicians through these considerations, the PGHD Trust Canvas enhances confidence in decision-making and improves patient safety by reducing the risk of

relying on untrustworthy data. Its validation, through the perspectives and feedback of the clinicians who used it, ensures that the tool is practical, usable, and responsive to real-world clinical needs. Additionally, the development process culminated in a live, functional version of the tool, which is now available online at https://trustedhealthdata.web.app/canvas. As a result, the PGHD Trust Canvas serves as a key contribution of this thesis, addressing a pressing gap in healthcare by facilitating the integration of PGHD into clinical practice.

1.6.2 Minor contribution

A minor contribution of this thesis is the in-depth knowledge gained on the clinician perspective on trusting PGHD. This study contributes to scientific knowledge by addressing a significant gap in research on clinician trust in PGHD, which is underexplored despite the growing use of digital health technologies. By investigating factors such as data quality, provenance, and associated risks from the perspective of 13 clinicians, and identifying other factors such as necessity, this qualitative research provides critical insights into how PGHD can be trusted and integrated into clinical decision-making. The study reveals that while PGHD has potential, its adoption is hindered by a lack of clear governance, guidance, and clinician familiarity with the technology.

This research offers valuable contributions not only for developing policies, standards, and training but also for informing the design of electronic health record (EHR) systems and clinical decision-support tools. These insights help address specific challenges faced by clinicians when working with PGHD and can lead to the creation of tools and frameworks that better integrate PGHD into healthcare workflows. By contributing to the development of safer and more effective methods for integrating PGHD, this research opens new avenues for future studies, enhances the trust in digital health innovations, and supports the ongoing advancement of clinical practices.

1.7 Publications

Two publications resulted from this thesis:

- **2023 IEEE 36th International Symposium on Computer-Based Medical Systems (CBMS)**
  Clinician's perspective on trusting Patient Generated Health Data for use in clinical decision-making: A qualitative interview study
  This study, as a minor contribution to the overall thesis, focuses on clinician trust in PGHD and explores the factors that influence its integration into clinical decision-making. A qualitative research approach was employed, involving semi-structured interviews with 13 clinicians from various medical disciplines. The study identified key themes such as data quality, provenance, risk, and the need for governance and guidance, which significantly shape clinicians' willingness to trust and use PGHD. The findings highlight the challenges clinicians face when incorporating PGHD into their practice, such as a lack of formal guidelines and concerns about data accuracy. While this study contributes to a specific aspect of the broader thesis on clinician-patient data interactions, its insights are valuable for informing future developments in digital health policy and practice.
- **2024 IEEE 37th International Symposium on Computer-Based Medical Systems (CBMS)**
  Co-development of a tool to help clinicians decide upon the trustworthiness of Patient Generated Health Data
  This study describes the development of the major contribution to the thesis, focusing on the co-development of the PGHD Trust Canvas, a tool designed to help clinicians assess the trustworthiness of PGHD for use in clinical decision-making. Developed through an iterative process with input from nine clinicians across various healthcare disciplines, the PGHD Trust Canvas was inspired by models such as the Business Model Canvas, the Ethics Canvas, and the Trust Canvas. It provides a structured framework for evaluating key aspects of PGHD, including

clinical quality, provenance, risk, and governance. The tool aims to support clinicians in the decision whether to trust or distrust PGHD, by providing clarity and confidence of the clinicians' decision. While this study culminated in the creation of an advanced prototype of the PGHD Trust Canvas, it has also laid the groundwork for its validation through subsequent research, underscoring its potential to significantly advance the safe and effective use of PGHD in healthcare.

- **2024-2025 intended journal output in Digital Health Interventions for Universal Health Coverage from Oxford University Press.**
  Validation of a tool to help clinicians decide upon the trustworthiness of Patient Generated Health Data: A qualitative interview study
  The PGHD trust canvas validation study was conducted to evaluate the usability and perceived usefulness of a tool designed to help clinicians decide whether to trust or distrust PGHD in their clinical decision-making. This qualitative study involved 11 clinicians from various healthcare backgrounds, including nursing, physiotherapy, paramedics, and general practice. Through semi-structured interviews, participants provided insights into the tool's effectiveness in guiding their assessment of PGHD across critical areas such as data quality, origin, and relevance. The study found that clinicians appreciated the structured approach of the PGHD Trust Canvas, particularly its potential in non-urgent care settings like nursing homes, where decisions are made more thoughtfully and less frequently. The tool also showed promise in documenting and reflecting clinicians' thought processes, serving as a valuable educational resource for training new clinicians. Despite some limitations in time-sensitive environments, the study demonstrated that the PGHD Trust Canvas could play an essential role in improving trust in PGHD and enhancing clinical decision-making.

1.8 Overview of the thesis

This thesis addresses the growing significance of PGHD in clinical decision-making and the challenges clinicians face in trusting or distrusting PGHD. The study not only explores the nature of PGHD, the barriers to its adoption, and the trust factors that clinicians must navigate, but it also provides a detailed account of the development of a tool—the PGHD Trust Canvas—to address these issues. This decision-support tool assists clinicians in making well-directed trust or distrust decisions regarding PGHD in clinical workflows, ultimately aiming to improve patient outcomes.

The research is structured across several key chapters:

- **Chapter 1** introduces the research topic, presenting the central research question: How can clinicians be assisted in deciding whether to trust or distrust PGHD for clinical decision-making? It outlines the objectives, which include reviewing the state of the art, identifying key factors influencing trust in PGHD, developing a decision-support tool, and validating its usefulness.

- **Chapter 2** provides a comprehensive literature review, discussing the definition of PGHD and its diverse sources, the complexities involved in its use, and the challenges clinicians face when integrating it into clinical workflows. This chapter also introduces the concept of trust, examining its role in clinical practice and the factors that influence clinicians' trust in PGHD, such as data quality, provenance, and risk.

- **Chapter 3** details the methodological approach of the research, justifying the use of qualitative methods, particularly grounded theory. The chapter explains the rationale for using semi-structured interviews and co-development techniques to gain deep insights into clinicians' perspectives on PGHD and to iteratively develop the PGHD Trust Canvas.

- **Chapter 4** presents the findings of a qualitative interview study with clinicians, identifying key factors such as governance, data quality, and provenance that influence trust in PGHD. These findings inform the design of the PGHD Trust Canvas and highlight the challenges clinicians face in making trust decisions.

- **Chapter 5** describes the co-development of the PGHD Trust Canvas, a decision-support tool designed to help clinicians systematically evaluate PGHD across dimensions such as data quality, provenance, and risk. The chapter outlines the iterative design process and the involvement of clinicians in refining the tool to ensure its practical relevance and usability.

- **Chapter 6** presents the validation study of the PGHD Trust Canvas, where clinicians evaluated its usability and usefulness in clinical decision-making. The findings show that while the tool is valuable in non-urgent care settings, it may not be suitable for high-pressure environments. The tool's educational potential is also discussed, as it can help clinicians develop their reasoning skills for evaluating PGHD.

- **Chapter 7** discusses the fulfillment of research objectives, linking the research findings to the initial research questions and objectives. The discussion also highlights the contributions of the thesis, including the development of the PGHD Trust Canvas and the in-depth understanding of clinician perspectives on PGHD trust, which can inform future policies, standards, and the design of electronic health records (EHR) and decision-support tools.

- **Chapter 8** concludes the thesis by summarizing its contributions and outlining recommendations for practice. It emphasizes the importance of developing regulatory frameworks and training programs to support the integration of PGHD into clinical workflows.

- **Chapter 9** provides details of the bibliography referenced in this thesis.

- **Chapter 10** provides supporting documentation in the form of appendix.

The structure of this thesis reflects the journey from understanding the challenges of trusting PGHD to developing and validating a practical tool to support clinicians in making informed decisions. The thesis contributes significantly to the field of digital health by addressing critical trust issues in the adoption of PGHD and offering a structured solution to facilitate its use in clinical practice.

Chapter 2. Literature review

2.1 Introduction

The growing prevalence of PGHD in healthcare has introduced both opportunities and challenges for clinicians and healthcare systems. PGHD, which includes data such as biometric readings, patient-reported outcomes, and lifestyle information collected outside of clinical settings, holds the promise of enhancing patient engagement and personalizing care. However, its integration into clinical decision-making processes is far from straightforward, raising issues of several natures including the nature of the field of PGHD, the challenges to its integration as valid data for decision making, and the very nature of the clinical decision making process.

Section 2.2 provides a description of the search strategy adopted in this research, including the databases consulted, filtering methods, and key terms for searching databases.

Section 2.3 provides a comprehensive overview of PGHD, exploring its definitions, the types of data it includes, and the various sources from which it is derived. This section also discusses the diversity and complexity of PGHD, which stem from the wide range of devices and applications patients use to generate their health data.

Section 2.4 narrows the focus to the challenges clinicians face when considering the adoption of PGHD in their practice. It delves into issues such as workflow integration, standardization, and governance, all of which complicate the use of PGHD in clinical settings. The section also addresses the actionability of PGHD, highlighting the difficulties clinicians encounter when interpreting and acting on data that may not have been validated or standardized. Within this section, section 2.4.5 shifts the focus to the concept of trust, a critical factor in the successful integration of PGHD into clinical decision-making. This section examines the role of trust in clinical practice, particularly the challenges clinicians face when determining whether to trust or distrust the PGHD they receive. It also explores how trust is influenced by factors such as data provenance, quality, and the inherent uncertainty associated with clinical decisions based on PGHD.

Section 2.5 provides an overview of the issues surrounding the acceptance and adoption of technologies in healthcare. It discusses the key barriers clinicians face when incorporating new tools, particularly concerns about usability and integration into existing workflows. The section also reviews models such as the Technology Acceptance Model (TAM) and the Unified Theory of Acceptance and Use of Technology (UTAUT), which have been developed to guide the design and implementation of healthcare technologies, ensuring they meet the practical needs of clinicians.

Section 2.6 discusses the complexities of the clinical decision-making process, which already involves synthesizing diverse information from sources like EHRs and lab results. It emphasizes the use of decision-making tools, such as heuristics and decision analysis, and highlights the importance of creating evidence-based clinical policies. The text argues that the decision to include or exclude PGHD in clinical practice should be addressed during the development of Clinical Practice Guidelines, ensuring that the data is reliable and trustworthy for use in patient care.

Section 2.7 provides a summary of Chapter 2.

2.2 Search strategy

The strategy adopted to carry out this literature review involved three stages. The first stage concentrated on understanding the key concepts of PGHD, EHR, clinical decision, and the state of the art of the areas of electronic health, mobile health, health smart applications and related technology trends like standards. The second stage focused on narrowing into the challenges clinicians face when considering whether to adopt PGHD for making clinical decisions. This stage included challenges like workflow integration, standardization issues, limitations in governance of PGHD technologies, and actionability issues. The third stage was aimed at understanding the concept of trust, its role in clinical practice, and further focus on the challenges clinicians face when facing the decision whether to trust or distrust. These challenges include finding clarity about the evidence behind the various claims PGHD technologies make, the quality of the data, the provenance these technologies might disclose. This stage also delved into contextual factors that add to the complexity of the decision of trust, for example the inherent uncertainty associated with any clinical decision based on data, like the risk of harm to the patient.

Multiple academic databases were searched to gather a broad range of articles, including PubMed, Scopus, IEEE Xplore, Google Scholar and Cochrane library. The key words used to carry out searches included “Patient Generated Health Data”, “PGHD”, “digital health data”, “patient health records”, “mobile health”, “electronic health”, “clinical decision making AND patient data”, “barriers to adoption AND PGHD”, “barriers to adoption AND trust”. It is important to note that the above mentioned terms are not a low level list, but a general idea of the terms used. For example, the key words “Patient Generated Health Data” was searched, but also derivations like “patient generated health data”, “patient-generated health data”, “patient generated data” were included in the searches.

During the first stage, search filters did not take an important role, however, in the second stage and the third stage, only articles within the last 10 and 5 years were included. Filtering out papers that were not peer-reviewed also became important in the second and third stages, however, some concepts and search threads required that whitepapers and industry reports were included.

2.3 PGHD

PGHD has the potential to transform various aspects of healthcare delivery, including patient engagement, chronic disease management and clinician decision-making. It encompasses a wide range of data types, sources and uses, making it complex and diverse. This can be attributed to many reasons, one of which is the various forms of data it includes, like physiological, behavioural, symptomatic, etc. The diversity of sources like fitness trackers, smartwatches, etc. also adds to the complexity of the PGHD landscape. This landscape also seems to present a level of imminency when it comes to its arrival. Clinicians are using PGHD in their practice (Hederman, Berry and Ormazabal, 2023), and patients want their PGHD to be used in their healthcare (Lordon *et al.*, 2020).

2.3.1 Definitions of PGHD

For a definition of PGHD, most papers quote the whitepaper by M. Shapiro et al. (2012). The authors of the whitepaper held informal conversations with relevant stakeholders with the intention to achieve a working definition of the concept of PGHD and identify key issues and possible approaches to resolving them. Given that virtually all of the most interesting research papers (Boyne *et al.*, 2012; Jo Deering, 2013; Sands and Wald, 2014; Wood, Bennett and Basch, 2015; Cheng *et al.*, 2015; Chung and Basch, 2015; Sanger *et al.*, 2016; Abdolkhani, Borda and

Gray, 2018; Nittas *et al.*, 2018; Abdolkhani *et al.*, 2019, 2020; Demiris *et al.*, 2019) on the subject of PGHD quote in some form or another the definition by M. Shapiro et al. (2012) this could be considered the best definition and starting point to study PGHD. The definition achieved by Shapiro's whitepaper is as follows:

> *PGHD are health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern. PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways. First, patients, not providers, are primarily responsible for capturing or recording these data. Second, patients direct the sharing or distributing of these data to health care providers and other stakeholders. In these ways, PGHD complement provider-directed capture and flow of health-related data across the health care system.*

The first part of the definition clearly states that PGHD is data related to health with the particularity that it is "created, recorded, gathered, or inferred by or from patients or their designees", and further clarifies that the purpose is to address a health concern. The working definition goes on to clarify that it is the patients who are responsible to collect the data and that they hod a level of control of this data.

As with any topic, the definition of PGHD is used by many authors, who may interpret the seminal references from different perspectives or emphasising different aspects of these definitions. In his book "The patient will see you now: the future of medicine is in your hands" (Topol, 2015), Eric Topol explores how technology empowers patients to generate and control their health data. He broadens the definition of PGHD to include data derived from genomic testing, sensors, and other digital health technologies that patients might use independently of their healthcare providers. Another example would be the study "Use of a Connected Glucose Meter and Certified Diabetes Educator Coaching to Decrease the Likelihood of Abnormal Blood Glucose Excursions: The Livongo for Diabetes Program," (Downing, Bollyky and Schneider, 2017) published in the Journal of Medical Internet Research, which utilizes a definition of PGHD that aligns broadly with common understandings in the field but focuses particularly on the practical application of PGHD in a specific digital health intervention. While the study might not explicitly redefine PGHD away from the Shapiro et al. whitepaper's definition, it emphasizes aspects of PGHD that are crucial for digital health interventions, such as real-time data generation and immediate clinical use.

It is probably these difficulties together with geopolitical differences, that allow for a highly heterogenous, and often contradicting range of terminologies within the literature related to PGHD. Concepts like Personal Electronic Health Record (PEHR) (Damen *et al.*, 2022), Personal Health Record (PHR) (Burka *et al.*, 2005; Vogiatzaki, Rodríguez and Conejero-Lara, 2022), Patient Health Record (Also *PHR*)(Bouayad, Ialynytchev and Padmanabhan, 2017), Patient Portal (Lyles *et al.*, 2020), Shared Care Record (SCR), etc. often overlap each other and at times are used interchangeably.

As useful as the Shapiro et al. (2012) definition has proven, the nature of PGHD makes it very difficult to apply it rigorously as a form of scope since almost all of the literature that actually uses this definition, in one way or another, fails to fully comply with every aspect of it.

For example, many articles about remote monitoring, or telemonitoring systems use the term PGHD to describe the nature of the data created, however, it can be argued that patients rarely "…*direct the sharing or distributing of*" telemonitoring data. The article "Emerging uses of patient generated health data in clinical research"(Wood, Bennett and Basch, 2015) uses the example of a telemonitoring clinical trial (*Telemonitoring Study - for Chronic Myeloid Leukemia (CML)*, 2018) to track medication adherence and highlight it as a use of PGHD. This clinical trial, although prematurely discontinued, planned to use eMedonline to "automatically collect" medication data like dosing times, adherence, etc. In this case, patients do not direct the sharing or distributing of these data to healthcare providers.

In order to develop a comprehensive understanding while acknowledging the nuances and challenges associated with PGHD, it is also necessary to acknowledge that different patients, under different circumstances will hold varying levels of control over the data. Some technologies will grant the patient complete control over sharing data, others may only provide limited control, like in many cases of telemonitoring. Accepting a higher level of variability can provide a better, more realistic understanding of how PGHD can be trusted in decision making in the real world.

Similarly, articles reviewing PGHD associated with technologies targeting consumers, particularly those with special interest in data quality and quality management of wearables, use the term PGHD, even though the reason for collecting the data, originally would not be "to address a health concern", but rather for their own curiosity about wellbeing, simple interest or just the availability of the functionality in the device (Abdolkhani, Borda and Gray, 2018; Abdolkhani *et al.*, 2020). Some experts even go as far as describing the persons collecting the data as "health individuals" , where the person gathering the data is not a patient until they are admitted to the care of a health professional, rather than "patients" (Valentin Fuster, 2019), ultimately nullifying most of the experiences with wearable devices from being included in this definition.

It is important to clarify that, even though the definition developed by Shapiro, et al. (2012) has its imperfections, their whitepaper provides a comprehensive foundation to the majority of research in the topic of PGHD. The whitepaper also discusses valuable technical, operational, legal, and other issues; and defines the role of the US's Office of the National Coordinator as an enabler of flow and appropriate use of PGHD.

At the date of writing of this thesis, the lack of full compliance with the definition of PGHD seems to go unnoticed. A widely cited article by Wood, Bennet and Basch (2015) is a well cited source of information with 97 documents citing it, yet it discusses data streams from wearable devices, vital sign monitoring, and other forms of data that, in practice, are often controlled by healthcare providers rather than the patients themselves. These types of data are often collected through systems designed for remote patient monitoring, where the control over the data might be more in the hands of healthcare providers or third-party companies rather than the patients. This can blur the lines between true PGHD, as defined by Shapiro, and data that is more characteristic of traditional remote patient monitoring.

For the purpose of this research, it was decided that full compliance with the definition above wouldn't be a requirement for inclusion in this review. A flexible approach to scoping the topic will accommodate the complexities and variations present in different healthcare contexts.

While the definition by Shapiro et al. (2012) focuses on data captured by patients to address a health concern, the research reported in this thesis will include instances where the data is

collected for general health monitoring or life management, even if there is no immediate known health concern on behalf of the patient. Also, while the same definition emphasizes that "PGHD complement provider-directed capture and flow of health-related data…", this research will consider instances where it can be argued that it was the healthcare provider who directs the capture of the data. For example, diabetic patients with high levels of involvement in the management of their condition are going to be considered in this research, even though the initial order to use devices like connected insulin pumps was made from the clinical side. This is due to the high level of involvement and empowerment with which chronic diabetic patients are trusted.

2.3.2 Classification of PGHD

There are ways to classify the different sources and types of information about PGHD that don't rely strictly on compliance with the definition.

An article by Lee and Mohamed (2022) distinguishes 3 main types of PGHD: quantitative (blood pressure – glucose monitoring – body weight), qualitative (patient reported outcome questionnaires – pain scores – symptoms diary) and multimedia (photographs of wounds, lesions etc.).

Other classification systems used to organize and categorize information related to, or contained within patient-facing systems, organize, manage, and provide consistency through the use of taxonomies. These valuable tools for organizing complex information also allow effective communication and knowledge sharing across the different domains and regions.

One of these tools is Woods, Evans and Frisbee's (2016) taxonomy of PGHD. Perhaps the most interesting about this work in the field of PGHD is that this taxonomy originated from direct consultation with chronic disease patients. In this article, 17 types of data can be recognised based on the: Personal profile, preferences, health data review, health history, family history, patient agenda, medication information, health assessment, biometric tracking, symptom tracking, patient reported outcomes, multimedia observations, care goals, patient experience, documents and forms, ad hoc requests, and administrative data.

Another taxonomy for assessing PGHD types and functionalities was proposed by Bouayad, Ialynytchev and Padmanabhan (2017) based on earlier work by Archer et al. (2011), after consultation with clinicians, and validation by a group of clinical informatics experts. This taxonomy groups what they call patient health records data elements by source, format, and time of first mention. The data categories that the article found to be most cited, do not quite comply with our definition of PGHD, although the distinction whether it was generated by the patient, or the clinician is not explicit in the article. In this thesis it is argued that data elements like health history, treatments and diagnostics are not likely to be generated by the patient, providing a solid example of the difficulties in reviewing PGHD literature.

2.4 Challenges

Despite the many articles highlighting the potential of PGHD to improve the delivery of personalised patient care (Chung and Basch, 2015; Wood, Bennett and Basch, 2015; Petersen and DeMuro, 2015; Cohen *et al.*, 2016; Hsueh *et al.*, 2017; Nittas *et al.*, 2018; Park *et al.*, 2018; Reading and Merrill, 2018; Jim *et al.*, 2020; Victoria L. Tiase *et al.*, 2021; Winter and Davidson, 2021; Hussein *et al.*, 2021; Victoria L Tiase *et al.*, 2021) and its recent pandemic-associated demand (Rosner, Kvedar and Adler-Milstein, 2021), the adoption of PGHD into the clinical

decision process remains in promising stage (Hussein *et al.*, 2021), is met with scepticism (Tarassenko and Greenhalgh, 2020) and still presents technical, behavioural and organizational challenges (Abdolkhani *et al.*, 2020).

Challenges include workflow (Chung and Basch, 2015; Ye, 2021), lack of standards (Hsueh *et al.*, 2017), patient accessibility (Reading and Merrill, 2018) and general lack of integration into the electronic health records (Victoria L Tiase *et al.*, 2021). Azodo *et al.* (2020) add to the arguments that the technology is not suitable for inclusion in the clinical decision-making process. Other studies (Bender *et al.*, 2013; Chen and Schulz, 2016; Akbar, Coiera and Magrabi, 2020) also raised concerns about the possible harm to patients, pointing out the poor evidence base and poor validation of PGHD among other arguments.

2.4.1 Workflow

Integration of PGHD into clinical workflows has been slow. Demiris et al. (2019) conducted a systematic review to evaluate the current impact of PGHD in clinical settings and offer recommendations for its integration with EHRs. The review found that PGHD integration into EHRs remains limited, with Clinical Decision Support Systems (CDSS) offering only basic functionalities. These systems primarily provide clinicians with dashboards and graphs, but actionable insights are often constrained to simple alerts based on predefined parameters. There is little to no automation for decision-making, and patient-facing systems offer minimal guidance, typically advising patients to "consult their clinician."

Clinicians also voice concerns about the added burden of reviewing PGHD, which can overshadow potential efficiencies. PGHD systems frequently lead to longer workdays, unpredictable schedules, and increased cognitive demands, particularly for nurses, who tend to engage more with the data than physicians. This heightened workload further impedes the seamless integration of PGHD into clinical practice.

2.4.2 Standardization

The technical issues highlighted by Shapiro, et al. (2012) mainly focus on the lack of specific standards. In their view, these would need to be developed by stakeholders. A 2017 systematic literature review (Roehrs *et al.*, 2017) elaborates on these issues indicating that the integration of standards and interoperability are in a state of "stability and consolidation", focusing their concerns on confidentiality, integrity, authentication, scalability and user experience issues instead. Roehrs, et al.'s systematic review names the below standards as providers of structural and semantic standardization:

- HL7/FHIR/SMART
- ISO / TR (Technical Report) 14292 (PHR) and ISO/IEEE 11073 Personal Health Data.
- Open EHR
- ASC X12N (Accredited Standards Committee X12-INS)
- CCD (Specification for exchange clinical documents)
- CCR (Specification for sharing continuity of care content)
- CDA (Specification for clinical notes)
- DICOM (Medical digital imaging)
- EN13606 (EHR standards in Europe)
- XDT (German family of data exchange formats)

Addressing nomenclature and terminology the following are mentioned:

- HNA/NIC (Classification of nursing activities and interventions)
- ICDx (Family of international classification of diseases)
- LOINC (Identification of medical observations)
- SNOMED CT (Terminology of medical terms)
- UMLS (Medical volcabulary)

The paper also mentions privacy regulatory bodies, specific to the US and other open-source resources as providers of templates and technology platforms.

HL7 seems to be the technology that one way or another permeates into every non-proprietary application. Furthermore, Pais, Parry and Huang (2017) developed a conceptual data model to prove the suitability of Fast Healthcare Interoperable Resources applied to what they called wellness data. It is necessary to clarify at this point that in this context, the use of wellness data refers to something close to a PHR for chronic disease patients, rather than data created by consumer wearables. The paper concludes that their data model proves that using FHIR it was possible to achieve integration of observations into an EHR.

A standardized information model for PGHD was developed by Plastrias and O'Sullivan (2018). The information model modifies an earlier ontology-driven model (Plastiras, O'Sullivan and Weller, 2014) for PHRs and EHRs that contained roles, entities, acts and elements by extending the classes, ontology and mapping rules.

Perhaps most significant to this thesis, CEN ISO/TS 82304-2:2021 (ISO, 2021) focuses on health and wellness apps, providing a framework for assessing their quality and reliability. It outlines requirements applicable throughout the entire lifecycle of these apps and introduces a health app quality label to communicate their standards to users. The standard is designed for app manufacturers and app assessment organizations, aiming to help users like consumers, patients, healthcare professionals, and insurers make informed decisions about app selection or adoption.

The quality criteria are categorized under several key areas:

- Product information: Details about the app and the manufacturer.
- Health and safety: Ensuring the app is safe and provides health benefits without posing risks.
- Ease of use: User-friendly design, accessibility, and usability of the app.
- Data security: Protection of users' privacy and secure handling of data.
- Robustness: The technical reliability and interoperability of the app.

The standard also details the calculation of a health app quality score, along with a health app quality label, which visually represents the app's performance across these criteria. This label is intended to enhance transparency and trust in the use of health apps across various markets and applications.

2.4.3 Governance

Perhaps the strongest argument against including PGHD in the clinical decision-making process is the difficulty in implementing comprehensive governance frameworks (Metzer, 2018; Magrabi *et al.*, 2019; Winter and Davidson, 2021). Governance in this context goes beyond mere quality assurance. It must encompass clear standards for data accuracy, liability frameworks, and harm mitigation strategies. This includes defining who is accountable when PGHD contributes to incorrect or harmful clinical decisions, and establishing protocols for verifying the reliability of data sources.

In the realm of health apps, the lack of formalized governance is particularly evident, where no universally accepted standards ensure the validity and quality of patient-generated data (Bender *et al.*, 2013; Alyami *et al.*, 2017; Byambasuren *et al.*, 2018; Metzer, 2018). Without proper governance, there is an increased risk of harm to patients and potential legal liabilities for clinicians who rely on these data.

Moreover, addressing these governance gaps is essential for building institutional trust among providers. Lessons learned from the introduction of EHRs into clinical workflows have emphasized the importance of not only technical governance but also attitudinal factors like provider institutional trust (Davis, 1989; Lewicki, Tomlinson and Gillespie, 2006). If clinicians do not trust that institutions have adequate governance in place to ensure the integrity of PGHD, they will likely remain resistant to integrating it into their decision-making processes. Therefore, robust governance should not only regulate data quality but also address the legal, ethical, and trust-related dimensions that influence clinician adoption.

Lack of clarity of the types of legal liabilities clinicians face when presented with PGHD is another major obstacle to the incorporation of the data in the decision-making process. Clinicians simply don't know what the consequences are if harm is caused by the use of PGHD in making decisions (Tiase, 2017). Perhaps what is more of a difficulty is that clinicians are not clear on the liability of ***not*** reviewing PGHD that is shared with them, whether it is due to overload, or information gaps, etc; to the point that they may want to limit the information that flows towards them (Shapiro *et al.*, 2012).

2.4.4 Actionability

One of the key challenges in incorporating PGHD into clinical decision-making arises when clinicians encounter data that, while seemingly relevant, lacks clear actionability. Clinicians are often relied upon to use their professional judgment to assess the clinical relevance of any data received from patients. However, there are instances when the data cannot be acted upon effectively. Fiore-Gartland and Neff (2015) describe this as the "valence of actionability," referring to the expectation that data should be actionable or capable of informing a clinical decision.

Conflicts in the patient-clinician relationship arise when data is readily available to patients simply because it is easy to generate, such as obtaining 1,000 blood pressure readings at home through a wearable device. As Fiore-Gartland and Neff (2015) explain, while clinicians are well-versed in interpreting standard blood pressure readings taken in a clinical setting, they may find it challenging to determine the significance of extensive data from home devices, even if recently calibrated. For instance, in one testimony gathered, a clinician remarked, "If I have 1,000 (wearable blood pressure) readings, and some are high, I don't know what it means." Similarly, Shapiro et al. (2012) highlight this issue in their white paper as one of the many challenges in integrating such data into clinical practice.

This is further exemplified by a study that used PGHD on an unprecedented scale. Perez et al. (2019) reported an improvement in the positive predictive value of their wearable technology in accurately detecting the irregular pulse associated with atrial fibrillation (AF). There are concerns regarding the over-diagnosis of AF caused by the surge of wearable technologies, and the fact that there is no evidence of the benefits to patients when monitoring healthy patients for AF (Joice, 2018). The general reaction from physicians is that there's a need to proceed with extreme caution. In his closing statement of the American College of Cardiology, Dr Valentín

Fuster, points out that although the Perez study is interesting, what we can learn from it is very limited (Valentin Fuster, 2019).

2.4.5 Clinician trust

The assessment of information trustworthiness is a fundamental aspect of clinical practice, extensively addressed across medical literature, especially in discussions related to evidence-based practice, medical informatics, and clinical decision-making. Clinicians are expected to use their judgment to determine whether to trust the Patient-Generated Health Data (PGHD) presented to them or to disregard it (AMA, 2020). This evaluative process also applies to other types of clinical information utilized in decision-making (Ortega Egea and Román González, 2010; Acemyan and Kortum, 2012; Schwartz *et al.*, 2022). Like laboratory data, PGHD prompts clinicians to consider several critical questions from their subjective perspective when making decisions: *Is the data trustworthy? Is it applicable to the specific case at hand?* Such scrutiny is typical in all health data assessments involved in decision-making processes, often leading to redundant testing due to the practice of defensive medicine (Khereldeen and Baazeem, 2021).

The phrase, often attributed to W. Edwards Deming, 'In God we trust. All others must bring data,' amusingly captures the essence of data analysis and subtly references the null hypothesis. It underscores the inherent human challenge of distinguishing facts from fiction, reality from imagination, and truth from falsehood. In medicine, this phrase poignantly emphasizes the preference for 'evidence over eminence' in clinical practice. However, it overlooks the equally crucial need to establish trust in the data itself.

The grounds of trust can be based on reliability, where the trustee, although presenting little or no transparency, is predictable and reliable. Larosa and Danks (2018) use the analogy of one's trust in their car to start in the morning as it has been doing every morning for years. The driver might have an idea of how an engine works and the general idea of what makes a car run, but they are not likely to understand how to build or even repair a broken-down car. This type of trust is called *behavioural trust*.

A second type of grounds for trust would be the trust that relies on the understanding of the mechanisms within the trustee that makes them likely to fulfil the trustor's expectations. An example of this could be our trust in governance bodies that provide assurance of important aspects like the quality and safety of a product for human consumption. Even though the trustor is not perfectly aware of the exact quality assurance process, they have enough indicators to assume the expected outcome. The consumer has some understanding of the quality assurance, but they weren't there the day the chicken was killed and processed. Larosa and Danks call this *understanding trust*.

Overall, trust remains a crucial element in human interactions, affecting personal relationships, institutional dynamics, and decision-making processes. Rousseau et al. (1998) explain that across disciplines one of the necessary conditions for trust to occur is that there is uncertainty of an outcome and that there is some element of vulnerability and risk at stake. As the medical practice continues to understand and accept uncertainty (Simpkin and Schwartzstein, 2016) the need to understand how decision makers trust their resources, training and patients becomes crucial.

Huang and Fox (2006) list 3 essential components of trust: (1) expectancy: the trustor expects a specific behaviour of the trustee such as providing valid information or effectively performing cooperative actions; (2) belief: the trustor believes that expectancy is true, based on evidence of

the trustee's competence and goodwill; (3) willingness to be vulnerable: the trustor is willing to be vulnerable to that belief in a specific context where the information is used or the actions are applied.

Also, touching the topic of vulnerability, Fromm (1956) discusses various aspects of love, including its nature, forms, and challenges. While he doesn't provide a direct quote explicitly stating trust as a fundamental component of love, he does highlight the significance of trust in fostering genuine and intimate connections with others. This is done through the use of the word "faith", not in its religious context, but in the act of believing in the other person, relying on their sincerity, and opening oneself up to vulnerability.

More recently, different authors used behavioural economics games to measure trust with subtle, but significant differences. In a review of trust games, Alós-Ferrer and Farolfi (2019) differentiate between the different games ranging from qualitative depictions of trustees as a continuum of decision nodes like Berg, Dickhaut and McCabe (1995) trust game, to just binary choices for both, the trustor and the trustee, depicted by Kreps (1990).

2.4.5.1 Conceptualizing trust as a decision

Trust has traditionally been discussed as a relational construct rather than a decision-making process (Collard, 1989; Gambetta and Badcock, 1990; Berg, Dickhaut and McCabe, 1995; Gambetta, 2000; Söderström, 2009). Depending on the focus of their research, trust is understood by many authors in many different ways. It can be considered a psychological state (Huang and Fox, 2006), a relationship between individuals (Rousseau *et al.*, 1998), a personal willingness of becoming vulnerable (Fromm, 1956), etc. What all of the interpretations and points of view have in common, is that there is an element of decision when trust occurs. Thus, taking a similar approach as by Li, Turmunkh and Wakker (2019) or Evans and Krueger (2017), this thesis considers trust as a decision. A clinician can trust or distrust. This understanding of trust can be summarized in the following axiom.

"Trust is a binary decision whether to trust or to distrust".

The statement completely simplifies the term trust, while leaving the complexities inherent in the decision as factors in the trustee, trustor, and the context, which are described as components of the decision in section 2.4.5.2. These components form a triangle "trustor, trustee and context" that determine the decision of trust (See Figure 2).

Based on the above framework for the concept, trust is a verb: "to trust". However, one could wonder about the noun "trust". Questions like "Can you increase/establish/lose trust?" will continue to appear in discussions about trust and PGHD (Bickmore and Cassell, 2001; Söderström, Eriksson and Åhlfeldt, 2016). In the case of "increasing" trust, perhaps we should be asking what does "increase trust" really mean. Within context, most of the times "increasing" trust means to increase the likelihood that the decision of trust goes towards trusting, rather than distrusting. To "establish trust" also requires an etymological shift. Within the proposed framework, this would be the creation of clarity in the eyes of the trustor of positive contributing factors in the context, the trustee, and even in the factors inherent in the trustor themselves.

This perspective sees clinicians as trustors who decide whether the data presented to them is reliable enough to act upon, an approach perhaps similar to that taken by Li, Turmunkh and Wakker (2019) or Evans and Krueger (2017).

It is important to clarify that this thesis focuses on trust in information or data, with clinicians as the trustors and PGHD as the trustee. While many definitions of trust emphasize interpersonal relationships, where trustor and trustee are individuals, trust can also apply to non-personal entities. For example, in their extended version of the Technology Acceptance Model (TAM), Ortega Egea and Román González (2010) introduce institutional trust factors. The concept of institutional trust becomes relevant through its transitive nature: trust in the institution responsible for producing the technology often extends to the data generated by that technology. In other words, if a clinician trusts the institution or technology provider, they are more likely to trust the data produced by that technology.

2.4.5.2 Components of Trust: trustee, trustor and context

In order to be able to help clinicians with the decision it is necessary to frame the different components and variating factors of clinician trust within a conceptual framework that provides clarity regarding the nature of each of these factors. For the purpose of this thesis, the decision of trust is considered to be affected by three main components: the trustor, the trustee and the context in which the trust occurs (See Figure 2)

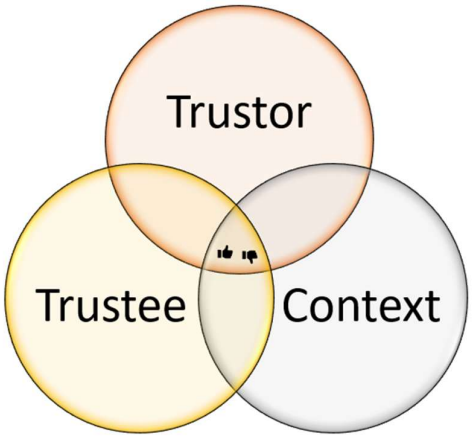


Figure 2 components of the trust decision

Mayer, Davis and David Schoorman (1995) talk about organizational trust breaking down the decision of trust by factors related to the trustor, trustee and the contex.

Trustor Factors -Characteristics of the Trustor- include the propensity to trust on behalf of the trustor, which in the case of this thesis, includes the clinician. This is shaped by personality traits, experiences and cultural background. Risk aversion is another example of a trustor factor.

Trustee Factors -Characteristics of the Trustee- include the trustor's perception of the trustee's ability or competence. In Mayer, Davis and David Schoorman's article, they mention the trustee's skills, expertise, and capabilities in a relevant domain. In the case of PGHD, the data's ability could be interpreted as data quality, but the trustor's ability could also be considered to be provenance by extension. For the clinician to trust data generated by the patient, it is necessary that they trust that the origin of the data was carried out by an able and competent patient.

Another factor inherent in the trustee -the data itself- is its integrity. In this case, the article refers to the principles and values that the trustor finds acceptable, which could also be interpreted as quality in the form of data integrity, completeness, accuracy; but also could be considered provenance, where information about the patient's intentions affect trust.

The topic of trust can be a highly dynamic, vague and ambiguous field. These decisions in interpretation can be considered arbitrary, however are necessary to create a framework that assists clinicians with the decision of trust.

Contextual Factors -Environmental or Situational Influences- Mayer, Davis and David Schoorman place situational norms and rules as contextual factors. These include the presence of formal regulations, policies and norms that govern behavious in a particular context as factors that influence trust. The field of PGHD is an example of a field that is starved of guidance governance and regulation. The article also mentions power dynamics and institutional safeguards, but this research will include the actual risk of harm to the patient as a contextual factor. Risk, as described by the American Society for Healthcare Risk Management (2009) is conceptualized as having two key dimensions: the likelihood of a negative outcome and the severity of that outcome. This is another example of ambiguity in the topic of trust, since it could be argued that the part of risk represented by the likelihood of a negarive outcome -if the outcome is just that the data is incorrect- is an antipode of data quality. For the sake of clarity and simplicity this ambiguity is acknowledged and disregarded in this research.

2.4.5.2.1 Trustor

As mentioned in section 2.4.5.2, the trustor is one of the three components in the decision to trust, as they are the one who ultimately makes the decision. In healthcare, the patient typically assumes the role of the trustor, seeking help from the clinician, who serves as the trustee. While extensive literature exists on trust from the patient's perspective, this thesis focuses on the clinician as the trustor. Section 2.4.5 explains that the clinician is responsible for deciding whether to trust or distrust PGHD.

This trust decision is influenced by several factors: characteristics of the trustee -in this case, the attributes of the data-, the context in which the trust decision is made, and personal attributes inherent to the trustor. Li, Turmunkh, and Wakker (2019) discuss how in strategic situations marked by ambiguity, personal traits of the trustor, such as risk aversion, significantly impact the decision to trust. This concept is also evident in the clinical decision-making literature, where clinicians must consider a multitude of factors when making decisions, including patient preferences as well as their own personal traits and experiences.

2.4.5.2.2 Trustee

The second of the three components of trust, according to the point of view of this thesis is the trustee, or in this case, attributes inherent in the PGHD itself. These attributes include the evidence behind the information represented by the PGHD, the quality of the data as well of the evidence, and the origins of the data. Also, Reave and Ba (2002) describe trustworthiness to that which properly invites trust and can honour it. Even though Reave and Ba talk about trust between patient and nurse from the interpersonal relationship, they understand trustworthiness as an attribute of the trustee, in this case the nurse.

2.4.5.2.2.1 Trustworthiness

The topic of data trustworthiness and trust in data has been a subject of interest to many statisticians who created many tools to detect anomalies or fraud in datasets. Perhaps the main concern in data analysis and statistics is the decision to exclude outliers, which is reflected in the number of techniques to assess the trustworthiness of data with examples like Benford’s law (Miller, 2015) analysing the frequency of digits in a random dataset, Z-score (Pearson, 2009), as a measure of the number of standard deviations a data point is from the mean of the dataset, Grubbs test (Grubbs, 1969), Dixon’s Q test (Grubbs, 1969), and many more.

Hadley Wickman, a prominent figure in the R programming community has written extensively on data manipulation, visualization, and data quality (Hofmann, Wickham and Kafadar, 2017), even proposing an alternative to boxplots that uses rules to estimate a threshold for trusting values in it (Fresques and Marco, 2019). His emphasis concentrates in the importance of data cleaning and proper handling of missing values to ensure trust in the results of data analyses.

Another large portion of the literature that deals with trust and trustworthiness, particularly in building and fomenting trust, is in cybersecurity and information theory. Anderson (2020) covers trust related topics like cybersecurity, data protection, privacy and the design of secure systems. Particularly in privacy decisions and "trade-offs", trust and trustworthiness become implicit and ever-present. This is evident in the works of Garfinkel (2000), and Acquisti and Grossklags (2005).

It is also relevant the perspective regarding trust that the discipline of computer science and artificial intelligence takes since the concept of trust becomes a crucial aspect, especially in the development and deployment of AI systems. Even though the book chapter Race and Gender by Timnit and Gebru, (2020) defines trust as a psychological state, rather than the binary decision definition that this thesis adopts, the book highlights the need for trustworthiness in the form of transparency and fairness in AI algorithms.

Furthermore, Marcus and Davis (2019) argue that the current state of artificial intelligence lacks trustworthiness due to its limitations and overhyped expectations. The authors advocate for a more nuanced and transparent approach to AI development, promoting the need for systems that are reliable, interpretable, and accountable. Finally, Zerilli *et al*. (2018) provide an excellent example of the ambiguity of criteria for trust, highlighting potential biases and ethical considerations in both, human and algorithmic decision-making.

In healthcare, the consistency of PGHD with other data becomes a high indicator of the data's trustworthiness. Cohen et al. (2016) discuss that clinicians may become skeptical about Patient-Generated Health Data (PGHD) when they encounter contradictions between PGHD and clinical data or established clinical norms. Such contradictions can challenge the perceived trustworthiness of PGHD, leading to concerns about the accuracy and clinical relevance of the data. When PGHD conflicts with traditional clinical measures, clinicians might hesitate to integrate the data into their decision-making process, as it introduces uncertainties that complicate clinical judgments

2.4.5.2.2.2 Evidence

PGHD-generating technologies vary not only in the type of information they provide to patients but also in the complexity of that information. Some devices offer basic physiological data, such as heart rates, while others deliver more advanced insights, such as AI-driven diagnoses of conditions like melanoma. The clinical relevance of the data produced by these technologies heavily depends on the accuracy and context in which it is presented, requiring the clinician's professional judgment to determine its incorporation into the clinical decision-making process. Regardless of the data's complexity, the reliability and validity of PGHD are crucial attributes that clinicians must evaluate to ensure the data can be trusted for its use in patient care.

Since the paradigmatic change towards the use of the best available research to health (Davidoff *et al.*, 1995; Sackett *et al.*, 1996) , evidence-based medicine (EBM) has become the gold standard in medicine. Central to any decision, understanding the evidence behind the tools used in medicine is crucial to making a decision, including when pondering the trustworthiness of PGHD.

Understanding EBM is vital when making clinical decisions, especially with the increasing use of PGHD. EBM ensures that patient care is based on the best available evidence, integrating PGHD with traditional clinical data to form a comprehensive view of a patient's health. This approach helps identify and mitigate biases inherent in PGHD, incorporates patient values and preferences into care plans, and guides the interpretation of diverse data sources provided by digital health tools. By aligning PGHD with established clinical guidelines and continuously improving practice, EBM supports safe, effective, and patient-centred healthcare. Kvedar, Coye and Everett (2014) emphasize the importance of using connected health technologies to extend care across populations and ensure high-quality care. It implicitly supports the notion that incorporating diverse data sources (including PGHD) can help mitigate biases and enhance patient-centered care, aligning with EBM principles.

EBM is a fundamental approach in modern healthcare, emphasizing the use of the best current evidence in making decisions about the care of individual patients. As a result of the emergence of the scientific method and statistical analysis in the 19th century, practitioners of medicine began to use evidence and statistical methods to evaluate treatments and make better clinical decisions (Guyatt *et al.*, 2015). The middle of the 20th century saw the emergence of the field of clinical epidemiology, which focuses on the study of the distribution and determinants of health and diseases in populations. This field applies epidemiological principles and methods to clinical problems and serves as a cornerstone for the practice of evidence-based medicine (Fletcher, 2019). Further, Cochrane (1972) emphasized the importance of using randomised controlled trials (RCTs). The randomized controlled trial continues to be the most reliable method for assessing the efficacy of healthcare interventions and establishing causation. Cochrane's arguments highlighted the need for healthcare decisions to be based on solid, scientifically sound evidence. He was concerned about the lack of reliable evidence behind many common medical practices of the time.

Furthermore, Cochrane's influence extended beyond this seminal text. His advocacy for systematic reviews of RCTs led to the establishment of the Cochrane Collaboration in the 1990s, an organization dedicated to creating up-to-date, accurate information about the effects of healthcare available worldwide. The Cochrane Library, particularly the Cochrane Database of Systematic Reviews, is now a key resource in evidence-based practice, providing comprehensive reviews that assess the benefits and harms of healthcare interventions based on the best available evidence, primarily from RCTs (Wiley, 2000).

The term Evidence-based medicine was formally introduced by a group of epidemiologists at McMaster University in Canada (Guyatt *et al.*, 2015) stressing the importance of using the best available evidence when making decisions about the care of patients. Sackett (2000), from the same university, further popularized the concept of EBM emphasizing the integration of clinical expertise with the best external clinical evidence from systematic research.

Through the 1990s and into the new century, EBM gained acceptance and has become the dominant paradigm in healthcare, particularly upon the inclusion of EBM in medical education. Greenhalgh (2010) contributed to the popularization of the paradigm, particularly with healthcare professionals who may not have a deep background in research methods or statistics. Her book has been instrumental in teaching healthcare professionals how to critically appraise medical literature. This skill is crucial for interpreting the validity and applicability of research findings, allowing clinicians to make better-informed decisions. Furthermore, and very significant to this thesis, the book encouraged a more questioning approach towards medical literature,

advocating for scepticism and thorough analysis rather than passive acceptance of published research.

Implementing EBM in real-world clinical settings continues to face challenges, including the need for improved access to high-quality evidence and tools for evidence appraisal. Evidence is extremely complex, and the rate of its advances outpace anyone's ability to examine it (Sackett *et al.*, 1996). As a result of the complexity in the body of research a rating system that provides hierarchy of evidence was devised by Guyatt and Rennie (1993) and later modified by Melnyk and Fineout-Overholt (2010). This hierarchy system allows clinicians to weigh evidence related to a patient's care (Melnyk, 2004), particularly when encountering contradicting authors. Table 1 shows the 7 levels of evidence where level I is the highest quality of evidence and VII is the lowest.

Table 1 Evidence hierarchy from Melnyk and Fineout-Overholt

Evidence level	Description
Level I	Evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCT) or evidence-based clinical practice guidelines based on RCTs.
Level II	Evidence obtained from at least one well designed RCT
Level III	Evidence obtained from well-designed controlled trials without randomization
Level IV	Evidence from well-designed case-control and cohort studies
Level V	Evidence from systematic reviews of descriptive and qualitative studies
Level VI	Evidence from a single descriptive or qualitative study
Level VII	Evidence from the opinion of authorities and/or reports of expert committees

2.4.5.2.2.3 Data Quality

Data quality is an attribute of the data itself, and therefore of the trustee. It refers to specific characteristics of the data, such as accuracy, completeness, consistency, timeliness, and relevance, that determine its usefulness and reliability for a given purpose. Wang and Strong (2015) discuss data quality dimensions like accuracy, completeness, and consistency as intrinsic attributes of data, which in this case is the trustee. It highlights how these attributes impact the usability of data for decision-making, which in turn influences its trustworthiness.

In Ireland, the HIQA established a framework that outlines various data quality dimensions critical for the healthcare sector (HIQA, 2018). These dimensions help ensure that health data is fit for its intended purposes, whether for direct patient care, research, or policymaking. The key data quality dimensions identified by HIQA include:

- Accuracy: Refers to how well the data correctly represents the real-world constructs it is intended to describe. Accurate data is critical for making reliable clinical decisions and ensuring patient safety.
- Completeness: This dimension assesses whether all necessary data is captured. Incomplete data can lead to incorrect assumptions or missing critical information in patient care or research.
- Consistency: Ensures that data is uniform across different datasets or systems. Consistent data prevents discrepancies and errors when data is transferred or aggregated from different sources.
- Timeliness: Timely data is up-to-date and available when needed. This dimension is particularly important in healthcare, where outdated information can lead to poor outcomes.
- Relevance: Data should be relevant to the purpose for which it is used. Irrelevant data can clutter systems and lead to inefficiencies in data processing and decision-making.

- Reliability: Refers to the trustworthiness of data over time. Reliable data remains consistent and accurate when repeated under the same conditions.
- Accessibility: Data should be easily accessible to those who need it, while ensuring proper security and confidentiality are maintained.

The relationship between quality and trust in data as a requirement for its use in decision making processes is also highlighted by Bertino et al. (2008). In this article the quality and trustworthiness requirements are referred to as high-assurance data integrity. It refers to the technical aspects of data integrity, which is closely related to the quality dimensions by HIQA (2018).

Still from the subjectivity of the clinician, the main gap between laboratory data and PGHD in terms of trust, lies in the clinician's understanding of the mechanisms for quality assurance and controls. The most persuading arguments against the use of PGHD in the clinical decision process focus on the uncertain nature of quality dimensions like accuracy (Bierbrier, Lo and Wu, 2014; Proesmans *et al.*, 2019; Freeman *et al.*, 2020) and weak evidence of reliability (Swendeman *et al.*, 2018). Laboratories must adhere to rigid regulations and standards, while most PGHD-generating devices or software remain unregulated or under-regulated.

Clinicians understand, not only the outputs from laboratories, but also the quality controls in place to assure a minimum level of certainty. They also trust the origin of the data in front of them, and if they don't, they simply order more tests from their familiar laboratory. Also, perhaps as important, there are legal, ethical, and technical frameworks that allow them to justify their trust in laboratory data.

Drawing from Bertino et al. (2008) and HIQA (2018) we explore high-assurance data integrity, a concept that encompasses technical integrity, data provenance, and trustworthiness. The concept is closely linked to provenance and trust scores, but from the point of view of metadata management and data validation and expands from integrity techniques like anti-tampering to focus on whether the data can be trusted. In the paper the example of data deception is brought up, which is different from data tampering in the sense that the data is transferred as it was collected, but it is simply untrue. In the case of medical decisions and trust in patient generated data, it is hard to understand how doctors work with patients if there is so little research on how they trust patients (Papautsky and Panganiban, 2018).

In terms of assessing the quality of health information and evidence for clinical decisions, there are several tools, particularly in the context of diagnostic accuracy and systematic reviews. The QUADAS tool (Quality Assessment of Diagnostic Accuracy Studies) (Whiting *et al.*, 2003) is designed to assess the quality of primary diagnostic accuracy studies included in systematic reviews. Developed using empirical evidence and expert consensus through a Delphi process, the tool consists of 14 key items. These items address potential biases, study validity, and applicability, covering areas such as patient selection, test execution, and the independence of reference standards. Each item is scored as "yes," "no," or "unclear" to determine study quality. QUADAS enhances the transparency and reliability of systematic reviews of diagnostic tests. Other similar tools include GRADE (Guyatt *et al.*, 2011), AMSTAR (Guyatt *et al.*, 2011), and QUADAS-2 (Whiting *et al.*, 2011).

It is important to point out that there is disagreement among the literature as to whether data quality is an attribute of the trustee's trustworthiness or vise versa. Naumann and Rolker (2005) discuss various information quality criteria, including trustworthiness as an integral part of the overall assessment of data quality. It argues that trust in the data is critical for users to consider

the data as high quality. Byabazaire, O'hare and Delaney (2020) also argue that trust allows the estimation of data quality when no other information is available to use as a gold standard.

2.4.5.2.2.4 Data Provenance

Data provenance is considered in this thesis as an attribute of the data itself and by extension, a factor related to the trustee in the decision of trust. In today's deluge of health data and health information, knowing the origin of the any data is crucial for clinicians' ability to trust it. Maintaining record of the lineage of any data destined to be used in clinical decision-making or any use, particularly when considering it for clinical decisions, is best done through the recording of provenance.
Along with quality, provenance has been identified as crucial to the integration of PGHD in the clinical decision process since the variance between sources of PGHD is too great to use where a decision on certain interventions carry a risk to the patient (Azodo et al., 2020).
For example, a clinician would not hesitate in administering insulin to a diabetic patient based on glucose measurements from a known and trusted source, like the point of care glucose monitors used in glycaemic control in hospitals. This seems to be the case, even where the accuracy of these devices continues to be challenged (Rajendran and Rayman, 2014). Adozo et al. (2020) determined, however, that their interviewees would find it problematic to use such clinical measurements from a consumer-grade device with unclear levels of accuracy.
According to the Encyclopaedia of data systems (Gupta, 2009) the term "data provenance" refers to "a record trail that accounts for the origin of a piece of data (in a database, document, or repository) together with an explanation of how and why it got to the present place."

Much of the literature that addresses trust in data originate from the world of business and marketing. Goranson et al. (2003) present knowledge management and enterprise modelling as key contributors to decision making in business. Fox and Huang (2005) talk about knowledge provenance and propose four levels of classification, based on the nature of knowledge and its relationship with trust: Static Knowledge Provenance (Static KP), the simplest and most robust type of knowledge, Dynamic Knowledge Provenance (Dynamic KP), which are Static KP that change over time, Uncertainty-oriented Knowledge Provenance (Uncertainty-oriented KP), where trust in knowledge is only to a certain degree, and Judgement-based Knowledge Provenance (Judgement-based KP).
Slightly closer to the purpose of this research, Groth, Luck and Moreau. (2004) provide a protocol for the recording of provenance in service-oriented architectures, where two types of provenance information should be recorded: provenance about interactions between actors and provenance about the actors themselves.

2.4.5.2.2.3 Context

When discussing clinician trust in PGHD, it is important to recognize that the term "context" is relative and encompasses various situational and environmental factors that shape clinicians' perceptions and evaluations of using PGHD in their decision-making process. The scope of "context" can vary based on factors such as the healthcare setting, the nature of the clinical decision, the type of PGHD involved, and individual clinician backgrounds and experiences.

Within this scope, it is necessary to distinguish between aspects that affect trust in PGHD as attributes of the data itself, rather than contextual factors. Factors such as quality and provenance fall under the category of attributes of the data, or the trustee, rather than being part of the contextual information surrounding the data. Quality, including accuracy and reliability, can be seen as inherent traits of the data. Provenance, which refers to the source and origin of the data, also falls within the realm of data attributes or trustee.

Contextual factors, on the other hand, pertain to the situational and environmental aspects that surround the clinical decision and influence the clinician's trust in PGHD. These factors may include the level of risk associated with the decision, the availability of guidance and governance mechanisms, availability of other sources of clinical information, the acuity of the situation in which the patient requires a decision being made, etc. They can also encompass geographical variances and cultural considerations that impact clinical decision-making.

Recognizing the relative nature of context is crucial because it emphasizes the need to consider specific circumstances and individual perspectives when addressing clinician trust in PGHD. This understanding underscores the importance of tailoring strategies, guidelines, and policies to suit different contexts and account for the diverse range of factors that influence trust in PGHD among healthcare professionals.

For the purpose of this research, the term 'context' is defined as any information that affects the decision of trust but is not related to either party involved in the decision. For example, metrics related to accuracy, such as sensitivity and specificity of an application in detecting a malignant melanoma, are considered inherent traits of the data (trustee) and thus fall under the concept of quality. Conversely, information like knowing the patient's holiday destination being a sunny location is considered as contextual information within the defined scope of this research.

2.4.5.2.3.1 Environmental or situational influence

As stated in 2.4.5.2, environmental and situational factors form part of the context that affects the decision of trust. The presence of formal regulations, policies, and norms that govern behavior in a particular context can influence the trust decision.

Fukuyama (1996) and Kramer and Tyler (1996) indicate that governance, guidance and policy, by setting the framework within which individuals and organizations operate, directly influences the level of trust people are willing to place in those entities. It does so by providing institutional safeguards, such as laws, regulations, and oversight mechanisms, which can reduce the perceived risk of trusting by ensuring that parties are held accountable. For instance, a well-governed organization with clear policies on ethical behavior and transparency might inspire greater trust among its employees and stakeholders.

In contexts where governance is strong, such as in highly regulated industries like finance or healthcare, the existence of stringent regulations can increase the likelihood of trust. Individuals may be more willing to trust organizations operating within a robust regulatory framework because they believe there are checks and balances in place to prevent misconduct.Therefore, this thesis considers governance as a contextual factor in trust decisions.

2.4.5.2.3.2 Uncertainty

Uncertainty can also be considered a significant contextual factor that affects trust. In the context of trust decisions, uncertainty plays a crucial role in shaping whether and how much trust an individual is willing to place in another person, organization, or system. Mayer, Davis and David Schoorman (1995) and Gambetta (2000) suggest that uncertainty as a contextual factor influences the trustor’s perception of risk and affects the decision of trust, particularly in situations where the outcomes are not easily predictable or where information is incomplete.

The concept of uncertainty was primarily discussed in the context of decision-making and economics. It refers to situations where the probabilities of different outcomes are unknown, incalculable, or unpredictable. It is a state of incomplete knowledge or information about what is expected in the future, which makes it challenging to make precise predictions or assessments.

One of the earliest and notable discussions about uncertainty can be found in the work of John Stuart Mill, a British philosopher and political economist. In his book "A System of Logic, Ratiocinative and Inductive" (Mill, 2013), Mill discussed the concept of induction, which involves making generalizations based on observed patterns and experiences. However, he acknowledged the limitations of induction when faced with uncertain situations, as it is not always possible to draw precise conclusions from past observations when the future is unpredictable.

2.4.5.2.3.2.1 Uncertainty v risk

Later, other economists and thinkers also touched upon the concept of uncertainty in different contexts. However, it was Frank Knight (1921) who provided a more formal and comprehensive treatment of uncertainty in the realm of economics in “Risk, uncertainty and profit”. Knight's work helped to lay the foundation for understanding uncertainty as a distinct and important aspect of decision-making and its implications for entrepreneurship and economic behaviour.

While many authors wrote about uncertainty, it was Knight who pioneered the distinction between risk and uncertainty. Since Knight, many economists and scholars have continued to explore and expand upon the concept of uncertainty, contributing to the field of decision theory, behavioural economics, and risk management. Uncertainty remains a vital topic of study, as it shapes the way individuals, businesses, and policymakers approach decision-making in an ever-changing and unpredictable world.

2.4.5.2.3.2.2 Radical uncertainty

The need for clinicians to make a decision about trust is supported by the understanding that regardless of anyone’s efforts to manage risks, there are some that simply can’t be resolved, measured or mitigated. Kay and King (2020) in “Radical uncertainty: Decision-making for an unknowable future” challenge conventional economic and financial models that assume a world of calculable risks and probabilities, in favour of accepting the inevitability of radical uncertainty. Although Kay and King coin the concept “radical uncertainty”, it is by no means the first time that the concept appears. Taleb (2015) talks about rare, high-impact, and unpredictable events, pointing out the limitations of traditional risk models and the need to account for uncertainty.

2.4.5.2.3.2.3 Uncertainty and Quality control

Uncertainty has also been the base of quality assurance and quality control laboratory techniques in medicine. With the introduction of the ISO 15189 "Medical laboratories - Particular requirements for quality and competence" (Burnett, 2003), outlining specific requirements for quality and competence in medical laboratories, it has become a consensus that laboratories should know the uncertainty of the results they produce in order for them to be clinically usable (Panteghini, 2010). Uncertainty methods like measurement uncertainty (ISO, 1995) can quantify and provide a metric and a classification of uncertainties that make laboratory information clinically useful. In medicine, these techniques are used to the extent to provide an uncertainty budget of the different types of uncertainties, providing more clarity to the information (Djulbegovic *et al.*, 1999; Braga and Panteghini, 2018).

2.5 Acceptance and adoption

In healthcare settings, clinicians often face cognitive overload due to complex workflows, multiple data sources, and time pressures. Technology that is designed to streamline decision-making, reduce cognitive load, and improve usability is crucial for fostering adoption in clinical environments. For instance, improving usability in EHRs and decision support systems has been found to reduce cognitive stress, enabling clinicians to focus on patient care more effectively

(Nazi, Newton and Armstrong, 2024). Lintern and Motavalli (2018) demonstrated that improving the design and usability of healthcare technologies, including EHRs, led to reduced cognitive load, enabling clinicians to complete tasks more efficiently and with fewer errors.

Addressing the need for a structured approach to solve this, the Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh *et al.*, 2003) and the Technology Acceptance Model (TAM)(Davis, Bagozzi and Warshaw, 1989; Dadayan and Ferro, 2005) are two of the most widely applied frameworks for understanding how and why users accept and use new technologies. Both models highlight critical factors influencing user adoption, with perceived usefulness and usability (or ease of use) playing central roles in both.

2.5.1 The Technology Acceptance Model (TAM)

The TAM, developed by Davis (1989), was one of the first theoretical models aimed at predicting user acceptance of technology. TAM posits that two key factors determine the adoption and use of new technologies: perceived usefulness and perceived ease of use. Perceived usefulness refers to the degree to which a person believes that using a particular technology will enhance their performance, while perceived ease of use (similar to usability) refers to how effortless the technology is to use. In clinical settings, perceived usefulness can directly affect whether clinicians see value in incorporating new tools, such as the PGHD Trust Canvas, into their workflows. If clinicians do not perceive that a tool will improve their decision-making or efficiency, they are unlikely to adopt it.

Davis' model has been widely validated and adapted across various fields, including healthcare. For example, studies have shown that healthcare professionals are more likely to adopt technologies that are perceived as useful for improving patient care and are intuitive to use without requiring extensive training

The focus on perceived usefulness is especially relevant in clinical environments where time and resource constraints make it essential that any new technology demonstrably improves efficiency and outcomes. Similarly, usability is critical, as tools that are difficult to use increase cognitive load and detract from patient care.

2.5.2 The Unified Theory of Acceptance and Use of Technology (UTAUT)

UTAUT, introduced by Venkatesh et al. (2003), builds on TAM by incorporating additional factors that influence technology adoption, including social influence, facilitating conditions, and user experience. However, performance expectancy (which closely aligns with perceived usefulness) and effort expectancy (similar to usability) remain key determinants in the model. In healthcare, performance expectancy addresses whether clinicians believe that a new tool, like the PGHD Trust Canvas, will improve their ability to deliver patient care by enhancing data reliability, decision-making accuracy, or workflow efficiency.

UTAUT also emphasizes the importance of effort expectancy, which relates to how easy clinicians find the technology to use. This aligns directly with usability—clinicians are more likely to adopt a tool if they feel it is intuitive and doesn't require significant additional effort to integrate into their existing workflows. In fact, studies show that a lack of ease of use can be one of the primary barriers to technology adoption in healthcare settings. For instance, the complexity of health technologies can detract from the time clinicians spend with patients, negatively impacting both user adoption and patient care.

2.5.3 Perceived Usefulness and Usability in Healthcare Technology

In both models, perceived usefulness and usability are critical for validating new healthcare tools. In the context of the PGHD trust canvas, perceived usefulness assesses whether clinicians believe the tool will help them make more informed decisions regarding the inclusion or exclusion of PGHD in clinical decision-making. If clinicians see a clear benefit in improving the accuracy of their decisions, they are more likely to adopt the tool. Meanwhile, usability ensures that the tool is intuitive and doesn't add unnecessary complexity to their workflow, increasing the likelihood of sustained use in clinical practice.

2.6 Clinical Decision Making

Clinical decision-making today involves synthesizing a vast amount of information from various sources, including electronic health records (EHRs), medical imaging, lab results, and clinical guidelines. Adding PGHD into this already complex mix requires careful consideration of how to integrate it without overwhelming clinicians or complicating decision-making further.

Woolever (2008) reminds his family practice colleagues of the different tools and paths to aid their decision-making process. These decisions are made through a variety of methods, suited to the individual clinician's preference and the case at hand. With emphasis on heuristics, the knowledge and experience of the clinician are at the centre of the process, while leaving room for questioning it. Approaches that are available to assist in the decision-making process include the recognition of patterns, the consideration of probabilities, differential diagnoses, treatment thresholds and even applying the scientific method to the individual case.

Decision trees and decision analysis are also used when decisions are made in situations of low evidence and where clinicians need to rely on their subjective intuition (Aleem, Schemitsch and Hanson, 2008). Examples of these situations can be triage in emergency situations, when clinicians need to make quick decisions without complete information, decision trees help triage patients by visually mapping possible treatments and outcomes. Another example would be in palliative care, in situations where evidence on specific treatments might be lacking (especially for rare conditions), decision analysis helps clinicians weigh different approaches based on both clinical intuition and patient preferences.

To further assist practitioners in making decisions Haynes and Haines (1996) propose a path for evidence to move from research to its use in clinical decision making portrayed in Figure 3. The wedge-shaped "generating evidence from research" represents the rigorous elimination of evidence through testing. Research and practice are joined by three steps required to harness the evidence that passes testing.

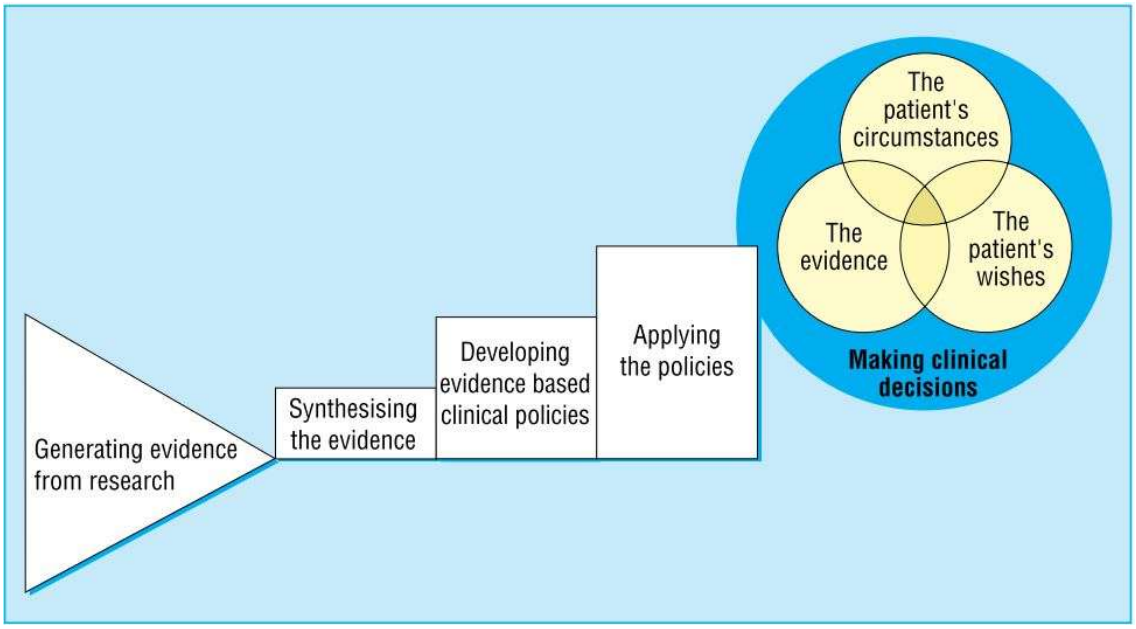


Figure 3 The evidence path from research to decision-making

First there is the synthesis of evidence. This allows readers to avoid the time-consuming task of appraising evidence and resort to libraries like the Cochrane library or electronic equivalents. Second is the creation of evidence based clinical policies. This step includes all relevant research and practical realities of healthcare. Haynes and Haines describe this step as problematic since there are limitations like gaps in evidence and conflicting public health interests. Clinical Practice Guidelines (CPG) are a contention point in healthcare organizations and a focus for criticism based on many factors like paradigmatic, ideological and idiosyncrasy differences at organizational, disciplinary, and national levels. The third step in the link between research and practice is applying the evidence-based policies. This includes training, dissemination, and communication of these guidelines.

At some point in the path described by Haines and Haynes the healthcare system is going to be face to face with the decision whether to include PGHD in or exclude it from the clinical decision process. It would be unrealistic to expect that a doctor would ponder much about the many quality dimensions of data coming from the patient's own device. Unless the clinician is familiar with the technology, the PGHD is not likely to be trustworthy enough to use. Instead, the development of clinical guidelines is perhaps the most suitable point in the process where the decision of inclusion or exclusion of a source of PGHD can be made.

2.7 Chapter summary

This chapter provides a comprehensive exploration of PGHD, beginning with an overview of what PGHD entails. PGHD is defined as health-related data created, recorded, or gathered by patients outside of clinical settings, which includes a broad range of data types such as biometric readings, symptom tracking, and lifestyle information. The document highlights the diversity and complexity of PGHD, stemming from the various devices and applications that patients use to generate this data. The integration of PGHD into healthcare holds great potential for enhancing patient engagement and personalizing care, yet it presents significant challenges.

The review then delves into the specific challenges clinicians face when attempting to adopt PGHD in their practice. One of the primary issues is the difficulty of integrating PGHD into existing clinical workflows. The lack of standardization across different sources of PGHD complicates its use, making it difficult for clinicians to interpret and act on the data. Governance issues also arise, particularly in ensuring the quality and reliability of PGHD, as well as in addressing the legal and ethical implications of using this data in clinical decision-making. Furthermore, clinicians often face challenges in determining the actionability of PGHD, as the data they receive may not always be validated or standardized, leading to uncertainty about its relevance and usefulness in patient care.

Trust is presented as a critical element in the successful integration of PGHD. The document emphasizes that clinicians must assess whether the data they receive is trustworthy, a process that involves evaluating its quality, provenance, and relevance. To facilitate this understanding, the document proposes a framework for trust, which includes three components: the clinician (as the trustor), the data (as the trustee), and the broader environmental or situational context. Data quality and provenance are identified as crucial attributes of PGHD that clinicians must consider. The document emphasizes that data must be accurate, complete, consistent, and timely to be considered reliable. Provenance, or the origin and history of the data, is equally important, as it helps clinicians determine the trustworthiness of the data they are using.

The chapter discusses the importance of contextual factors in shaping clinicians' trust in PGHD. These factors, such as governance, uncertainty, and risk, play a significant role in determining whether PGHD can be effectively integrated into clinical decision-making. The document concludes by emphasizing the need to carefully consider these contextual factors when developing strategies, guidelines, and policies for incorporating PGHD into healthcare practices.

The final section of the review addresses the complexities of the clinical decision-making process, especially when integrating PGHD. Clinical decision-making already involves synthesizing information from various sources, such as EHRs and lab results, and adding PGHD into this mix introduces additional layers of complexity. The document discusses the importance of EBM in guiding clinical decisions and highlights the challenges of incorporating PGHD into an evidence-based framework. The decision to include or exclude PGHD in clinical practice should be carefully considered during the development of clinical practice guidelines, ensuring that the data is reliable and trustworthy for use in patient care.

Chapter 3. Methodology

This chapter provides a high-level view and justification of the methodology principles used in this thesis. The methodology of each of the studies carried out during this PhD work is further detailed within the corresponding chapters for each study.

3.1 Introduction

This chapter commences with a detailed rationale behind the choice of qualitative research in Section 3.2, where we dissect the multifaceted PGHD landscape and the imperative for a methodology attuned to its diverse, unregulated nature. Subsequently, in Section 3.3, the chapter transitions to a discussion on Grounded Theory, shedding light on its suitability and advantages in the context of our study. Building further, Section 3.3.1 delves into the key concepts adopted in this thesis, elaborating on the critical components like thematic coding and constant comparison that underpin our qualitative research. Section 3.4 presents the principles of design used during Study 2 described in Chapter 5. The chapter culminates in Section 3.5 with a conclusion, synthesizing the methodological journey of this thesis.

3.2 Rationale behind qualitative approach

The PGHD landscape is characterized by a multitude of data sources, including wearable devices, mobile applications, social media platforms, and patient diaries. This landscape lacks standardized frameworks and guidelines governing the collection, analysis, and utilization of PGHD (Magrabi *et al.*, 2019). The absence of regulation necessitates a methodology capable of accommodating the diverse experiences, perspectives, and contextual factors influencing trust. Furthermore, much of the literature has been deemed to lack the in depth scrutiny necessary to understand the subjective nature of clinicians' acceptance of decision support systems (Newton *et al.*, 2023). While survey research provides a quantitative approach for data collection, it may not capture the depth and richness of the PGHD landscape and the intricate interplay of factors that influence trust. Similarly, case studies and experimental designs may not fully capture the complexity and variability present in the unregulated PGHD environment. Therefore, a qualitative approach is best suited to explore trust, allowing for flexibility and adaptability to the dynamic and evolving nature of the PGHD landscape.

Trust, as applied to PGHD, is a complex and multifaceted construct that defies precise definition and measurement due to its subjective and context-dependent nature. Trust encompasses factors such as data accuracy, privacy and security, patient engagement, clinical relevance, and perceived benefit. Attempting to capture trust through quantitative measures may overlook the nuanced meanings, interpretations, and contextual influences associated with trust. While survey research provides quantitative data that can derive into solid positivist conclusions, it may not fully capture the intricate interplay of these factors. Alternatively, case studies and experimental designs may focus on specific aspects of trust but lack the depth of qualitative exploration. Thus, a qualitative approach allows for the exploration of trust as a lived experience, unravelling the nuanced meanings, interpretations, and contextual influences associated with trust in PGHD.

Several methodologies were considered for this research, including survey research (Brant *et al.*, 2015), qualitative interviews (Boocock and Grahame, 2003), case studies (Priya, 2020), and experimental design (Cash, Stanković and Štorga, 2016). Survey research was initially contemplated due to its ability to gather data from a large sample efficiently. However, given the elusive and context-dependent nature of trust in PGHD, relying on survey responses may

limit the depth of understanding. Additionally, a mixed methods approach (Shorten and Smith, 2017) was considered for its ability to provide a numeric and therefore pragmatic element to this thesis.

Furthermore, case studies were considered as an option to examine trust in specific healthcare organizations or clinics. However, due to the vast, dynamic, and evolving nature of the PGHD landscape, it may be challenging to generalize findings from a limited number of cases. Experimental design was also contemplated to investigate the causal relationships between specific factors and trust, perhaps through the use of scenario-based interviews. While this approach offers control and manipulation of variables, trust is a complex and dynamic construct influenced by numerous interrelated factors, making it difficult to isolate and manipulate specific variables in an experimental setting. Furthermore, creating scenarios that would challenge clinicians would certainly prove impracticable. Therefore, the qualitative approach emerged as the most appropriate methodologies for this study, considering the unregulated and non-standardized nature of the PGHD landscape and the elusive, vague, and ambiguous nature of trust.

In light of the unregulated and non-standardized nature of the PGHD landscape and the elusive, vague, and ambiguous nature of trust, a qualitative approach is the most suitable methodology for this study. This approach allows for a flexible and deep exploration of trust within the diverse PGHD landscape, capturing the nuanced meanings, interpretations, and contextual influences associated with trust. Concentrating on qualitative data methods, this research aims to provide a comprehensive understanding of the multifaceted factors influencing trust in PGHD. While alternative methodologies, such as case studies and experimental design, were considered, they were found to be less suitable for capturing the complexity and variability present in the PGHD landscape and understanding trust in its entirety. The chosen methodology aligns with the research objectives and aims to contribute to the advancement of knowledge in this critical area of healthcare.

3.3 Grounded Theory

Taking grounded theory as the main approach is particularly well-suited for this study due to its unique advantages. It excels when researchers aim to develop new theories or concepts grounded in the data itself, enabling the discovery of emergent ideas and concepts (Glaser and Strauss, 2017). This approach is adaptable and versatile, making it suitable for researchers across various disciplines and research topics (Charmaz, 2014). Grounded theory encourages researchers to delve deeply into their data, facilitating a thorough exploration of phenomena, and emphasizes a holistic understanding of social processes and contexts, aligning well with the nuanced and multifaceted nature of trust (Strauss and Corbin, 1998). Furthermore, grounded theory research often yields findings with practical applications, addressing real-world issues (Birks and Mills, 2015). Given that clinicians are constantly making trust judgments regarding patient-generated data, grounded theory can provide valuable insights and guidance in this decision-making process (Hederman, Berry and Ormazabal, 2023). Lastly, grounded theory's iterative nature aligns seamlessly with patient-centred design principles, involving an iterative process of data collection and analysis that allows researchers to refine their theories and concepts as they gain a deeper understanding of the data.

The chosen grounded theory methodology aligns with the research objectives and aims to contribute to the advancement of knowledge in this critical area of healthcare, particularly due to its constructivist and flexible nature.

3.3.1 Key concepts adopted in this thesis.

The concepts of thematic coding, constant comparison, theoretical sampling, and saturation are key components of qualitative research methodologies, especially in approaches like grounded theory. Together, these concepts are fundamental in ensuring that qualitative research is systematic, thorough, and grounded in actual data, rather than being purely speculative or anecdotal. In this research they provide a framework for collecting, analysing, and interpreting data in a way that is rigorous and theoretically sound, which is crucial for the validity and reliability of qualitative research findings.

3.3.1.1 Coding

Thematic coding (Braun and Clarke, 2006) is a process used in qualitative research to identify and analyse patterns or themes within data. It involves closely examining the data, which can be text, images, or other forms of data, to identify recurring ideas or concepts. These are then labelled and categorized to facilitate in-depth analysis. This process helps researchers to organize and interpret data in a way that is meaningful and relevant to their research questions.

Thematic coding in this research was carried out in the studies detailed in Chapter 4, Chapter 5, and Chapter 6 to unveil the key themes of each of the interviews. The software used to create a codebook of the recorded interviews was NVivo12®.

3.3.1.2 Constant comparison

Constant comparison (Glasser and Strauss, 1999) is a core technique in grounded theory methodology. It involves comparing all aspects of the data throughout the research process. As new data is collected, it is continuously compared with existing data to identify similarities and differences. This ongoing process helps in refining and developing categories, and in building a robust theoretical framework. Constant comparison ensures that the emerging theory remains grounded in the data and evolves with the collection of new insights.

3.3.1.3 Theoretical sampling

Unlike statistical sampling used in quantitative research, theoretical sampling (Glasser and Strauss, 1999) in qualitative research involves selecting participants, cases, or data based on the emerging theory. The choice of what or whom to sample next is guided by the developing theory, with the aim of exploring and expanding on the concepts and relationships that are being identified. This sampling continues until no new insights are being gained, which leads to the concept of saturation.

3.3.1.4 Saturation

In qualitative research, saturation (Wuetherick, 2010) occurs when additional data no longer contribute to new insights or further development of the theory. It is a key criterion for judging the adequacy of data collection in qualitative research, especially in grounded theory. Reaching saturation implies that the data are sufficiently comprehensive to explain the phenomena of interest and that the emerging theory is well-developed and grounded in the data.

3.4 Co-Development

Chapter 5 of this thesis details the development of the PGHD trust canvas, a tool that helps clinicians evaluate and decide whether they should trust or distrust PGHD based on many factors, including quality, provenance, risk, governance, etc. The methodology followed for the development of the tool closely followed the co-development approach advocated by Marc Berg in his seminal work on healthcare technology design (Berg, 1999). Berg's methodology emphasizes that the success of healthcare technologies lies in their ability to integrate into the

complex socio-technical environment of clinical practice. This informed the decision to involve clinicians in the co-development process, ensuring that the PGHD trust canvas was both relevant and easy to use.

One of the key insights from Berg's framework is the importance of practical integration. Healthcare is an intricate ecosystem, where new technologies must enhance, rather than disrupt, clinical workflows. By engaging with clinicians from the outset, the development of the PGHD trust canvas was guided by their practical needs, ensuring the tool was intuitive and fit seamlessly into their decision whether to trust PGHD. This collaborative process ensured that the canvas directly addressed the clinicians' concerns about PGHD, such as quality and provenance, and risk.

Iterative design for usability was another central principle derived from Berg's co-development guidance. Through repeated cycles of testing, feedback, and refinement, the PGHD Trust Canvas evolved in response to real world input from healthcare professionals. This iterative approach allowed for constant improvements to the tool's usability in response to feedback, ensuring that the final product was aligned with the clinicians' needs, easy to use, and suitable to different clinical contexts.

Lastly, Berg's framework underscores the necessity of designing for complex healthcare needs. Healthcare is not a uniform field; it involves a wide range of technical, social, and organizational challenges. Applying this principle ensured that the PGHD trust canvas would be flexible and adaptive, addressing the varied requirements of different clinicians and contexts. The tool was designed to provide clinicians with clarity in evaluating PGHD across diverse settings, which is essential given the range of data sources and patient conditions involved in modern healthcare.

3.5 Chapter summary

In this chapter, we have extensively discussed the methodological framework adopted in this thesis, focusing on the exploration of trust in the context of PGHD. The decision to employ a qualitative approach is a testament to the complexity and dynamic nature of trust in the PGHD landscape. This approach, characterized by its flexibility and depth, is particularly suited to address the intricate and multifaceted aspects of trust in an environment marked by the absence of standardized frameworks and guidelines.

The qualitative methods approach enables a comprehensive understanding of trust, capturing the qualitative nuances and contextual factors at a level of depth that best serves the clinician in their decision whether to trust or distrust PGHD. This is crucial in this context, where trust is not only about data accuracy and security but also encompasses broader issues like patient engagement and clinical relevance. The chosen methodology allows for a more holistic exploration of these factors, ensuring that the research remains grounded in the actual experiences and perceptions of clinicians and patients.

The adoption of grounded theory further strengthens the research methodology. Its iterative nature aligns well with the dynamic landscape of PGHD, allowing for the continuous refinement of theories and concepts as more data is gathered and analysed. Grounded theory's focus on developing new theories from the data itself is particularly advantageous in an area like PGHD, where pre-existing theories may not fully capture the complexity of the trust decision.

Key concepts such as thematic coding, constant comparison, theoretical sampling, and saturation have played vital roles in ensuring that the research is systematic, rigorous, and

grounded in empirical data. The use of NVivo12® for thematic coding has facilitated an organized and detailed analysis of the qualitative data, enhancing the reliability and validity of the findings.

By basing the development of the PGHD trust canvas on Berg's co-development methodology, I ensured that the tool was built with the practical, social, and organizational realities of healthcare in mind, providing a clear, easy to use framework for clinicians to evaluate and integrate PGHD into their practice.

In conclusion, the methodological choices made in this thesis – a combination of qualitative, grounded in grounded theory principles, inclusive design, and employing key qualitative research techniques – ensure a robust and comprehensive exploration of trust in the context of PGHD. This approach not only aligns with the research objectives but also significantly contributes to the advancement of knowledge in the critical area of healthcare, specifically in the understanding and management of PGHD. The findings of this research have the potential to inform future policies, guidelines, and practices, ultimately enhancing the utilization and acceptance of PGHD in clinical settings.

Chapter 4. Clinician Perspective on Trusting PGHD

4.1 Introduction

This chapter presents Study 1. Within the structure of this thesis, Study 1 addresses the first objective (O1.a intended to identify and understand the main factors that affect clinician trust in PGHD and part of sub-research question 1 (SRQ1) which questioned the current state of the art on clinician trust in PGHD and partially sub-research question 2 (SRQ2), which questioned how healthcare providers can evaluate PGHD for its use in making clinical decisions.

While technological innovations like PGHD have the potential to transform personalized healthcare, clinicians have been slow to fully embrace these tools. A key reason for this hesitation is the lack of trust many clinicians have in the quality, reliability, and usefulness of PGHD for informing clinical decisions. Informal discussions with clinicians before this study revealed concerns about the quality control of PGHD technologies, the uncertainty surrounding the data's sources, and the risks of using potentially inaccurate data in patient care. These concerns contribute significantly to the non-adoption of PGHD in clinical decision-making. Recognizing the pivotal role trust played in the adoption of EHRs, this study draws parallels, seeking to unearth similar underpinnings in the realm of PGHD.

The study employs an exploratory qualitative approach, utilizing in-depth interviews to capture the multifaceted nature of clinicians' trust in PGHD. This methodology, outlined in section 4.3, is pivotal in transforming interview data into profound knowledge, shedding light on the barriers and facilitators influencing clinicians' trust in PGHD.

Within the methodology section, section 4.3.2 details the process of recruitment, section 4.3.3 details the data collection process, section 4.3.4 defines the inclusion criteria, and 4.3.5 data analysis. The results of this study, presented in Section 4.4, emerge from the voices of clinicians themselves, revealing themes of governance, quality, provenance, and the contextual factors influencing their trust in PGHD. The implications of these results are discussed in further detail in section 4.5.

This study was published in the proceedings of IEEE 36th International Symposium on Computer-Based Medical Systems (CBMS) in June 2023.

4.2 Overview

This study aimed to explore the factors influencing clinicians' trust in PGHD for clinical decision-making. While PGHD offers the potential to transform personalized healthcare by incorporating real-time patient data, its adoption has been slow, largely due to clinicians' concerns about the reliability and quality of the data. This research seeks to identify the key barriers that prevent clinicians from fully trusting and utilizing PGHD, drawing on qualitative insights gathered from interviews with healthcare professionals. Understanding these barriers will help inform the development of tools and strategies to increase the effective use of PGHD in clinical practice.

Informal conversations between the researcher and key expert informants revealed that lack of understanding of the quality assurance processes behind PGHD-generating technologies; lack of familiarity with the institutions behind these technologies; and the risk of harming patients due to the inclusion of unsuitable data in the clinical decision-making process, may be key aspects to clinician trust in PGHD.
Furthermore, limitations in quality assurance (West *et al.*, 2017; Abdolkhani, Borda and Gray, 2018), governance frameworks (Cresswell *et al.*, 2018) and general trustworthiness (West *et al.*,

2018) have been identified as common barriers to the adoption of PGHD for clinical decision-making.

The topic of clinician trust in patient's information is little discussed in the literature (Papautsky and Panganiban, 2018), particularly when addressing possibly disruptive digital interventions. This may be an indication that the topic is complex, but also that it is of a somewhat sensitive nature to clinicians since they might be reluctant to admit that their trust in patients is limited, presenting a conflict with bioethics principles. It can also be an indication that a large proportion of clinicians are simply not interested in the psychosocial aspects of their trust in PGHD.

This study uses one explorative and informative round of interviews to understand the main barriers to trust in the adoption of PGHD for clinical decision-making. These interviews informed the development of the second study in this thesis (see Chapter 5), which develops a reflection tool to aid clinicians in deciding, and at least partially, justifying whether to include or exclude a source of PGHD for their clinical decisions. Qualitative methods of analysis are used to convert the interview data into knowledge.

4.3 Methods

4.3.1 Study design

This study has been designed as an exploratory qualitative study on HCP's perspective of the key factors that influence trust in PGHD. Online semi-structured in-depth interviews were carried out using questions based on the extensive literature review described in Chapter 2 on the concepts of PGHD, its potential and key challenges to trust in PGHD for clinical decision-making.

4.3.2 Recruitment

Participants were recruited using Snowball sampling (Browne, 2007) with one participant identified due to their interest and experience working at a management level in an Irish hospital. Exponential snowball sampling can address the difficulties in recruiting participants with an interest in the topic, and that have invested some time in considering their stance on trusting patients generated information. Participants were asked to propose at least one main referral and one backup if possible. They in turn were asked for referrals of clinicians who also have an opinion on PGHD and/or some involvement in projects regarding new ways to deliver healthcare. These can include nurses, physicians and other clinical staff that may have seen examples of PGHD in their practice. Each referring participant needed to consent that their name is mentioned only for the purpose of contacting the referred participant. 14 participants were recruited for this study, although on completion of interview number 3, it was decided to exclude it, since the clinician did not meet the inclusion criteria.

4.3.2.1 Ethics approval

Ethical approval for this study was granted by the Research Ethics Committee in the School of Computer Science and Statistics of Trinity College Dublin.

4.3.3 Data collection

The study consisted of semi-structured interviews lasting between 20 and 40 minutes. Each participant was informed in advance of the topics to be discussed to make the best use of the time allocated. The interviews were audio recorded, and the recordings were transcribed a posteriori. Participants were made aware of their right to decline at any point before, during or after the interview. They also were made aware of their right to decline referring further participants.

Participants were given the choice of declaring their professional status and asked if their responses could be used in direct quotation without mentioning their identity or any other identifiable details. At the end of each interview, they were asked for one referral to the next participant and one referral to a backup participant.

4.3.4 Inclusion criteria

Participants were clinicians who have been exposed to or presented with some form of PGHD in their practice and have formed an opinion on whether PGHD should be included in their clinical decision process.

4.3.5 Data analysis

The interviews were audio recorded, transcribed, and analysed using NVivo12® software. The data collected was analysed using Grounded Theory (Charmaz, 2001). The thematic coding process took place in three stages. The first stage comprised of open, line by line coding, where every statement was assigned to a code or where no existing code was appropriate, a new code was created. The second stage was axial coding, where the existing codes were grouped into domains and subdomains. As a third and final stage, the recognition of themes was finalised and organised into themes.

4.3.6 Interview guide

The interview guide was designed with flexibility and concisiveness in mind. The questions were structured in a way that clearly directed the participant to reflect on the key factors that affect trust that became evident in the literature review described in 2.4.5 (See Table 2). The follow up questions are designed to continue to guide conversation with the participant towards the intended topic, whatever the initial answer would be.

Table 2 Interview guide for Study 1

Patient Generated Health Data (PGHD) is any data related to a patient's health that has been recorded, gathered, or inferred by the patient or on their behalf. The main difference between PGHD and clinical data is that it is the patient who is responsible for, and in control of the data. Have you ever used PGHD to inform a clinical decision?	
YES	NO
Can you share some information about the context and results of that decision?	Have you ever encountered PGHD in a clinical setting?
What gave you the confidence that you could use this data to help making the decision? • Would you say you trusted the source enough in this case? • Why?	(YES) What stopped you/ (NO)Would stop you from including that data in your decision-making process? • What would it take for you to feel confident using PGHD? • Why?
Would you do it again in similar circumstances? • Why? • What would make PGHD more trustworthy in this case?	Do you think there is a place for PGHD in clinical decision-making? • What would make PGHD closer to being trustworthy? • Are there any circumstances where hypothetically PGHD can be used in your opinion?

How likely are you to try or become familiar with other sources of PGHD? • Why? • What would be the main things you would be looking for in a source of PGHD to even consider using it in clinical decision?	What do you think could be the negative consequences of you including PGHD in your clinical decision-making process? • What are the main barriers for clinicians to adoption of PGHD for decision-making in your opinion?
Do you know of any explicit or implicit guidance in your institution regarding the use of PGHD?	
If you were in a situation where the only data you have at hand is generated by the patient and a decision can't be delayed, would you say that it would justify using PGHD alone?	

4.3.7 Ethics approval

Ethical approval was sought from the Research Ethics Committee at the School of Computer Science and Statistics in Trinity College Dublin. Approval was granted on 23rd of September 2022 (See 10.1).

4.4 Results

A total of 21 clinicians were invited to participate, of which 13 accepted the invitation before saturation was achieved. The majority of participants (N=11) were clinicians living and practising in Ireland, while the remaining 2 were living and practising in the Unites States. The professional distribution of the participants is as follows:

- Nursing (N=5)
- Physiotherapy (N=2)
- Pre-hospital care (N=2)
- General practice (N=3)
- Mental health (N=1)

As outlined in Chapter 3, this section presents the findings of a thematic analysis based on interviews with 13 clinicians, which took place between October and December 2022. Each interview lasted approximately 40 minutes, and participants were recruited via snowball sampling. Clinicians included a range of healthcare providers who were in regular contact with patients and made clinical decisions based on various sources of health data, including PGHD.

Thematic analysis of the interview data, following the stages of open and axial coding described in Chapter 3, revealed one overarching theme named "General", that includes instances where clinicians are exposed to PGHD in their clinical practice, and the general impression of the clinician's placement of PGHD within their current clinical decision process. This initial theme is followed by four specific themes that influence clinician trust in PGHD:

- General
- Guidance, Governance, and Regulation
- Quality
- Provenance
- Contextual Factors

The codebook in Table 3 summarizes the themes that emerged from the axial coding stage of the analysis of the data gathered. The five themes are described in detail in the following sections.

4.4.1 General

During the interviews, participants were first asked whether they had been presented with unsolicited PGHD by their patients. The majority of clinicians (10 out of 13) reported that patients had brought PGHD to their attention during appointments. Of the remaining three participants, one followed a policy of not using PGHD, another stated that patients did not bring PGHD but that they prompted patients to share it, and the last participant had not encountered PGHD or considered it a concern.

After confirming their familiarity with PGHD, clinicians were asked about their use of PGHD in practice. Eight clinicians reported that PGHD was most commonly used as part of a patient's account of symptoms. One participant explained:

> *"So that would be one where patients would often come to me and kind of say, 'Oh well, I was only doing 3000 steps a day, and now I'm doing 6000 steps a day, so I feel I'm getting better.' I would be very comfortable with accepting that."*

4.4.2 Guidance, governance, and regulation

All participants that were asked, nine in total, agreed that there is little or no guidance on the inclusion or exclusion of PGHD to support their clinical decision-making.

> *"I mean there are some guidelines, but not... I mean the data that you are going to trust or not depends on your clinical judgment."*

Also, five interviewees mentioned the need to make decisions whether to include or exclude PGHD from the clinical decision process.

> *"… even though the patient doesn't always understand that we're very quickly filtering out what's not useful to us and what is"*

4.4.3 Quality

Thematic analysis of the data revealed that quality is a theme in the concerns mentioned by clinicians when deciding whether to trust or distrust PGHD. Accuracy was a major concern among the interviewees. seven clinicians explicitly mentioned accuracy when asked about what it takes for them to trust PGHD.

> *"Or if you're trying to monitor them, you know, like remote monitoring, you need to be confident that whatever is monitoring is doing is calibrated is correct, is accurate."*

Clinicians also mentioned the need to see evidence behind the PGHD technology. Six clinicians mentioned scientific evidence as a factor in the decision whether to trust or distrust.

> *"Actually, because it's new. And so, there would have to be a certain length of trials, and if you could prove that it it's sensitive and specific, being what you're trying to measure, that would be one stage of it."*

Another aspect of quality mentioned by five clinicians is that the technology as an intervention or a diagnostics tool may not be clinically adequate for every patient.

"So, with the fitness trackers sometimes I know my own Fitbit, it can be kind of coaching you a little better or kind of going "Oh, you need to take more steps you need to take more steps" so I would coach my patients as to what is appropriate for them."

4.4.4 Provenance

As presented in section 2.4.5.2.2.4 of the literature review in Chapter 2, data provenance refers to the origins and history of data, including information about its creation, processing and handling (Jo Deering, 2013). Data that possesses known and verifiable provenance is logically more likely to be trusted than data with unknown or questionable provenance.

Provenance, as an influential factor to clinician trust emerged from the analysis of the interviews, but heavily weiging the human side of the data provenance. Clinicians will take into account the trustworthiness of the individual, the organization behind the PGHD, and whether the technology used to collect PGHD is prescribed or preapproved.

Six out of 13 clinicians mentioned that they would trust the data if the initiative for the patient collecting the data came from the clinicians' side, rather than the patients.

Clinicians considered that the trustworthiness of the patient, whether related to their capabilities or intentions, is an important factor that affects their trust in PGHD. Most participants mentioned that understanding the patient's intentions will affect their decision whether to include or exclude PGHD.

"First of all, if there's any legal case pending this current presentation of symptoms on day one with that patient. And then we would also like to know if a patient is off work, for example response of a disability allowance or if there's any potential for kind of secondary gain."

Four participants mentioned that the patient's capabilities also have an effect on the clinicians' likelihood to include or exclude PGHD from their decision process.

"…is kind of the comfort of knowing that the device is reliable as much as the patient is reliable in giving you the information."

4.4.5 Contextual factors

In Section 2.4.5.1 the conceptual framework includes as one of three main actors in the decision of trust as the context. Contextual factors in the conceptual framework includes, but is not limited to environmental or situational influence, uncertainty and risk. The contextual factors mentioned in the interviews are related the risk to patient safety, and the necessity to use the PGHD, which was discussed as a situational factor of influence.

In terms of risk, the main theme that emerged is that PGHD could be used if the severity of the consequences of decisions based on the PGHD is low.

"So, if it was just for something like blood pressure monitoring and if there wasn't a critical care element to it, I would take into account that information when it was normal, and it was not life critical."

Also, one participant mentioned the risk of liability when making a decision using unconventional sources of data.

"So, like if I screw up or I take off the wrong lesion, or if I misdiagnose somebody, I'll be the one losing my license and in court. So, I think a lot of doctors and nurses (…) we're very

conscious of that. We do tend to err on the side of caution and that's why we don't 100 percent trust the technology."

The necessity to use PGHD, usually due to extraordinary circumstances, has proven to be a factor in the decision to trust PGHD. Three clinicians mentioned that COVID-19 was a large determinant in the decision to include PGHD technologies in their clinical decision process.

"But we had to do it because they couldn't come into the department because diabetes patients were at such high risk of catching COVID. And our sickest patients that were in ICU during COVID were diabetic patients. So, we had to look at another way of still managing our cohort of patients safely and communicating with them."

Table 3 Codebook for Study 1

Results		**No of interviews**	**13**
Theme name	**Description**	**Participants that mentioned it**	**% of participants that were asked**
	General		
Exposure to PGHD	These are examples of patients bringing their PGHD to the consultation room because they want it to be included.	10	77%
PGHD is the Patient's account	Situations where clinicians see PGHD as a part of the patient's account of symptoms, but with the added value of some objectivity.	8	62%
	Guidance, Governance and Regulation		
Lack of guidance	Clinicians responding that they are not aware of any guidance relating to trusting or including PGHD in the clinical decision process.	9	100%
Clinicians ponder upon PGHD	These are references to the decision whether to include or exclude, that clinicians must face when seeing PGHD or any kind of information.	5	38%
	Quality		
Accuracy	Examples of clinicians mentioning accuracy as an important part of trusting and including PGHD.	7	54%
Evidence	These are examples of clinicians mentioning that to use PGHD in the clinical decision process, first they want to see that there is evidence to prove the effectiveness and/or efficacy and other quality aspects.	6	46%
Clinical adequacy	These reference to circumstances where the data is adequate to the needs of the clinician, based on the context of the decision to be made.	5	38%
	Provenance		
Prescribed PGHD is trustworthy	These are examples of circumstances where the clinician is comfortable with the PGHD, because it is initiated on the clinician side.	6	46%

Results		No of interviews	13
Theme name	**Description**	**Participants that mentioned it**	**% of participants that were asked**
Patient's intentions	These are examples of clinicians mentioning that they want to know the patient's intentions when deciding whether to trust any information that comes from the patient.	7	54%
Patient's capabilities	These are situations where the capability of the patient in creating trustworthy data is mentioned as a factor for trusting information coming from the patient.	4	31%
Organization behind the tech	These are examples of clinicians being more inclined to trust data with provenance from reputable companies	5	38%
Familiarity with the technology	These are mentions where the lack of familiarity with the technology can make it difficult for a clinician to trust it and include it in the clinical decision process.	8	62%
Patient's subjectivity	These are mentions about clinicians being concerned about data that is being biased by the patient's subjectivity or situations where there is no way to measure something subjectively. This would be ambiguous and vague	5	38%
Contextual factors			
Severity of consequences	These are references of PGHD being used in low-risk context.	5	38%
Need to use PGHD	Mentions of situations where PGHD appeared as a solution to a problem.	3	23%

4.5 Discussion

4.5.1 Guidance, governance, and regulation

Effective governance mechanisms can help ensure that PGHD is of sufficient quality and reliability to be used in clinical decision-making and can provide reassurance to clinicians that PGHD is being used in a responsible and ethical manner (De Lusignan *et al.*, 2014). One important aspect of governance in the context of PGHD is the establishment of clear standards for data quality and reliability. This can include guidelines for how data should be collected and reported, as well as quality control mechanisms to ensure that the data is accurate and reliable. Additionally, governance mechanisms can help ensure that PGHD is integrated into the clinical decision-making process in a responsible and effective manner, and that clinicians are trained on how to use PGHD appropriately.

The need for guidance and governance extends to the decision clinicians have to make about whether to trust or distrust PGHD (Patel, Asch and Volpp, 2015). The results of this research suggest that this need is still present and that such guidance would be welcome by clinicians. This is of particularly sensitive nature when addressing concerns of liability.

4.5.2 Quality

Unsurprisingly, quality was voiced as a major determinant in the likelihood of a clinician to trust PGHD. In the same way that clinical decision support use GRADE (Guyatt *et al.*, 2011), or the QUADAS (Whiting *et al.*, 2003) tools to assess the quality of health information, assessing the validity of PGHD is likely to require a similar tool. Although great developments have been made, like the publication of ISO's technical specification CEN ISO/TS82304-2 (ISO, 2021), the results of this Study 1 suggest that the ultimate decision whether to trust or distrust any piece of information still falls under the clinical judgement of the healthcare provider.

4.5.3 Provenance

Understanding the provenance of PGHD can help clinicians assess the data's quality and reliability. If patient-generated health data comes from a trusted source, such as a well-known and established health app, and has been collected and processed in a transparent and accountable manner, clinicians are more likely to trust the data and use it to inform their decision-making (De Lusignan *et al.*, 2014).

Another major aspect of provenance is the knowledge clinicians have of their patient. Clinicians often have an established relationship with their patients and may have a good understanding of their medical history, current health status, and behaviour. If a patient-generated health data aligns with the clinician's existing knowledge of the patient, the clinician may be more likely to trust the data and use it to inform their decision-making. If, however, the patient-generated health data contradicts the clinician's existing knowledge of the patient or seems inconsistent with the patient's medical history, the clinician may be more sceptical and may seek additional information or testing to confirm or refute the PGHD (Cohen *et al.*, 2016). This is consistent with the results of this research.

Clinicians' understanding of data provenance differs from its technical definition used in IT. Instead, clinicians focused on non-technical aspects, such as the intentions and capabilities of the patient, and whether the data were "prescribed" by a clinician. This human-centered view of provenance influenced trust more than the technical specifics of data generation.

In addition, the interviews found that the clinician's perception of the patient's reliability and credibility can also affect their trust in PGHD. If the clinician trusts the patient and believes that they are providing accurate and reliable information, they may be more likely to trust the PGHD.

4.5.4 Risk

When clinicians prioritize patient safety, they usually closely link their perception of data quality with the risk of harming the patient. During the interviews, it became clear that if the risk associated with using the PGHD is high, such as in cases where the PGHD is likely to lead to a significant deviation from standard clinical practice or a significant adverse outcome, clinicians may be less likely to trust PGHD. Conversely, acknowledging and putting the PGHD in a place within the clinical decision process that bares a comfortable level of risk, seemed acceptable. It is this type of integration between logic and intuition that Kim and Lee talk (2018) about in their article about clinicians coping with uncertainty.

4.5.5 Necessity

The necessity of using PGHD can be an important contextual factor in clinicians' willingness to trust PGHD to make clinical decisions. Examples of telemedicine in remote areas have shown that, particularly with chronic illnesses, the adoption of PGHD is fundamentally driven by the necessity of delivering healthcare to inaccessible areas (Siminerio *et al.*, 2014). Although the case of a small European country like Ireland seemed unlikely to present a scenario of similar inaccessibility, the COVID-19 pandemic proved otherwise. Some participants in this study have experienced this need and furthered their adoption of PGHD into their clinical decision process.

4.5.6 Limitations

This section outlines the key limitations encountered in the first study of this research, particularly focusing on the methodological challenges posed by the use of grounded theory and snowball sampling. While both approaches offered valuable insights into the data and participant recruitment, they also introduced potential concerns related to researcher bias, subjectivity, and generalizability. Despite efforts to mitigate these limitations, it is important to acknowledge the inherent constraints of these methods and their impact on the study's findings.

4.5.6.1 Grounded theory

Grounded theory is a widely-used qualitative research method that emphasizes the inductive development of theory from data. While this approach has several advantages, it is not without its limitations. Grounded theory heavily relies on the skills and experience of the researcher to collect and interpret data. This can lead to issues with subjectivity and bias on behalf of the researcher. This research is particularly affected by this as only the PhD student recruited, interviewed, transcribed, and initially coded the transcripts. Analysis, however, was carried out by the PhD student and both supervisors.

Glaser and Strauss (Glaser and Strauss, 1999) note that the researcher must constantly engage in "theoretical sensitivity" in order to recognize and develop concepts that are grounded in the data, but also caution that this sensitivity can be influenced by the researcher's personal biases and assumptions. For this study, great efforts were made to reduce the effect of researcher dependence.

Grounded theory studies are typically focused on specific research settings or populations, which can limit their generalizability to other contexts or populations. This can make it difficult to draw broad conclusions or develop theories with wide applicability. Glaser and Strauss argue that this limitation is not necessarily a weakness of grounded theory, but rather a natural

consequence of the approach. Participants in this study are from multiple disciplines, at different clinical levels and from multiple countries, some of which spoke English as a second language. This means that while grounded theory is typically limited in its generalizability due to its focus on specific contexts, the diversity of your study's participants may help mitigate this limitation to some extent, providing a broader base for the development of a framework.

4.5.6.2 Snowball sampling

Snowball sampling is a type of non-probability sampling in which participants are recruited through referrals from other participants (Browne, 2007). While this approach can be useful in some contexts, it is not without its limitations when used in qualitative research interviews.

There is potential for issues like sampling bias, since participants are recruited through referrals, the sampling may not be representative of the population of interest. Participants may be more likely to refer others who share their perspectives and experiences, which could lead to an over-representation of certain points of view. As an attempt to mitigate this, while requesting referrals, the researcher clarified that the next candidate/s don't necessarily need to share their views.

4.6 Chapter summary

In conclusion, the study provides clinicians' perspectives on the key factors that influence their trust in PGHD for clinical decision-making. The study identifies four main themes: guidance, governance, and regulation; quality aspects of the information; the provenance of the PGHD; and the context of the clinical decision. The study reveals that there is little or no guidance on the inclusion or exclusion of PGHD to support clinical decision-making, and clinicians need to make decisions about whether to include or exclude PGHD from the clinical decision process. The accuracy of PGHD was identified as a major concern among clinicians, and they also emphasized the need to see scientific evidence behind the technology used to collect PGHD. The trustworthiness of the individual, organization behind the PGHD, and technology used to collect PGHD also emerged as key factors that influence clinician trust in PGHD.

The findings of this study provide insights into the factors that influence clinician trust in PGHD, which can be used to develop guidelines and policies for the use of PGHD in clinical decision-making. The results also highlight the importance of ensuring the accuracy and quality of PGHD and the need for further research to establish scientific evidence to support the use of PGHD in clinical decision-making. Future studies could also explore the perspectives of patients on the use of PGHD and how they can be engaged in the decision-making process. Overall, the study contributes to the growing body of literature on the use of PGHD in healthcare and can inform the development of strategies for the effective and safe use of PGHD in clinical practice.

Chapter 5. Co-development of the PGHD trust canvas

Having established the factors which impact on decisions to trust PGHD from the literature review in Chapter 2 and from interviews with clinicians in Chapter 4, this chapter describes the development of a tool to help clinicians decide whether they trust or distrust the various types and sources of PGHD for its use in the clinical decision-making process.

This addresses O3 (*Develop a tool to help clinicians with the decision whether to include or exclude PGHD from their clinical decision process*) and SRQ3 (*What type of decision support tool can be developed to support healthcare providers facing the decision whether to trust PGHD for its use in clinical decision-making process?*).

This co-development study was published in the proceedings of IEEE 37th International Symposium on Computer-Based Medical Systems (CBMS) in June 2024.

5.1 Overview

Building on the insights gained from the previous chapter on clinicians' perspectives regarding the factors that affect their trust in PGHD, it is evident that while the use of PGHD in clinical practice is not unknown, providing a framework for the thought processes through which clinicians decide whether to trust or distrust PGHD presents significant challenges. One of the primary concerns highlighted was the need for reliable and standardized methods to assess the trustworthiness of PGHD. Given the increasing prevalence of PGHD and its potential to enhance patient care, developing a systematic approach to evaluate this data is crucial. This follow-up study aims to address this gap by co-developing a tool that clinicians can use to make informed decisions when considering PGHD for clinical decisions.

Clinical decision-making is a complex process that involves the integration of multiple sources of information, including patient history, physical examination, diagnostic tests, and clinician experience. However, the information used to make these decisions is often ambiguous and vague, making the process even more challenging. For instance, patient symptoms may be nonspecific, diagnostic tests may be inconclusive, and clinical guidelines may be ambiguous or conflicting. Moreover, patients may have comorbidities, allergies, or other medical conditions that complicate the decision-making process. In such situations, clinicians need to rely on their clinical judgement, experience, and expertise to make informed decisions that optimize patient outcomes while minimizing the risk of adverse events. Clinicians also have to use their clinical judgement when deciding upon the trustworthiness of the data they are going to use. This applies to all the clinical data they use, including, and perhaps particularly PGHD.

A validated tool to evaluate and decide upon the trustworthiness of PGHD could aid clinicians in making informed decisions on the PGHD, allowing them to confidently use or disregard it. This study describes the co-development of such a tool.

5.2 Objective

The objective of this study is to co-develop an advanced prototype of a tool to help clinicians decide whether to trust or distrust PGHD. This chapter describes in detail the iterative process of development of the PGHD Trust Canvas.

5.3 Methodology

5.3.1 Recruitment

Participants were recruited from a list of clinicians who had shown interest in the subject in the past. The contact was made through email and participation was strictly voluntary.

5.3.1.1 Inclusion criteria

Participants were clinicians who had been exposed to or presented with some form of PGHD in their practice and had formed an opinion on whether PGHD should be included in their clinical decision process.

5.3.1.2 Study period

The interviews took place between the 5th of September and the 20th of December of 2023.

5.3.1.3 Ethics approval

Ethical approval for this study was granted by the Research Ethics Committee in the School of Computer Science and Statistics of Trinity College Dublin on the 30th of August 2023 (See 10.2) .

5.3.2 Data collection

The interviews took place over Zoom video conferencing. The conversations were recorded and transcribed using online MS Word. Notes were taken during and after each interview and a summary was compiled after each interview. A list of suggested meaningful modifications was made after each iteration and the prototype was also modified accordingly after each iteration.

At the beginning of the interview participants were given an overview of the design, how it was inspired by the Ethics Canvass, and thoroughly explained the concept, objectives and aims of the tool. This was done through a demonstration of both, the current prototype and the existing similar tool, the Ethics Canvas. Following this introduction, the recording started, and participants were first asked about their general impressions of the tool. Then the headers, their order, and wording in the latest iteration of the canvas were discussed. Then participants were asked about the prompt questions, their wording and importance. At the end of the interview, they were asked if there was anything that they thought they could add, remove, or modify about the tool.

During interviews previous versions of the prototype were shown to the participant when discussing recent modifications to the design.

5.3.3 Saturation

The data collection stage of this study was considered complete when no meaningful modifications were suggested by participants. Only modifications that, in the opinion of the researcher and participant, furthered the design towards fulfilling the purpose and requirements of the tool were considered meaningful and were deployed in the prototype before the next interview. Iterative data analysis and constant comparison (Glasser and Strauss, 1999) were used to establish this.

After interview 5, only one partial modification with debatable meaningfulness was suggested, which allows us to conclude that saturation was achieved. A summary of the modifications of each interview are provided in Figure 4.

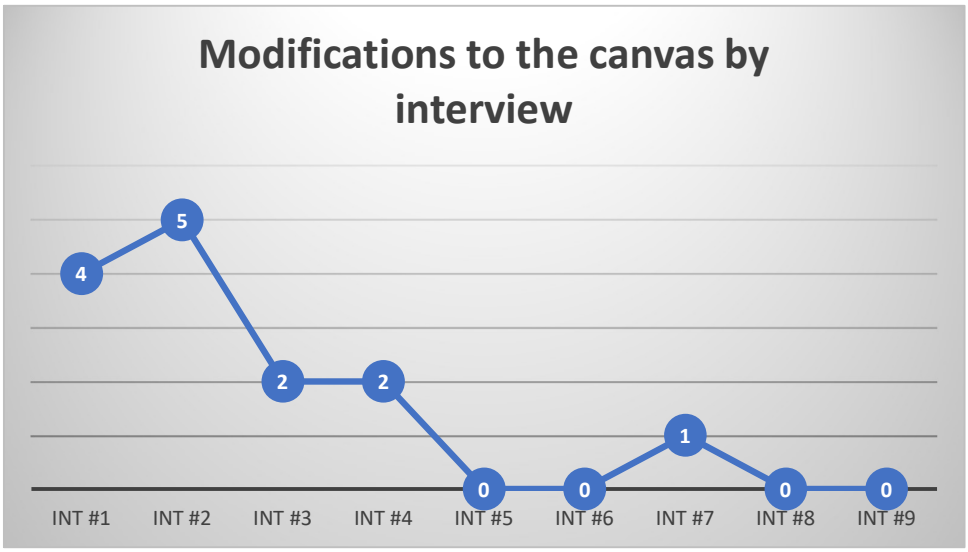


Figure 4 Number of modifications and point of saturation

5.3.4 Study design

This study was a rigorous iterative process of design that focused on usability, usefulness and providing clarity for clinicians when considering PGHD.

Heavily influenced by Berg's (Berg, 1999) acknowledgement of the nuances of trying to reflect the day to day nature of healthcare work, an iterative design approach to the development of the tool was chosen. This is characterized by the proposal of an initial prototype based on the requirements, followed by analysis and implementation and evaluation. The design was then tested through a series of interviews with participants representative of the proposed user group and evaluated against the original requirements, to restart the cycle. This cycle of design iterations resulted in the development of the final prototype.

The initial prototype of the PGHD Trust Canvas was created within MS Word (see Figure 5) and shown to the first clinician who was interested in providing feedback for the design. Each iteration resulted in improvements in the language used, the layout of the design and the prompt questions that appear upon mouse hovering. The iterations continued until reaching saturation, where no meaningful changes to the prototype were suggested by participants. Previous versions of the design were kept on record to show to new participants in case of conflicting preferences of design features.

5.3.5 Tool purpose

Determining the purpose of the tool is a crucial and foundational step in its development. Defining a clear purpose provides general direction for the design, development, and evaluation of the tool. When used correctly, a tool to help clinicians with the decision of whether to trust or distrust PGHD should:

- Provide clinicians with an evidence-based framework to evaluate the trustworthiness of PGHD.
- Provide a level of certainty and guidance in the process of evaluating the trustworthiness of PGHD for its use in clinical decisions.

- Help clinicians understand their own decisions regarding the trustworthiness of PGHD.

5.3.6 Tool Requirements

When using the tool to decide upon the trustworthiness of PGHD that they are not sure about, clinicians must find clarity and confidence. The tool must provide the highest possible level of perceived usefulness and usability, while fulfilling the purpose of the tool.

5.3.7 Tool design considerations

The tool is based on the Business Model Canvas (AG, no date), the Ethics Canvas (*The Ethics Canvas*, no date), and the Trust Canvas (Pikulev, no date). These canvases encourage participants to achieve a comprehensive understanding of how an organization can deliver value, impact society, or establish actions that preserve trust within a group. They use a visual-textual plane which is structured in blocks that correspond with each of the factors that affect each topic. This way participants can engage in group discussions and make group decisions with clear actionable pathways. Even though the context in which the PGHD Trust Canvas is assumed to be used is not that of a group collaboration, the concept allows for its use in collaboration settings, should the users require it.

The initial prototype is further informed by a comprehensive literature review in Chapter 2, primary research on the key aspects that affect clinician trust in PGHD (Hederman, Berry and Ormazabal, 2023), ISO technical specification ISO/TS82304-2 (ISO, 2021), and HPRA guide to the classification of a medical device (Products Regulatory Authority, 2009).

In the development of the general concept of the tool, various methodologies were evaluated, incorporating principles such as fuzzy logic (Zadeh, 1965), adaptive decision-making (Bettman, Johnson and Payne, 1993), and Bayesian decision-making (Pratt, Raiffa and Schlaifer, 1995), among others. These could be used to provide a more distinct, perhaps binary answer to the user as to whether to trust or not to trust. After all, clinicians are well familiar with working with decision tools like decision trees, algorithms, and decision thresholds. However, given the dynamic nature of both the clinical decision process and the decision whether to trust information, a holistic and visual approach was chosen, inspired in the tools described in sections 5.3.7.1, 5.3.7.2, and 5.3.7.3.

5.3.7.1 Business Model Canvas

The Business Model Canvas, developed by Alexander Osterwalder, is a strategic management tool that provides a visual framework for developing and documenting business models. It consists of nine key components: Customer Segments, Value Propositions, Channels, Customer Relationships, Revenue Streams, Key Resources, Key Activities, Key Partnerships, and Cost Structure. The canvas is designed to be a simple, visual representation that helps teams collaboratively brainstorm, discuss, and iterate on business models. Its structured yet flexible approach allows users to see the interconnections between different elements of their business, making it easier to innovate and adapt (Osterwalder and Pigneur, 2010).

5.3.7.2 Ethics Canvas

The Ethics Canvas, created to help organizations systematically address ethical considerations in their projects, provides a structured yet flexible framework for identifying and evaluating ethical issues. It typically includes sections such as Stakeholders, Ethical Values, Ethical Issues, Solutions, and Actions. This tool encourages collaborative discussion and reflection on the ethical dimensions of a project, helping teams to consider the impact of their decisions on various stakeholders and to develop strategies to mitigate ethical risks. Its visual and participatory

nature makes it effective for engaging diverse teams in complex ethical deliberations (*The Ethics Canvas*, no date; Cahill, 2020).

5.3.7.3 Trust Canvas

The Trust Canvas is designed to help teams build and maintain trust within organizations or projects. It includes components like Trust Drivers, Trust Barriers, Actions to Build Trust, and Metrics to Measure Trust. By providing a clear and visual layout, the Trust Canvas facilitates discussions about trust factors, allowing teams to collaboratively identify areas where trust needs to be built or improved and to develop concrete actions to enhance trustworthiness. This approach emphasizes the dynamic and multifaceted nature of trust, making it a useful tool for addressing trust-related challenges in a structured way (Pikulev, no date; Plays-In-Business, no date).

The initial PGHD Trust Canvas prototype was informed by the literature review in Chapter 2, which included risk-based frameworks for medical device classification (Scanlon, Karsh and Saran, 2008), quality assessment tools like the CAPOCI (Lenaerts *et al.*, 2021) standards for health app labelling quality requirements (ISO, 2021), and Study 1 described in Chapter 4 (Hederman, Berry and Ormazabal, 2023). This research was instrumental in determining the specific user needs and features our tool should incorporate, as well as informing the first iteration of the tool prototype. The study established that effective governance mechanisms including clear standards and guidelines are essential to reassure clinicians. It also identified quality as a major determinant of trust on PGHD. Provenance was also identified as it plays a crucial role, since data from trusted sources and consistent with the clinician's knowledge of the patient is more likely to be trusted. Risk perception is closely linked to data quality, with higher perceived risks reducing trust. Lastly, the necessity of using PGHD, particularly highlighted during the COVID-19 pandemic and in remote telemedicine contexts, can drive its adoption and trust among clinicians.

5.3.8 Initial prototype

The initial prototype consists of a table with 7 headers and text areas below for the user to enter their reflections on each field (See Figure 5). The 4 headers in the top row are “Clinical Quality”, “Provenance”, “Risk”, and “Governance”. The second row consists of 2 headers, which are “Need” and “Transitivity”. The third row consists of only one field with one header called “Personal experience”.

- **Clinical Quality:** The inclusion of “Clinical Quality” is informed by the discussions in Chapter 2 (Section 2.4.5.2.2.2 and 0), where the importance of data quality in clinical decision-making is emphasized. Clinicians need access to PGHD that is accurate, relevant, and timely. As noted in Section 2.4.5, data quality forms a core element of trust, as variability and inconsistencies in data quality can lead to significant doubts about the reliability of the information provided.
- **Provenance:** As explored in both Chapter 2 (Section2.4.5.2.2.4) and Chapter 4 (Section 4.5.3), clinicians require clear knowledge about the source of the data, particularly who generated it and how it was collected. Provenance directly affects the trustworthiness of PGHD, as noted in Chapter 4 findings on the need for transparency to mitigate risks and ensure accountability. The provenance of data informs clinicians' decision to trust the PGHD, ensuring the data is both credible and relevant.
- **Risk:** In both Chapter 2 (Section 2.4.5.2.3.2) and Chapter 4 (Section 4.5.4), the discussion centers on the risks associated with using PGHD in clinical practice. The uncertainty and lack of verification of some PGHD increase the potential for harm if used incorrectly. Considerations

about risk is essential in evaluating whether PGHD should be trusted for clinical decision-making, particularly when it comes to ensuring patient safety.

- **Governance:** The importance of governance is explored in Chapter 2 (Section 2.4.3) and Chapter 4 (Section 4.5.1), where the lack of structured governance frameworks is identified as a significant barrier to the use of PGHD. This section outlines how proper governance can address concerns around data reliability, clinician liability, and patient safety. A robust governance structure helps clinicians feel more secure in trusting PGHD.
- **Need:** The header "Need" is justified by discussions in Chapter 4 (Section 4.5.5), which details how during times of high necessity, like in the case of the 2020 COVID pandemic, the need to use PGHD outweighed other considerations making clinicians more likely to include PGHD in their clinical decision making processes. The decision to trust PGHD is influenced by whether the data is necessary within the context of patient care.
- **Transitivity:** The concept of transitivity is discussed in Chapter 2 (Section 2.4.5.2.3.1) in relation to institutional trust. Clinicians often trust PGHD based on their trust in the systems or institutions that provide the data. This transitive trust extends to the data itself, provided the institution or technology generating the data is deemed reliable. Including "Transitivity" in the prototype allows clinicians to reflect on the broader network of trust factors, including institutional and system-level trust.
- **Personal Experience:** "Personal Experience" reflects the insights shared in Chapter 4 (Section 4.4.4), where clinicians note that their personal experiences with PGHD shape their trust in its use. Positive past interactions with PGHD, or similar types of data, increase the likelihood that clinicians will trust future data. Including this header enables clinicians to reflect on how their experiences inform their decision-making process regarding PGHD.

The text areas directly below the headers would admit longer text and, for the purpose of the iterative process, will display the prompt questions to guide the user's reflection on the PGHD to evaluate. The web-version of this tool displays the prompt questions as pop-up messages upon mouse hovering. The prompt questions in the initial prototype were based on the reference materials cited in the "General Considerations" section of this document (See 5.3.7).

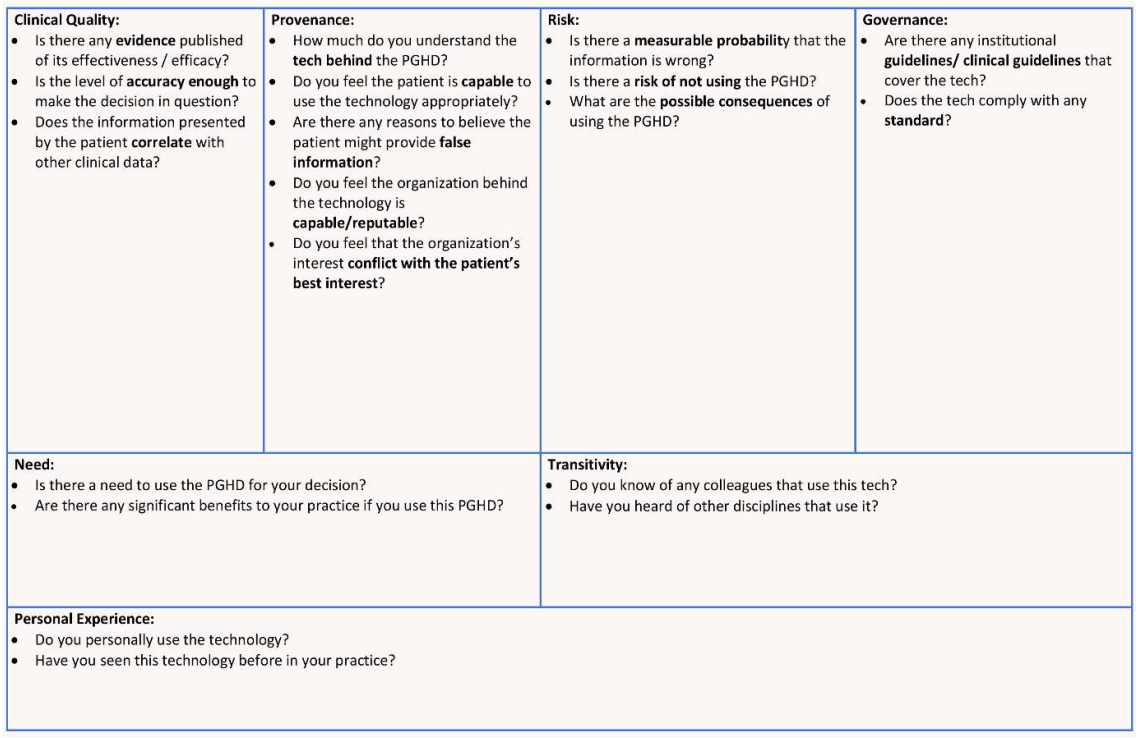


Figure 5 Initial prototype shown to the first participant

5.4 Results

A total of 16 clinicians were invited to participate, of which 9 accepted the invitation before saturation was achieved. The majority of participants (N=7) were clinicians living and practising in Ireland, while the remaining 2 were living and practising in Belgium. The professional distribution of the participants is as follows:

- Nursing (N=3)
- Physiotherapy (N=2)
- Pre-hospital care (N=2)
- General practice (N=1)
- Mental health (N=1)

Table 4 Table of modifications from initial to final prototype

Theme name	Description
1st Interview	
Header wording	To add a hover over the headers with a definition. we talked about how provenance is difficult to understand, and an explanation would be helpful.
Header wording	To change the name of the header "Need" for "Necessity".
Header wording	To find a better name for "Transitivity". "Trusted by peers" was suggested with emphasis on the words "Peer".
Order of the blocks	To change the order of the blocks for the following: First Quality, then Risk, then provenance, Necessity, Peer trust and last personal experience.

Theme name	Description
2nd Interview	
Prompt question	To add a patient's security prompt question to the risk section.
Header wording	To change the name of "Provenance" for another name. I chose "Information origin/journey".
Header wording	To change "trusted by peers" to "used by peers" since used implies that the technology is adopted
Order of the blocks	To change the order of governance and provenance (Information origin/Journey) with each other
Prompt question	To change the last question in provenance about the organization's conflict of interest for a question regarding the patient's experience in using the tech
3rd Interview	
Prompt question	To combine the first and second prompt questions in Provenance
Header wording	To change "Provenance" header for "Origin.
4th Interview	
Order of blocks	To combine the fields of "Used by Peers" and "Personal experience" into one field.
Header wording	To name the new field "Prior usage".
5th Interview	
No changes	No meaningful changes suggested.
6th Interview	
No changes	No meaningful changes suggested.
7th Interview	
Header wording	To add the words "Guidance" and "Policies" to the "Governance" field.
8th Interview	
No changes	No meaningful changes suggested.
9th Interview	
No changes	No meaningful changes suggested.

5.4.1 Interviews

This section provides brief summaries of each interview, pointing out the topics discussed, and the modifications made to the prototype. The summaries aim at capturing the essence of the conversation from the transcripts. Each summary was written immediately after each interview.

5.4.1.1 Interview 1

Figure 5 shows the initial prototype that was presented to participant 1 in the interview.

5.4.1.1.1 Summary of interview

Participant 1 was a nurse trainer, who was familiar with health informatics, reflective practice, and clinical education. This interview highlights the tool's need to be user-friendly and cater to the diversity of data types and clinicians' experience levels. Participant 1 stresses the importance of the

tool in facilitating clinician contemplation of ethical, quality, and safety aspects of PGHD. Both the participant and the researcher agree on the necessity to avoid complex jargon like "provenance," favouring simpler language or providing definitions to aid understanding. Terms such as "governance" are seen as less problematic due to their common use in clinical settings.

The discussion touches on the use of terms that clinicians can resonate with, like "trusted by peers," emphasizing the importance of mutual professional trust. The term "necessity" is preferred over "need" to underline the critical use of information. Moreover, Participant 1

agrees with the researcher's F-pattern layout for the tool, which is aimed at providing strategic organization of the content that corresponds with typical reading patterns.

The F-pattern is also central in ensuring that all information is noticed and considered by the viewer, with the bottom left content designed not to be ignored. Trust is dissected as a binary decision in the clinician's judgment of PGHD, leading to a potential application for companies to use the tool to ensure their health data is trustworthy.

Risk management emerges as a crucial aspect of the tool, with the Researcher wanting to maintain simplicity while highlighting the significance of the likelihood and consequences of incorrect data. Participant 1, as a clinician, recommends prominently featuring risk in the tool's layout to align with clinical priorities, in contrast to companies that might place provenance first. The conversation concludes with the participant's suggestion to place risk in a significant position within the F-pattern layout to stress its importance to clinicians immediately. The interview wraps up acknowledging time constraints.

5.4.1.1.2 List of modifications:

- To add a hover over the headers with a definition. We talked about how provenance is difficult to understand, and an explanation would be helpful.
  The definition is as follows: Provenance is a record about the data from creation, through its journey till the moment it’s displayed on your screen.
- To change the name of the header “Need” for “Necessity”.
- To find a better name for transitivity. It was suggested "trusted by peers" with emphasis on the word "Peer ".
- To change the order of the boxes for the order that clinicians are likely first to think. First Quality, then Risk, then Provenance, Necessity, Peer trust and last Personal Experience

5.4.1.2 Interview 2

Before the interview with participant 2, the researchers were discussing the importance of understanding purposes when making a decision. The discussion centred around the need to have clear objectives and considering the impact and implications of decisions. The researchers came to the realization that this conversation should be included in the design decisions of the prototype. Therefore, the researchers came to the conclusion that an additional field titled "Purpose" was to be added to the prototype.

Figure 6 shows the prototype presented to participant 2 in the interview.

Purpose:

This is the reason for you to include the PGHD as part of the data you will use to make a clinical decision.

- Think about what decision you are trying to make.
- What question do you intend to answer by using the PGHD.

Clinical Quality:

- Is there any **evidence** published of its effectiveness / efficacy?
- Is the level of **accuracy enough** to make the decision in question?
- Does the information presented by the patient **correlate** with other clinical data?

Risk:

Risk is formed by two aspects: the likelihood of the information to be incorrect and the severity of the consequences for the wrong decision.

- Is there a **measurable probability** that the information is wrong?
- Is there a **risk of not using** the PGHD?
- What are the **possible consequences** of using the PGHD?

Provenance:

Provenance is a record about the data from creation, through its journey till the moment it's displayed on your screen.

- How much do you understand the **tech behind** the PGHD?
- Do you feel the patient is **capable** to use the technology appropriately?
- Are there any reasons to believe the patient might provide **false information**?
- Do you feel the organization behind the technology is **capable/reputable**?
- Do you feel that the organization's interest **conflict with the patient's best interest**?

Governance:

This involves the establishment of policies, standards, and procedures for including PGHD into the decision-making process.

- Are there any institutional **guidelines/ clinical guidelines** that cover the tech?
- Does the tech comply with any **standard**?

Necessity:

- Is there a **need to use** the PGHD for your decision?
- Are there any significant **benefits to your practice** if you use this PGHD?

Trusted by peers:

This refers to the transitivity of trust between clinical staff and between disciplines.

- Do you know of any **colleagues** that use this tech?
- Have you heard of **other disciplines** that use similar tech?

Personal Experience:

Your own personal experience using this technology to gather data and inform any of your decisions.

- Do **you** personally use the technology?
- Have you seen this technology before **in your practice**?

Figure 6 Second prototype of the PGHD trust canvas

5.4.1.2.1 Summary of interview

Participant 2 is a nurse manager, who is in general somewhat sceptical about ground-breaking and disruptive technologies in healthcare. Although computer literate, participant 2 wouldn't consider themselves as a technology enthusiast.

In the interview, the Researcher and Participant 2 delve into the intricacies of developing a reflective tool for clinicians that evaluates the trustworthiness of PGHD. The discussion centres on various pivotal aspects of clinician trust in PGHD, such as the potential risks, the importance of security in safeguarding against cyber threats and breaches, and the concept of provenance, which concerns the origin and journey of data. Provenance is earmarked as a critical but complex aspect, proposed to be relabelled more accessibly as "data creation" for the tool's purposes.

Governance, the framework of regulations and policies that encompass PGHD, is another vital element discussed, as well as the necessity of utilizing PGHD, which is depicted as a choice rather than an obligatory need. Trust is further examined through the lens of peer adoption and confidence in the data, with a consensus that trust alone isn't sufficient—the system must be intuitive and have widespread acceptance.

The conversation also turns to the aesthetics and functionality of a webpage designed for healthcare professionals. As for the tool content, Participant 2 suggests a reorganization of sections, advising that 'provenance' not be the first section but instead grouped with 'clinical quality,' 'risk,' and 'governance' due to their relatedness in the healthcare sphere.

Further deliberation involves how patients interact with technology, highlighting the importance of their compliance and the technology's capability to deliver positive experiences and benefits. The potential inclusion of the patient's perspective in the webpage design is contemplated, recognizing the need to prioritize questions that encapsulate patient engagement and their experiences with the technology.

The necessity for closed-loop communication is emphasized, ensuring patients receive feedback and understand their contributions are both effective and valued. The challenge lies in maintaining a sense of personal attention and connection when technology substitutes personal interactions. The dialogue concludes with mutual acknowledgment from the researcher and participant of the importance of integrating these elements into the webpage design, accepting the complexity they introduce to both the design and the questions it aims to address.

Combining both parts, the interview not only sheds light on the multiple dimensions of establishing trust in PGHD but also addresses the practical considerations in designing an interactive and user-centric webpage that serves the needs of both clinicians and patients.

5.4.1.2.2 List of modifications

- To add a patient's security prompt question to the risk section.
- To change the name of provenance for another name. I went with Information origin/journey.
- To change "trusted by peers" to "used by peers" since used implies that the technology is adopted.
- To change the order of governance and provenance (Information origin/Journey) with each other.
- To change the last question in provenance about the organization's conflict of interest for a question regarding the patient's experience in using the tech.

5.4.1.3 Interview 3

Figure 7 shows the prototype presented to participant 3 in the interview.

Purpose:

This is the reason for you to include the PGHD as part of the data you will use to make a clinical decision.

- Think about what decision you are trying to make.
- What question do you intend to answer by using the PGHD?

Clinical Quality:

- Is there any **evidence** published of its effectiveness / efficacy?
- Is the level of **accuracy enough** to make the decision in question?
- Does the information presented by the patient **correlate** with other clinical data?

Risk:

Risk is formed by two aspects: the likelihood of the information to be incorrect and the severity of the consequences for the wrong decision.

- Is there a **measurable probability** that the information is wrong?
- Is there a **risk of not using** the PGHD?
- What are the **possible consequences** of using the PGHD?
- Are there any **security risks** by having the patient use this technology?

Governance:

This involves the establishment of policies, standards, and procedures for including PGHD into the decision-making process.

- Are there any institutional **guidelines/ clinical guidelines** that cover the tech?
- Does the tech comply with any **standard**?

Provenance

Provenance is a record about the data from creation, through its journey till the moment it's displayed on your screen.

- How much do you understand the **tech behind** the PGHD?
- Do you feel the patient is **capable** to use the technology appropriately?
- Are there any reasons to believe the patient might provide **false information**?
- Do you feel the organization behind the technology is **capable/reputable**?
- Is the **patient's experience** good using this technology

Necessity:

- Is there a **need to use** the PGHD for your decision?
- Are there any significant **benefits to your practice** if you use this PGHD?

Used by peers:

This refers to the transitivity of trust between clinical staff and between disciplines.

- Do you know of any **colleagues** that use this tech?
- Have you heard of **other disciplines** that use similar tech?

Personal Experience:

Your own personal experience using this technology to gather data and inform any of your decisions.

- Do **you** personally use the technology?
- Have you seen this technology before **in your practice**?

Figure 7 Third prototype of the PGHD trust canvas

5.4.1.3.1 Summary of interview

Participant 3 is involved in pre-hospital care in Ireland. In this interview, the researcher and participant examine various aspects necessary for the tool's effectiveness.

With the potential to benefit clinicians, app developers, and medical educators, the tool serves to gauge the validity and practicality of PGHD, factoring in the patient's understanding of technology, capability, and data origins. It was discussed that taking as an example from Canadian community paramedics' use of PGHD in pre-hospital care, the need for accurate data

in clinical judgment was highlighted. The dialogue extended to the ease of technology use for both patients and clinicians, the sustainability of health app companies, and the simplification of technology for patient comprehension. Participant 3 underscores the vital role of clearly presenting technology's advantages to bolster its use and contribution to healthcare.

Continuing the conversation, the parties deliberate on effectively communicating technology's significance to older patients who may doubt its benefits. Participant 3 conveys that comprehending the technology's advantages can lead to enhanced patient engagement and data integrity. They propose the amalgamation of interview questions to remain succinct while still stressing patient comprehension to promote honest participation. They confront challenges in titling the section 'information origins/journey,' which doesn't quite capture the intended message. They continue to consider renaming it to better reflect the dual concepts of data reliability and patients' capacity to produce or log data. They concur on the necessity to refine the term 'reliability' for more precision of wording.

Throughout the interview, they seek a header that effectively summarizes data provenance and patient technology interaction, concluding that the section needs to be more clearly defined to better understand how patients manage and convey their health data.

5.4.1.3.2 List of modifications

- To combine the first and second prompt question in Provenance.
- To change provenance header for “Information Origin”.

5.4.1.4 *Interview 4*

Figure 8 shows the prototype presented to participant 4 in the interview.

Purpose:

This is the reason for you to include the PGHD as part of the data you will use to make a clinical decision.

- Think about what decision you are trying to make.
- What question do you intend to answer by using the PGHD?

Clinical Quality:

- Is there any **evidence** published of its effectiveness / efficacy?
- Is the level of **accuracy enough** to make the decision in question?
- Does the information presented by the patient **correlate** with other clinical data?

Risk:

Risk is formed by two aspects: the likelihood of the information to be incorrect and the severity of the consequences for the wrong decision.

- Is there a **measurable probability** that the information is wrong?
- Is there a **risk of not using** the PGHD?
- What are the **possible consequences** of using the PGHD?
- Are there any **security risks** by having the patient use this technology?

Governance:

This involves the establishment of policies, standards, and procedures for including PGHD into the decision-making process.

- Are there any institutional **guidelines/ clinical guidelines** that cover the tech?
- Does the tech comply with any **standard**?

Information Origins

Provenance is a record about the data from creation, through its journey till the moment it's displayed on your screen.

- How much do you understand the **tech behind** the PGHD?
- Do you feel the patient is **capable** to use the technology appropriately?
- Are there any reasons to believe the patient might provide **false information**?
- Do you feel the organization behind the technology is **capable/reputable**?
- Is the **patient's experience** good using this technology

Necessity:

- Is there a **need to use** the PGHD for your decision?
- Are there any significant **benefits to your practice** if you use this PGHD?

Used by peers:

This refers to the transitivity of trust between clinical staff and between disciplines.

- Do you know of any **colleagues** that use this tech?
- Have you heard of **other disciplines** that use similar tech?

Personal Experience:

Your own personal experience using this technology to gather data and inform any of your decisions.

- Do **you** personally use the technology?
- Have you seen this technology before **in your practice**?

Figure 8 Fourth prototype of the PGHD trust canvas

5.4.1.4.1 Summary of interview

Participant 4, who is a nurse, acknowledges the potential utility of such a tool, although the need for it may fluctuate based on the number of international patients requiring care.

The interview discusses the clarity of the tool's sections, such as 'purpose' and 'risk,' and how these should be presented to clinicians. 'Purpose' is understood to be the clinician's use of PGHD for informing decisions, but 'risk' necessitates a clearer emphasis on the probability of data inaccuracy and the gravity of any potential consequences. The 'governance' aspect is also

scrutinized, considering whether clinicians are adequately informed about the technologies used to collect PGHD, as unfamiliarity can impede effective decision-making.

Further, the dialogue explores the decision-making structure of the tool, with Participant 4 suggesting a decision-tree approach to address the fluid and dynamic aspects of trust. There's an important emphasis on the real-time accessibility of PGHD, which can bolster trust and accountability in clinical decisions. The conversation also touches upon the finite number of trusted technologies available in certain fields, like diabetes, suggesting that known technologies are generally more trusted.

The participant and researcher consider whether the tool effectively prompts clinicians to reflect on the necessity of using PGHD and the advantages of data that is automatically transmitted over verbally communicated information, which also serves as a protective measure for clinicians.

Lastly, they evaluate the terminology used in the tool's headers, like "used by peers" and "personal experience," debating enhancements for intuitiveness and the potential merging of sections due to overlapping objectives. The participant agrees to devise a more apt header that captures the essence of trustworthiness based on peer and personal experience with the technology. This tool is envisioned not only as a means to assess PGHD but also as a safeguard and guide for clinicians navigating the complexities of modern patient care.

End of interview.

After the interview there was further communication with participant 4 over text messages. Participant 4 asked the researcher if she could have a closer look at the design files to later communicate the modifications that she was considering. The researcher agreed and forwarded the trust canvas prototype and the link below with hypothetical scenarios.

https://sway.office.com/ywbx5ZPHyAGMbFHs?ref=Link

Participant 4's reply is as follows:

> *"(I suggest) merging these 2 areas (used by peers and personal experience) and calling them: Prior usage (or) Prior assessment of tech"*

> *"I wouldn't use the word Peer. A peer is someone at your own level. In the diabetes scenario- if asking colleagues about prior usage/ assessment of the tech, you could be asking someone above or below your level, not just peers"*

5.4.1.4.2 List of modifications

- To combine the fields of "Used by Peers" and "Personal experience" into one field.
- To name the new field "Prior experience"

5.4.1.5 Interview 5

Figure 9 shows the prototype presented to participant 5 in the interview.

Purpose:

This is the reason for you to include the PGHD as part of the data you will use to make a clinical decision.

- Think about what decision you are trying to make.
- What question do you intend to answer by using the PGHD?

Clinical Quality:

- Is there any **evidence** published of its effectiveness / efficacy?
- Is the level of **accuracy enough** to make the decision in question?
- Does the information presented by the patient **correlate** with other clinical data?
- Is the information **relevant**?

Risk:

Risk is formed by two aspects: the likelihood of the information to be incorrect and the severity of the consequences for the wrong decision.

- Is there a **measurable probabilit**y that the information is wrong?
- Is there a **risk of not using** the PGHD?
- What are the **possible consequences** of using the PGHD?
- Are there any **security risks** by having the patient use this technology?

Governance:

This involves the establishment of policies, standards, and procedures for including PGHD into the decision-making process.

- Are there any institutional **guidelines/ clinical guidelines** that cover the tech?
- Does the tech comply with any **standard**?

Information Origins

Provenance is a record about the data from creation, through its journey till the moment it's displayed on your screen.

- How much do you understand the **tech behind** the PGHD?
- Do you feel the patient is **capable** to use the technology appropriately?
- Are there any reasons to believe the patient might provide **false information**?
- Do you feel the organization behind the technology is **capable/reputable**?
- Is the **patient's experience** good using this technology

Necessity:

- Is there a **need to use** the PGHD for your decision?
- Are there any significant **benefits to your practice** if you use this PGHD?

Prior Experience:

This refers to the transitivity of trust between clinical staff and between disciplines and the personal experience of the clinician with the technology.

- Do you know of any **colleagues** that use this tech?
- Have you heard of **other disciplines** that use similar tech?
- Do you **personally use** this technology?
- Do you use this technology to make other decisions **in your practice**?

Figure 9 Fifth prototype of the PGHD trust canvas

5.4.1.5.1 Summary of interview

Participant 5 is a pre-hospital care clinician. The discussion, primarily led by Participant 5, explores scenarios in healthcare where patients provide their own health data using devices like glucometers, blood pressure monitors, and Fitbits.

Participant 5 emphasizes the critical balance between trust and scepticism in assessing PGHD. Clinicians are advised to initially trust patient-provided data but also to remain sceptical, particularly if the data conflicts with the patient's current health status or medical history. This

approach underscores the importance of a holistic assessment, where device readings are integrated with the overall clinical presentation and context.

The conversation highlights the reliability of medical devices, acknowledging the greater confidence in medical-grade equipment while noting their potential for errors or calibration issues. Participant 5 also discusses the significance of correlating historical data from devices with current clinical assessments, emphasizing the patient's present condition as crucial in decision-making.

The discussion extends to medical professionals' trust in new devices, built over time through peer usage and personal experience. The variance in trust and usage between formal medical environments and fewer formal settings is noted.

Finally, the researcher and Participant 5 concur on the necessity of incorporating 'relevance' and 'timeliness' as criteria in the tool being developed. The importance of acting on relevant and timely data in clinical decision-making is highlighted, with a focus on the changing relevance of information based on the immediacy and context of the clinical situation. The interview encapsulates the complexities and considerations in integrating PGHD into clinical practice, emphasizing the need for a nuanced and integrated evaluation method to inform clinician decision-making.
Participant 5 suggested to include relevance and timeliness to the field of clinical quality, however the researcher decided not to make the modifications to the prototype. The suggestions would be discussed with later participants to seek confirmation of the choice.

5.4.1.5.2 List of modifications

- No changes made to the prototype.

5.4.1.6 Interview 6

Figure 9 shows the prototype presented to participant 6 in the interview.

5.4.1.6.1 Summary of interview

Participant 6 is a physiotherapist who is very familiar with PGHD from a research point of view. In this interview, the researcher and Participant 6 discuss the design of the tool, focusing on a new field called "prior usage" and the possibility to add relevance and timeliness to the clinical quality field.

Participant 6 agrees with the idea of combining peer usage and personal experience because relying solely on peer assessments might lead to bias. They highlight that what works for one physical therapist's patient population might not work for others. The participant emphasizes the importance of considering personal experience with the technology or data and checking if it is also peer-reviewed.

They discuss the relevance of step counts in physical therapy, particularly for patients with lower limb injuries. For Participant 6, the step count is an essential objective measure to identify the causes of flare-ups. They express that they would quickly prompt patients about their step count, as it's a critical part of their assessment process.

The researcher enquires about the importance of having explanations for different fields like purpose, purpose, and information origins within the framework of using PGHD. Participant 6 believes it's crucial to provide clear explanations, especially for physical therapists who may not be familiar with concepts like PGHD or clinical quality and risk.

Participant 6 also discusses the importance of considering the risk of not using PGHD and the potential for patients to provide false information. They note that physical therapists might be biased against patient-reported data if it does not align with their clinical judgment.

The participant acknowledges the potential of PGHD in various contexts, like tracking the performance of athletes or monitoring patients with chronic conditions. They stress the need for accuracy in PGHD but also recognize its value in providing a broader picture of a patient's health and activities.

Overall, the interview did not reveal or suggest any changes to the design, and it confirms the decision to combine the fields of "used by peers" and "personal experience" into one field called "Prior usage" suggested in interview 4. The interview also suggests that there is no need to add relevance and timeliness to the clinical quality.

5.4.1.6.2 List of modifications

- No changes made to the prototype.

5.4.1.7 Interview 7

Figure 9 shows the prototype presented to participant 7 in the interview.

5.4.1.7.1 Summary of interview

The interview with Participant 7, who is a GP, focused on the tool's role in aiding clinicians, with an emphasis on critical thinking in evaluating new technologies and staying current with medical evidence. They describe the practice of "journal clubs" in their field, where clinicians critically analyse medical papers without relying solely on conclusions, but by focusing on the data and assessing the honesty and bias of the authors.

The researcher then discusses the tool's design, including its educational value in teaching clinicians to compartmentalize their thinking for better decision-making. Participant 7 suggests that while the design of the tool might be less important to them personally, it can be very useful in an educational context.

The conversation shifts to the terminology used in the tool, particularly the use of the word "governance." Participant 7 finds this term inappropriate for the medical field, suggesting it implies a level of authority and prescriptiveness that doesn't align with the autonomy and decision-making process in clinical settings. They propose "guidance" as a more appropriate term, as it suggests wisdom and recommendations from the scientific community without being overly directive.

The researcher acknowledges this feedback, considering changing "governance" to "guidance" or a similar term. They discuss the importance of language and how different terms resonate differently with various professionals.

Even though the participant suggested to change the header field of governance for guidance, however it was decided not to completely remove “Governance”, but to change it to “Governance:/ Guidance:/ Policies” since the researcher suspected that this aversion to the word “Governance” was due to the participant’s not being an English speaker as a first language.

5.4.1.7.2 List of modifications

- To change “Governance” for “Governance/ Guidance/ Policies:” as a header of the “Governance” field.

5.4.1.8 Interview 8

Figure 10 shows the prototype presented to participant 8 in the interview.

Purpose:

This is the reason for you to include the PGHD as part of the data you will use to make a clinical decision.

- Think about what decision you are trying to make.
- What question do you intend to answer by using the PGHD?

Clinical Quality:

- Is there any **evidence** published of its effectiveness / efficacy?
- Is the level of **accuracy enough** to make the decision in question?
- Does the information presented by the patient **correlate** with other clinical data?

Risk:

Risk is formed by two aspects: the likelihood of the information to be incorrect and the severity of the consequences for the wrong decision.

- Is there a **measurable probability** that the information is wrong?
- Is there a **risk of not using** the PGHD?
- What are the **possible consequences** of using the PGHD?
- Are there any **security risks** by having the patient use this technology?

Governance/ Guidance/ Policies:

This involves the establishment of policies, standards, and procedures for including PGHD into the decision-making process.

- Are there any institutional **guidelines/ clinical guidelines** that cover the tech?
- Does the tech comply with any **standard**?

Information Origins

Provenance is a record about the data from creation, through its journey till the moment it's displayed on your screen.

- How much do you understand the **tech behind** the PGHD?
- Do you feel the patient is **capable** to use the technology appropriately?
- Are there any reasons to believe the patient might provide **false information**?
- Do you feel the organization behind the technology is **capable/reputable**?
- Is the **patient's experience** good using this technology?

Necessity:

- Is there a **need to use** the PGHD for your decision?
- Are there any significant **benefits to your practice** if you use this PGHD?

Prior usage:

This refers to the transitivity of trust between clinical staff and between disciplines and the personal experience of the clinician with the technology.

- Do you know of any **colleagues** that use this tech?
- Have you heard of **other disciplines** that use similar tech?
- Do you **personally use** this technology?
- Do you use this technology to make other decisions **in your practice**?

Figure 10 Sixth prototype of the PGHD trust canvas

5.4.1.8.1 Summary of interview

Participant 8 is a physiotherapist who is unfamiliar with PGHD technologies. Participant 8 acknowledges the importance of the tool's purpose, especially concerning trustworthiness,

which is a key factor in evaluating PGHD. The discussion involves evaluating the order and relevance of the tool's features, although specific details are not explicitly stated.

The conversation also touches upon the decision-making process in a clinical context. Participant 8 highlights the importance of clinical quality and risk assessment in decision-making, indicating the role of guidelines and clinical standards in supporting these decisions, particularly in surgeries.

The use of technology and information in clinical decision-making is another focal point. Participant 8 notes the potential benefits and limitations of technology in gathering patient data, acknowledging their own limitations in using certain technologies and the varying tech capabilities among patients.

Furthermore, the importance of clinical guidelines and governance in decision-making is emphasized, indicating that these guidelines are crucial in the context of evaluating PGHD.

In summary, the interview explores the complexities of developing a tool for clinicians to evaluate the trustworthiness of PGHD. It highlights the need to balance technological capabilities, clinical guidelines, and individual practitioner's expertise in the process of making informed healthcare decisions.

5.4.1.8.2 List of modifications

- No changes made to the prototype.

5.4.1.9 Interview 9

Figure 10 shows the prototype presented to participant 9 in the interview.

5.4.1.9.1 Summary of interview

Participant 9, who is a psychiatrist, finds the tool's use of clinical language commendable, ensuring it is understandable to clinicians. However, they suggest some sections might benefit from clearer or more detailed explanations, particularly concerning risk assessment.

A significant part of the discussion centres on the importance of accuracy in clinical decision-making. Participant 9 points out the tool's emphasis on this aspect and stresses the importance of understanding the implications of decisions. There is advice to refine the wording in the risk section to avoid ambiguity, especially regarding the consequences of incorrect decisions.

The inclusion of patient experience and institutional guidelines in the tool is noted, highlighting their importance in the clinical decision-making process. Participant 9 and the researcher touch upon the adaptability of clinicians to new interventions, like the COVID vaccine, and the need to balance benefits and risks.

Participant 9 points out that some terms, such as 'transitivity,' might not be immediately clear to clinicians, pointing out the definition under "Prior use". They suggest rephrasing these terms or providing definitions for better understanding. The researcher clarifies that the tool is not intended for everyday patient consultations but rather for aiding clinicians in making decisions about new technologies or information they encounter.

The interview also delves into how clinicians deal with uncertainties in technology and medicine. This highlights the need for tools that assist in making informed decisions amidst such uncertainties. Participant 9 provides detailed feedback on various aspects of the tool, aiming to improve its effectiveness and usability for clinicians.

In summary, the interview focuses on the evaluation and refinement of a tool designed to assist clinicians in decision-making. The feedback from Participant 9 centres on enhancing the tool's clarity, effectiveness, and relevance to clinical practice, emphasizing accuracy, risk assessment, patient experience, and adaptability to new medical technologies.

Participant 9 suggested to change the word “transitivity” in the field “Prior use” for a more recognizable word. However, this suggestion is not followed, since the objective of this change would be to simplify the language, which has already been done in the header of the field.

5.4.1.9.2 List of modifications

- No changes made to the prototype.

5.4.2 Final prototype

Figure 4 shows the number of modifications in sequence, showing that from a total of 14 modifications to the canvas more than 90% of the modifications occurred in the first four interviews, while the last five interviews only resulted in one modification, which was qualitative considered minor due to a culture-linguistic issue with the participant who was a Belgian national. This resulted in the decision to consider that saturation as explained in Section 5.3.3 had been reached.

Figure 11 shows the final prototype. This was used to create a web-based application that complies with the wording of the prompt questions, headers, and definitions, as well as the layout of the tool. The web-based version can be found in the following link: https://trustedhealthdata.web.app/account/login

<table>
<tr><td colspan="4">Purpose:
This is the reason for you to include the PGHD as part of the data you will use to make a clinical decision.
• Think about what decision you are trying to make.
• What question do you intend to answer by using the PGHD?</td></tr>
<tr><td>Clinical Quality:
• Is there any evidence published of its effectiveness / efficacy?
• Is the level of accuracy enough to make the decision in question?
• Does the information presented by the patient correlate with other clinical data?</td><td>Risk:
Risk is formed by two aspects: the likelihood of the information to be incorrect and the severity of the consequences for the incorrect decision.
• Is there a measurable probability that the information is wrong?
• Is there a risk of not using the PGHD?
• What are the possible consequences of using the PGHD?
• Are there any security risks by having the patient use this technology?</td><td>Governance:/ Guidance:/ Policies:
This involves the establishment of policies, standards, and procedures for including PGHD into the decision-making process.
• Are there any institutional guidelines/ clinical guidelines that cover the tech?
• Does the tech comply with any standard?</td><td>Information Origins
Provenance is a record about the data from creation, through its journey till the moment it's displayed on your screen.
• How much do you understand the tech behind the PGHD?
• Do you feel the patient is capable to use the technology appropriately?
• Are there any reasons to believe the patient might provide false information?
• Do you feel the organization behind the technology is capable/reputable?
• Is the patient's experience good using this technology?</td></tr>
<tr><td colspan="2">Necessity:
• Is there a need to use the PGHD for your decision?
• Are there any significant benefits to your practice if you use this PGHD?</td><td colspan="2">Prior usage:
This refers to the transitivity of trust between clinical staff and between disciplines and the personal experience of the clinician with the technology.
• Do you know of any colleagues that use this tech?
• Have you heard of other disciplines that use similar tech?
• Do you personally use this technology?
• Do you use this technology to make other decisions in your practice?</td></tr>
</table>

Figure 11 Final prototype of the PGHD trust canvas

5.5 Discussion

5.5.1 Initial Prototype

The initial design decisions focused on two main domains: decisions on the trust factors, and decisions that improve the canvas' usability. These two domains are discussed in the next sections.

5.5.1.1 Trust factor focus

Based on the conceptual framework in section 2.4.5.2 the trustor is the clinician, the trustee is the data, and the context is represented by any factors related to the conditions in which the trust decision is going to be made. Seven fields were proposed in the initial prototype, with two related to the trustee, two related to the trustor and three related to the context of the trust decision.

It is important to emphasise that the conceptual framework in 2.4.5.2 must allow for a minimum of ambiguity and vagueness. The allocation of the factors can be argued from different perspectives. For example, Risk is mostly considered a contextual factor, since it describes a situational variable in the trust decision. However, any observations and notes made by the clinician in the field of risk is intrinsically affected by their own attitude towards risk. Similarly, a clinician might note that the quality of the data is low, meaning that the accuracy is inadequately low, while another clinician might notice the same, but make a note that there is a high risk of the information being incorrect. Understanding this, the following classifications describe the initial intention of the researcher.

- Trustor fields
    - Transitivity:
      The logic behind the field transitivity is that if other clinicians trust certain PGHD, it is more likely that the clinician will decide to include it in the decision-making process.
    - Personal experience:
      The logic behind the field Personal experience is that if the clinician creates the same type of PGHD for their personal use, and feel familiarity with it, they are more likely to include it in the decision-making process.
- Trustee fields
    - Clinical quality:
      The field of data quality is vast, and there are differences in the language that clinicians use compared to that of a computer scientist. A clinician, talking about quality, is likely referring to accuracy, precision, relevance, which doesn't conflict with the interpretation of a computer scientist. However a clinician talking about quality may also be referring in terms used in their field, terms like Positive Predictive Value (PPV) might be of interest instead, or risk terms like Number Needed to Harm.
    - Provenance:
      The field of provenance is usually related to the metadata that the PGHD supports, however in the case of the canvas, this field also includes human aspects of the origin of the data itself. Aspects like the ability of the patient to generate high quality data, or whether the patient seeks a certain diagnosis, are included in the field of Provenance.
- Context:
    - Governance:
      Whether the clinician considers that there is governance that make allowance for the data in question is included in this field. The intention at the time of creation of the canvas was to implicitly include guidance in the field since the two concepts serve distinct but complementary roles in ensuring the quality, safety and efficiency of healthcare delivery.
    - Need:
      The realization that the necessity of using PGHD as a factor that affects trust came as a surprise is discussed in 4.5.5, where the example of clinicians using PGHD out of shear necessity during the 2020 COVID pandemic were mentioned. The field also includes the subtle need to use PGHD to improve healthcare in terms of efficiency and the potential benefits described in 2.3.
    - Risk:
      The two-part composition of the concept of risk described in 2.4.5.2.3.2.1 was considered when the prototype was first developed. This included the probability that the information is wrong, and the possible consequences of using inaccurate data in the clinical decision. However, the field also includes the risk of not using the data, which includes the possible ethical and liability issues of disregarding information that could be proven correct in the future.

5.5.1.2 Usability focus

Based on the example of previous canvases like the Ethics Canvas and the Business Model Canvas, each field would include at least two prompt questions that aid the clinician in reflecting on the different trust factors of PGHD. The language used in these prompt questions was heavily influenced by the clinicians' perspective captured in the interviews described in Chapter 4. This is also true for the order of the prompt questions and the order of the fields themselves.

The layout of the first prototype of the canvas adopted some resemblance to the "F" pattern, where the top horizontal line is the one that is horizontally scanned, the second horizontal line only is initially scanned to quickly move to the rest of the content vertically downwards. This design decision was not meant to bear any rigorous compliance, but to guide the initial pattern.

5.5.2 Final prototype

The final prototype was the result of the modifications that happened through the nine iterations of the co-development process and detailed in section 5.4. It is discussed further in this section.

This study has successfully developed the prototype of a comprehensive and user-centred tool for clinicians to evaluate the trustworthiness of PGHD in clinical decision-making. The iterative design process, informed by extensive literature review and clinician feedback, has resulted in a tool that not only addresses the dynamic and complex nature of clinical decision-making but also caters to the specific needs and concerns of clinicians regarding PGHD.

The final prototype of the tool effectively integrates crucial aspects of PGHD assessment, including Purpose, Clinical Quality, Risk, Governance, Provenance (Information origins), Necessity, and Prior Usage. Each category is designed to prompt thoughtful reflection and analysis by clinicians, enabling them to make informed decisions about the incorporation of PGHD into their clinical practice.

5.5.2.1 Refinement of headers

Throughout the iterative development process of the PGHD Trust Canvas, several key differences emerged between the initial and final prototypes. The initial version of the tool was designed with a focus on core conceptual elements, such as "Clinical Quality," "Provenance," "Risk," and "Governance." These headers aimed to capture the most significant factors clinicians identified as influencing their trust in PGHD. However, as the tool was iteratively tested with clinicians, it became clear that some aspects needed refinement to enhance clarity and practical relevance.

One of the major differences between the two versions was the refinement of the headers and their organization. For instance, in the initial prototype, terms like "Provenance" and "Transitivity" were less familiar to some clinicians and required rewording or further explanation. In response to feedback, the headers were adjusted to ensure that each concept was intuitive and immediately understandable without additional explanation. Additionally, as the prototype evolved, the structure of the tool was modified to make the layout more user-friendly, ensuring that clinicians could easily navigate and engage with the tool without disrupting their workflow. These changes led to a final version that was more aligned with clinicians' expectations and better suited to the clinical decision-making environment, demonstrating a significant improvement in usability and applicability.

5.5.2.2 Combinationof two fields

Another example of during interview 4 presented in 5.4.1.4 the participant suggested that the fields of “Used by peers” and “Personal experience” into one new field called “Prior usage” since the word peer might lead to confusion. The unification of the fields also made the canvas more concise. By merging the two fields, the final prototype not only simplified the process for clinicians but also allowed for more efficient evaluation of PGHD. The decision to combine these fields demonstrated the importance of balancing comprehensiveness with practicality. While the initial prototype aimed to address every factor separately, the iterative process revealed that clinicians preferred a more integrated approach when assessing data trustworthiness. This change reflects a shift from an overly detailed model to a more functional one, aligning with the feedback that clinicians required fewer, more actionable categories to make swift, informed decisions in their workflow. The combination of these fields, therefore, represents a significant improvement in the tool's design, making it more user-friendly and better suited to real-world clinical applications.

5.5.2.3 Purpose field

The purpose for the information included in any decision has a pivotal role in the decision, since it determines what information is relevant (Simon, 1979). Decision-makers need to sift through large amounts of data, selecting only the information that helps achieve the specific goal or purpose. Irrelevant data can cloud judgment and lead to suboptimal decisions. Furthermore, when information aligns with the decision’s purpose, it helps streamline the decision-making process. Focused, purpose-driven information allows decision-makers to act swiftly without being bogged down by unnecessary details (Keeney and Keeney, 2009). While using the PGHD trust canvas, considering the purpose of PGHD ensures that clinicians maintain focus on the clinical relevance. The placement of the added field at the top of the canvas and spanning the full width of the canvas, is intended to signify an overarching presence of the focus on purpose.

5.5.3 Next stage

The next stage of this research detailed in Chapter 6 focuses on the implementation of a working prototype and eventual validation of the tool’s acceptance on behalf of clinicians. This provides insights into its effectiveness and impact on clinical practice and identify areas for further refinement.

5.6 Chapter summary

This chapter details the development of the PGHD Trust Canvas, the primary contribution of this thesis, designed to support clinicians in making informed decisions about whether to trust or distrust PGHD in clinical decision-making. The chapter outlines the co-development process, which involved nine iterations and extensive feedback from clinicians across various disciplines. Each iteration incorporated specific suggestions from participants, leading to significant refinements in the canvas’s structure, terminology, and usability.

A key focus of the design process was balancing comprehensiveness with practicality. Initial design decisions centered around two primary areas: identifying the key trust factors—such as clinical quality, provenance, risk, governance, and necessity—and ensuring the canvas's usability in real-world clinical environments. Clinician feedback drove important changes, such as the combination of overlapping fields (e.g., "Used by Peers" and "Personal Experience" merged into "Prior Usage") and the refinement of headers to improve clarity and relevance. These adjustments resulted in a more streamlined tool that simplified the decision-making process for clinicians without sacrificing depth.

The final version of the PGHD Trust Canvas integrates crucial factors that influence trust decisions, including clinical quality, provenance, risk, governance, necessity, and prior usage, along with the newly added "Purpose" field, which was introduced to emphasize the alignment of PGHD with specific clinical goals. These modifications enhance the tool's usability and relevance, making it more aligned with clinicians' expectations and better suited for integration into various clinical workflows.

The iterative development and refinement of the PGHD Trust Canvas represent a significant contribution to addressing the complexities of using PGHD in healthcare. By offering a practical, user-centered tool, this work supports clinicians in navigating the challenges of PGHD trust, ensuring that they can make more informed and reliable decisions. The next stage of this research, detailed in Chapter 6, will describe the implementation and validation of the working prototype in clinical practice to evaluate its effectiveness and further refine its design.

Chapter 6. PGHD trust canvas validation study

This chapter presents the qualitative validation of the PGHD Trust Canvas, a tool developed to assist clinicians in navigating the complexities of incorporating PGHD into their clinical practice. As discussed in previous chapters, while PGHD holds great potential for enhancing healthcare delivery, it also presents significant challenges, particularly concerning trust and decision-making. Building on the conceptual framework in section 2.4.5.2, the knowledge gained regarding the factors that affect trust in Chapter 4, and tool development covered in Chapter 5, this chapter presents the results of a study aimed at evaluating the practical usefulness, usability, and potential applications of the PGHD trust canvas in real-world clinical settings. By analysing feedback from clinicians, this chapter provides insights into how the tool can support clinical decision-making and contribute to improving the integration of PGHD in healthcare

The study presented in this chapter addresses SRQ4 (Do clinicians find the tool developed useful to make the decision whether to trust or distrust PGHD?) and O4 (establish the validity of the tool developed in the fulfilment of O3 for clinicians deciding whether to use PGHD as part of specific clinical decisions).

6.1 Overview

In the preceding chapters, this thesis explored the complex landscape of PGHD, highlighting both its potential to enhance clinical decision-making and the significant challenges it presents, particularly in terms of trust and usability. Chapter 5 described the co-development of the PGHD Trust Canvas, a decision-support tool designed to help clinicians navigate these challenges by providing a structured framework to assess whether PGHD should be incorporated into their clinical decision-making processes.

This chapter builds on the earlier development of the PGHD Trust Canvas by presenting a qualitative validation study aimed at evaluating its practical utility and acceptance among clinicians. Using insights from Chapter 2 and Chapter 4, the study employed online semi-structured, in-depth interviews with clinicians actively involved in patient care and clinical decisions. The goal was to gather feedback on the perceived usefulness and usability of the PGHD Trust Canvas.

By analysing clinicians' responses, this study sought to explore the tool's practical applications, potential limitations, and areas for improvement, as well as its potential use cases in clinical practice. The findings provide a deeper understanding of the PGHD Trust Canvas' strengths and limitations, shedding light on how it can be integrated into various clinical contexts, its ability to bolster confidence in decision-making, and its educational value.

6.2 Methods

6.2.1 Study design

This study employs a qualitative research design to validate the PGHD Trust Canvas, focusing on clinicians' perceptions of its perceived usefulness and usability. These two constructs, derived from the TAM and the UTAUT, are key indicators of whether a tool will be adopted in real-world settings. Perceived usefulness reflects the extent to which clinicians believe the PGHD Trust Canvas enhances their decision-making, while usability assesses how easy and intuitive the tool is to use in a clinical environment.

The study was structured around online semi-structured, in-depth interviews, chosen for their ability to capture detailed insights into clinicians' experiences and perspectives. This approach

allowed for a flexible exploration of the PGHD Trust Canvas, enabling participants to discuss their thoughts and experiences in a natural, conversational manner while still addressing key themes identified through prior research. By focusing on perceived usefulness and usability, this study aligns with established models of technology acceptance, ensuring that the validation process considers both the practical benefits and the ease of integrating the tool into clinical practice.

6.2.2 Study population and sampling method

Participants were contacted from a list of clinicians that showed interest in the subject and that offered to help on past occasions. The sample size was determined by the principle of theoretical saturation (Glasser and Strauss, 1999), continuing recruitment until no new themes or insights emerged from the interviews. Participants were selected through purposive sampling, targeting clinicians actively engaged in patient care and decision-making processes.

6.2.3 Ethics approval

Ethical approval for this study was granted by the Research Ethics Committee in the School of Computer Science and Statistics of Trinity College Dublin on the 2nd of May 2024 (See 10.3) .

6.2.4 Data collection and analysis

The data collection and analysis in this study is similar to that of Study 1 (see Chapter 4), where interviews were audio recorded using Zoom, transcribed using MS word Online, and analysed using NVivo 12 software. The transcripts were also analysed using grounded theory (Charmaz, 2001). The thematic coding was carried out in 3 stages: first was open, line by line coding, where every statement was matched to a node; second was axial coding, where the nodes were grouped into domains and subdomains; third was the recognition and organization of the themes.

6.3 Results

This section presents the findings from the qualitative validation study of the PGHD Trust Canvas. The results are organized into two key themes that emerged from the interviews with clinicians. These themes are (1) the perceived general usefulness and limitations, and (2) the features which, in the clinicians' opinion, make the tool useful and easy to use. Section describes the codes included in the theme of general usefulness, while section 6.3.2 details the codes related to the tool's useful features. Table 5 provides a summary of the codes.

6.3.1 Usefulness

A total of 11 clinicians participated in the interviews, each lasting between 35 and 45 minutes. Following a brief explanation and demonstration of an initial prototype, participants were asked for their general impressions of the PGHD Trust Canvas. Eight participants initially expressed that the tool seemed useful, primarily due to the potential of PGHD to improve efficiency in healthcare delivery.

> *"I think the value of this tool is that it can create a more efficient environment because you would save time and resources."*

Another participant emphasized the tool's potential for assessing new technologies and their adoption:

> *"I think where your tool will be really useful is around interventions and technology adoption."*

However, seven participants pointed out that the tool's usefulness would be limited in time-sensitive scenarios, where clinicians may not have the luxury of completing it regularly:

> *"Realistically, as a clinician, having time to open an application and fill it in regularly is kind of unrealistic."*

Although the primary purpose of the PGHD Trust Canvas is to assist clinicians in the binary decision of whether to include or exclude PGHD from their decision-making process, over half (7 of the 11) of the clinicians saw potential for the tool beyond this initial aim. Seven participants suggested that the tool could be valuable for recording their thought processes when making trust-related decisions:

> *"I want to be able to know where my thought process was at that time. And yeah, you've mapped it out well there, so you can see why the decision was made."*

Similarly, seven clinicians indicated that the tool could help justify their decisions, especially if it allowed them to electronically save and retrieve previous canvases:

> *"So this is your decision—a protocol assisting you in logically explaining your rationale for why you made that decision. Absolutely, yeah. That would work."*

Six participants also found the tool useful as a record of the information available at the time the trust decision was made:

> *"Why did I think that? Why did I send that referral? If I had something like this and it saved... OK, this is the information we had at the time."*

Additionally, the tool's potential for educational use was highlighted in seven interviews, where participants saw value in its application in training or educating clinicians in PGHD.

> *"…so that can certainly be used in a training in, you know, in nurse training that's 100% because it's it's reflective writing…"*

6.3.2 Useful features

During the interviews, clinicians were encouraged to share their opinions and comment on the specific features of the tool they found useful. Five participants noted that the tool was easy to use, while another five highlighted that it effectively reflects the clinician's thought process. Additionally, four participants felt that the tool helps instill confidence in the decisions being made.

Three clinicians suggested that the ability to save completed canvases for future reference would be a valuable addition, and one participant mentioned that the tool's flexibility to accommodate different types of clinicians was particularly beneficial.

Several specific elements of the canvas were also highlighted for their usefulness. Five participants found the prompt questions to be helpful in guiding the user through the decision-making process. Other features that were frequently mentioned included the fields for Information Origins, Purpose, and Clinical Quality, each noted by four participants. The fields for Prior Usage and Necessity were mentioned in two interviews each.

Name	Description	Files	Ref
Useful features			
Field of Clinical quality	These are references of the clinical quality field as a useful feature of the tool.	4	8
Field of Information origin	These are references of the Information origin field as a useful feature of the tool.	4	6
Field of Necessity	These are references of the Necessity field as a useful feature of the tool.	2	3
Field of Prior usage	These are references of the Prior usage field as a useful feature of the tool.	2	4
Field of Purpose	These are references of the Purpose field as a useful feature of the tool.	4	6
Prompt questions are useful	These are references where the participant highlights the prompt questions as being useful.	5	6
Saving their canvasses would be useful	These are references where the participant points out that saving the canvasses for later review would be useful.	3	5
Tool caters for different types of clinicians	This is a reference to the ability of the tool to cater for the needs of different types of clinicians when they need to make a decision whether to trust PGHD.	1	1
Tool helps the clinician by making them confident	These are references where the clinician emphasizes that the tool can help the clinician feel confident about the decision whether to include or exclude the PGHD.	4	4
Tool is easy to use	These are references where the participant considered the tool easy to use.	5	7
Tool reflects the thought process of the clinician	This node includes references of the tool's usefulness due to its ability to capture the clinician's thought process.	5	6
Usefulness			
Generally useful	These are references to the tool being generally useful.	8	8
The tool would be useful in scenarios where it's not time sensitive	This node includes references where the clinician considered that the tool's utility has an inherent limitation to scenarios where lack of time is not a major factor.	7	17
Useful around technology adoption	These are references to the tool being useful for the adoption of technology on behalf of the clinicians.	1	2

Name	Description	Files	Ref
Useful as a record of the information available at the time	This node includes references to the tool's ability to function as a record of the information available at the time of making the decision whether to include or exclude PGHD.	6	8
Useful as a record of the thought process	This node includes references of the tool's ability to function as a record of the thought process when using their clinical judgement to decide whether to include or exclude PGHD.	7	18
Useful in education	This node includes references of clinicians stating the possible usefulness of the tool as an educational tool.	7	10
Useful to justify decisions	This node includes references to the tool's usefulness at helping clinicians justify their decisions when using PGHD.	7	9

Table 5 Codebook for Study 3

6.4 Discussion

The results of this study highlight both the limitations aof the PGHD Trust Canvas and its potential usefulness. While the tool's requirement for note-making presents a significant limitation, especially in time-sensitive situations, it also shows promise in less acute settings. This section discusses these aspects in detail, exploring the contexts where the tool could be most beneficial and how it records and reflects clinicians' thought processes when deciding whether to trust. Through examples and feedback from participants, this discussion provides an understanding of the tool's practical applications and areas for improvement.

6.4.1 Tool limitation

A significant limitation of the PGHD Trust Canvas is that it requires clinicians to make notes, a time-consuming process. Many participants, particularly those in pre-hospital care, highlighted this drawback, recognizing that the tool may be better suited to low-acuity settings. Clinicians working in time-sensitive environments, such as emergency or pre-hospital care, frequently mentioned this concern. The issue was raised 17 times, reflecting how strongly some clinicians felt about the potential burden to their workflow.

Despite this, clinicians did not view the limitation as a deterrent to the tool's usefulness in certain settings. For example, within the Irish National Ambulance Service, the PGHD trust canvas could be well-suited for use by community paramedics, whose role focuses on managing chronic conditions, providing preventive care, and reducing unnecessary hospital admissions in non-emergency environments. Unlike traditional paramedics who respond to emergencies, community paramedics operate in less time-pressured contexts, making the tool more feasible for use.

The PGHD Trust Canvas is particularly well-suited for disciplines where care plans evolve infrequently and with deliberation. One clinician working in a nursing home noted that care plan adjustments are made less frequently and involve careful consideration, making the canvas a valuable tool for assessing PGHD in these environments. The slower, more reflective decision-making process aligns well with the canvas's design, helping clinicians determine whether new data should influence long-term care plans.

In nursing homes, where many residents live with chronic conditions such as dementia, diabetes, or heart disease, care plans are often stable and adjusted only gradually. The multidisciplinary approach to care plan changes involves various professionals—nurses, doctors, dietitians, and therapists—who collaborate to ensure that any modifications are well-considered and in the patient's best interest. This comprehensive, thoughtful process is ideal for the use of the PGHD trust canvas, which supports the careful integration of new data into ongoing care.

6.4.2 Usefulness

The theme of usefulness emerges prominently in the results of this study. Overall, the findings suggest that the PGHD Trust Canvas has the potential to become a valuable resource for clinicians in their practice. From its conception, the canvas was designed to aid clinicians in making the binary decision of whether to trust or distrust PGHD presented by patients. A key goal was to accurately reflect the clinicians' thought processes during this decision-making, which revealed several potential benefits, particularly in keeping records related to these thought processes.

Recording the clinicians' decision-making process is inherently challenging. During the interviews, participants did not report being aware of any existing tool that provides this

functionality. One illustrative example involved a nurse who made the unusual decision to trust PGHD from a wearable device due to an extraordinary necessity. The nurse referred a patient to a dermatologist based on data from the patient's smartphone app, a deviation from standard procedure. When the specialist queried the referral decision, the nurse could not easily explain the rationale behind it. If the nurse had used the PGHD Trust Canvas, she could have reviewed her records and explained all the factors that led to the referral.

In addition to aiding in decision-making, the PGHD Trust Canvas was perceived as a valuable tool for recording the information available at the time trust decisions were made. For instance, a clinician interviewed for the study dismissed PGHD from a patient's smartwatch, citing concerns about the accuracy of the technology. In a hypothetical scenario where later research validates the smartwatch's accuracy, the clinician could have used the Trust Canvas to review their records and understand that their initial decision was based on the knowledge available at that time. This highlights the dynamic nature of trust in technology and the canvas's potential role in documenting the evolving rationale behind clinical decisions.

6.4.3 Education affordances

The potential of the tool in clinical education was highlighted by seven participants, as it systematically captures and records clinicians' thought processes, offering a valuable resource for both training and reflection. By documenting each step of the decision-making process, the PGHD Trust Canvas provides a clear and structured approach for trainees to observe how experienced clinicians evaluate and trust PGHD. This feature can be especially beneficial in educational settings, where understanding the rationale behind clinical decisions is crucial. Furthermore, the tool's ability to save and review past records facilitates continuous learning and improvement, making it an excellent resource for both novice and seasoned clinicians alike.

Unexpectedly, its potential usefulness extends beyond the evaluation of PGHD. One participant involved in clinical education noted that the tool could also be effective in teaching clinical reasoning skills. They remarked:

> *"… when you're trying to help people develop those kinds of clinical reasoning skills. And I suppose when we start clinical reasoning anyway, you do use these frameworks or you kind of lay it all out."*

This suggests that the PGHD Trust Canvas could potentially serve as a broader educational tool, aiding not only in decision-making related to PGHD but also in developing general clinical reasoning through its structured, reflective framework.

6.5 Chapter summary

This chapter presented the qualitative validation of the PGHD Trust Canvas, a decision-support tool aimed at assisting clinicians in determining the trustworthiness of patient-generated health data. Through in-depth interviews with clinicians, the study explored the perceived usefulness and usability of the tool, highlighting both its strengths and limitations. The results indicate that the PGHD trust canvas holds significant potential for supporting decision-making in non-emergency clinical settings, providing a structured framework to document and reflect on the rationale behind trust decisions around PGHD.

While the tool was recognized as valuable for capturing clinicians' thought processes and providing a record of decisions made, its time-consuming nature was seen as a limitation in fast-paced environments. However, its utility in less time-sensitive settings, such as chronic care management and nursing homes, was emphasized. Additionally, the PGHD Trust Canvas showed

promise as an educational tool, with participants suggesting that it could be used to teach clinical reasoning skills, offering a structured way to reflect on and improve decision-making processes.

Overall, this chapter demonstrated that the PGHD trust canvas has the potential to enhance clinical practice by improving the integration of PGHD and supporting continuous learning. Future iterations of the tool may focus on addressing its limitations in time-pressured environments while leveraging its strengths in structured decision-making and education.

Chapter 7. Discussion

This chapter synthesizes the findings from the research and aligns them with the original research questions and objectives outlined in Chapter 1. The discussion reflects on how the research has addressed the complexities of clinician trust in PGHD and examines the significance of the PGHD trust canvas as a decision-support tool.

The chapter is organized into two key sections: first, a reflection on how the research questions have been fulfilled, with detailed analysis and response to each sub-research question, and second, an exploration of how the research objectives have been achieved, focusing on the development, validation, and potential of the PGHD Trust Canvas in clinical practice. The discussion also considers the broader implications of these findings for future research and clinical application.

7.1 Fulfilment of research questions

This thesis set out to explore how clinicians can be assisted in making informed decisions about whether to trust or distrust PGHD for clinical decision-making. The research question for this research outlined in section 1.2 was:

How can clinicians be assisted with the decision whether to trust or distrust PGHD in the context of clinical decision-making?

The complexity of this question was partitioned into 4 sub research questions:

SRQ1 **What is the current state of the art (SOA) on clinician trust in PGHD?**
Answering SRQ1 required an understanding of PGHD that allowed for flexibility in compliance with the definition of PGHD described in section 2.3, a review of the art and science of clinical decision making described in section 2.6, and a thorough review of the challenges in the incorporation of PGHD in the clinical decision-making process described in section 2.4. It also required the development of a concept of trust as a binary decision, rather than a complex and dynamic relationship, with the classification of affecting factors, pivoting on the component to which they could be assigned described in 2.4.5.1.

SRQ2 **How can healthcare providers evaluate the various sources and context of PGHD for its use in the clinical decision-making process?**
Answering SRQ2 involved an exploration of the factors that clinicians consider when deciding whether to trust or distrust PGHD. As detailed in Chapter 4, semi-structured interviews were conducted to gather insights into the key factors that influence clinician decision-making regarding PGHD. The analysis revealed five main factors: guidance/governance, data quality, data provenance, risk, and necessity. These factors were categorized into three broader areas — trustor, trustee, and context — which were pivotal to understanding how clinicians evaluate PGHD in practice. Furthermore, the review of existing literature highlighted that clinicians often struggle with evaluating the reliability of PGHD, especially when it comes from consumer-grade devices or lacks clinical oversight. By identifying these factors, this research provided the foundation for developing a structured approach to guide clinicians in assessing the trustworthiness of PGHD.

SRQ3 **What type of decision support tool can be developed to support healthcare providers facing the decision whether to trust PGHD for its use in clinical decision-making process?**
Answering SRQ3 required the design and development of a tool that would support clinicians in assessing whether PGHD can be trusted. This challenge was approached through a co-development process with clinicians, informed by insights gained from the interviews (Chapter 4) and the literature review (Chapter 2). It became evident that a holistic decision-support tool was needed, one that could address the multidimensional factors affecting trust, including data

quality, provenance, risk, and governance. The result was the creation of the PGHD trust canvas, a structured tool that guides clinicians through a reflective process, allowing them to consider all relevant aspects of PGHD before integrating it into clinical decision-making. This iterative development process, centered around user engagement, ensured that the tool was practical, user-friendly, and adaptable to various clinical settings.

SRQ4 Do clinicians find the tool developed useful to make the decision whether to trust or distrust PGHD?

Answering SRQ4 involved validating the PGHD trust canvas through qualitative feedback from clinicians who used the tool in simulated clinical scenarios. The interviews and feedback sessions (Chapter 6) revealed that clinicians appreciated the structured approach provided by the canvas, which helped them systematically evaluate the trustworthiness of PGHD. Particularly in non-urgent care settings, clinicians found the tool useful for guiding their decision-making, as it allowed them to assess critical factors like data quality, provenance, and associated risks. This validation confirmed the canvas's potential to support clinicians in making informed trust decisions, though further research is needed to explore its effectiveness in time-sensitive environments and across a broader range of clinical contexts.

7.2 Fulfilment of research objectives

Each of the sub research question aligns with a corresponding research objective. SRQ1 guides research objective O1.a and O1.b, SRQ2 guides research objective O2, SRQ3 guides research objective O3, and SRQ4 guides research objective O4.

7.2.1 Research objective 1

The first research objective was *"Review the state of the art on the topics of clinician trust in data focusing on: a) understanding of PGHD and clinician trust, including quantification or trust, and b) identification within the literature and understanding of the main factors that affect clinician trust in PGHD".*

O1.a was accomplished by conducting a SOA review of PGHD, its potential and challenges, clinician trust, and clinical decision-making detailed in Chapter 2.

O1.b was accomplished by the development of a conceptual framework that viewed the factors affecting trust in three areas: the trustor, the trustee and the context (See Figure 2).

7.2.1.1 SOA of PGHD (O1.a)

The sub-research question in section SRQ1 of section 1.2 in this thesis requires a comprehensive review of the current SOA regarding clinician trust in PGHD. This review, presented in section 2.3, explores the definition and classification of PGHD, as well as the unique challenges that arise from the nature of this definition. The review highlights key issues related to the incorporation of PGHD into the clinical decision-making process, such as difficulties in workflow integration, the lack of standardized frameworks for PGHD, governance challenges, and concerns about the actionability of the data.

Central to these challenges is the issue of clinician trust, which became the focal point of this research as it is critical for the effective use of PGHD in clinical practice.Understanding the state of the art of clinician trust required a thorough review of the study of trust, from the philosophical origins to those studies aimed to understand the relationship between the clinician and the patient. With the many interpretations and views of the topic of trust it was necessary to narrow the concept and axiomatically decide for a definition of trust as a decision, rather than

a relationship, state of mind, or any other of the conceptualizations of trust. This was viewed as the most useful point of view since it aligned with the research question in 1.2.

7.2.1.2 Conceptual framework

To better understand clinician trust in PGHD, the factors that affect trust were framed across three categories: the trustor (clinician), the trustee (PGHD), and the context.

7.2.1.2.1 Trustor factors (2.4.5.2.1)

These include factors inherent in the clinician. Factors like the clinician's aversion or tolerance to risk, the nature of the clinician's training, personal understanding of the technology, etc.

7.2.1.2.2 Trustee factors (2.4.5.2.2)

These include the trustworthiness of the data, its quality (accuracy, completeness, relevance), provenance, and the evidence supporting the data. Clinicians emphasized the importance of data quality, particularly when making decisions based on patient-generated data.

7.2.1.2.3 Context factors (2.4.5.2.3)

Environmental or situational factors, such as the type and composition of the risk involved the clinical decision, the guidance available, the acuity of the patient's condition, and the availability of other clinical information, also affect trust. Uncertainty and the severity of potential adverse outcomes were particularly impactful when making trust decisions.

7.2.2 Research objective 2

The second research objective was *"Identify and classify the key factors that, from the clinician's perspective affect the decision whether to include or exclude PGHD from their clinical decision process". O2* was accomplished through an interview study detailed in Chapter 4 which included a series of semi-structured interviews that after analysis using qualitative methods, resulted in the identification of 5 main factors: guidance, governance and regulation; quality; provenance; risk, and necessity.

7.2.2.1 Guidance/Governance/Regulation

Clinicians often encounter situations where they must decide whether to trust or distrust PGHD. The interviews revealed a strong desire for a decision-support tool to assist in this process, which led to the development of the PGHD trust canvas. This tool serves as a framework for clinicians to find clarity and to make more confident trust decisions.

7.2.2.2 Quality

The quality of PGHD was highlighted as a critical factor influencing trust. Dimensions such as accuracy, relevance to clinical context, and evidence supporting the data were particularly important. While other dimensions of data quality are also crucial, clinicians were most concerned with those directly impacting patient care.

7.2.2.3 Provenance

Perhaps the most noticeable learning about clinicians and data provenance is that clinicians don't use the term and don't usually know what it means. As another example of the different frames of mind between clinicians and computer scientists, provenance as known by the IT community seemed irrelevant when trusting or distrusting data. The analysis of the interviews revealed themes related to provenance that were mostly non-technical. Clinicians seemed to show interest in knowing human aspects of the origin of the data like the patient's intentions, capabilities and the organization behind the technology. Another finding that is not likely to surprise, is that clinicians tended to see PGHD that were "prescribed" as more worthy of their

trust. This furthers the argument that clinicians are more interested in human aspects of the data, rather than those of a technical nature.

7.2.2.4 Risk

Within the context of the trust decision, risk emerged as another major concern for clinicians. Although not explicitly stated, risk was understood as a two-part concept constituted on the one hand by the likelihood of the clinical decision to have any adverse effect, and on the other, the severity of such adverse effect. For instance, a clinician that decides to use PGHD created by Skinvision, an app that detects malignant lesions in the skin, to make the clinical decision whether to refer their patient to the dermatologist, can cause unnecessary concern to the patient and a burden to the system if it turns out that the lesion was not a concern. In this case, although significant, the severity of the adverse consequence is mild compared to other decisions that can mean severe injury or harm to the patient. It is only through the understanding of these two aspects of risk, and the rest of the factors from a holistic perspective that the decision of trust can be made correctly.

7.2.2.5 Necessity

The study revealed that the necessity to use PGHD can be a major factor in the likelihood of clinicians trusting PGHD. Although an obvious factor in the decision to trust or distrust, the necessity of trust due to any factors was only taken into account by the researcher after the first study. Many of the participants in the study mentioned that during the COVID pandemic that started in 2020, they had to rely on PGHD to provide any care to their patients. Anyone that couldn't afford a reliable car and had to go to work in an unreliable vehicle would not argue with this.

Also, related to necessity, but from a positive perspective, any considerable benefit to the clinician, like an improvement of their workflow, would affect the likelihood of clinicians trusting PGHD. The use of PGHD by diabetes clinics is a clear example of this.

7.2.2.6 Repercussion on this research

The findings from this research directly shaped the development of the PGHD trust canvas (Chapter 5) by identifying key factors such as guidance/governance, data quality, provenance, risk, and necessity that clinicians consider when deciding to trust or distrust PGHD. These factors were incorporated into the canvas, prompting clinicians to reflect on the quality and relevance of the data, its origin, and the potential risks involved in using it for decision-making. The emphasis on the human aspects of data generation and provenance influenced the inclusion of considerations beyond technical data quality. Additionally, the tool was designed to help clinicians reflect on risk, balancing the likelihood and severity of potential outcomes, and to be flexible in contexts where PGHD is critical, such as during remote care, based on their judgement about the necessity of PGHD. These insights ensured that the canvas is both practical and aligned with clinicians' real-world clinician needs.

7.2.3 Research objective 3

The third research objective was *"to develop a tool to help clinicians with the decision whether to include or exclude PGHD from their clinical decision process"*. O3 was accomplished through the development of the PGHD trust canvas, a structured decision-support tool that guides clinicians in evaluating the trustworthiness of PGHD. The need for such a tool became evident during the literature review (Chapter 2) and the interviews with clinicians (Chapter 4), which highlighted the complexity clinicians face when integrating PGHD into their workflows, due to variability in data quality, provenance, and risk.

7.2.3.1 The Need for a Holistic Approach

The analysis of the literature review (Chapter 2) and the clinicians' perspective on trusting PGHD (Chapter 4) revealed that the decision of whether to trust PGHD could not be simplified into a binary yes-or-no framework without considering the broader context. Clinicians expressed the need for a tool that would allow them to systematically assess different dimensions of PGHD, rather than relying solely on intuition or experience. The complexity of clinical decision-making, particularly with new and unfamiliar data types generated by wearable devices and patient self-reporting, required a holistic approach that considered both the technical and human factors influencing data trustworthiness.

This insight led to the conclusion that creating a tool that simply provided a definitive answer on whether to trust or distrust PGHD was not feasible. Instead, a decision-support tool that encouraged reflection on multiple factors, allowing clinicians to make informed, context-sensitive decisions, was more appropriate. This shifted the focus from a static, binary tool to a flexible, user-centered framework designed to guide clinicians through a structured evaluation process.

7.2.3.2 Co-Development and Iterative Design

The development of the PGHD Trust Canvas was carried out through an iterative co-development process involving clinicians, ensuring the tool was practical and grounded in real-world clinical needs. Input from clinicians, gathered through interviews and feedback sessions, was critical in shaping the design of the canvas. This user-centered approach ensured that the tool was not only theoretically sound but also aligned with the everyday challenges faced by healthcare providers.

Clinicians upheld several key factors that influenced their trust in PGHD: data quality, provenance, risk, guidance, governance, and necessity. Each of these factors was incorporated into the structure of the canvas, prompting clinicians to reflect on specific elements of PGHD during their decision-making process. For example, emphasis on data quality was steered towards dimensions such as accuracy, relevance to the clinical context, and the evidence supporting the data. Provenance focused on understanding the origins of the data, with clinicians particularly interested in the patient's role and the technology or organization behind the data collection process.

7.2.3.3 Incorporating Key Factors into the Canvas

The design of the PGHD Trust Canvas was guided by several key factors identified in the research:

7.2.3.3.1 Data Quality:

Clinicians highlighted the need to evaluate data accuracy, relevance, and evidence. These dimensions were built into the canvas as prompts to guide reflection on whether PGHD meets clinical standards.

7.2.3.3.2 Provenance:

While clinicians were unfamiliar with the technical term, they valued knowing the source of the data. The canvas includes prompts that encourage reflection on the human aspects of data generation, such as patient capabilities and clinical oversight.

7.2.3.3.3 Risk:

Risk emerged as a major factor, with the canvas including a section for clinicians to assess the likelihood and severity of adverse outcomes when using PGHD.

7.2.3.3.4 Guidance and Governance:

Clinicians often faced uncertainty due to a lack of clear guidelines. The canvas helps assess how PGHD aligns with existing governance frameworks and regulatory standards.

7.2.3.3.5 Necessity:

The tool includes considerations of whether PGHD is essential, particularly in scenarios where alternative data is unavailable, such as during remote care or the pandemic.

7.2.3.4 Flexibility and Usability

The PGHD Trust Canvas was designed to be flexible in terms of format, allowing clinicians to use it in both print and digital versions depending on their preferences. However, its usability is most suitable in non-urgent, reflective care settings, such as nursing homes or outpatient clinics, where clinicians have the time to thoughtfully assess data quality, provenance, and risk. In these environments, the tool supports clinicians by guiding them through a structured evaluation process, enabling them to make more informed decisions about whether to trust or distrust PGHD.

Importantly, the PGHD Trust Canvas is not intended for use in high-pressure, time-sensitive environments, such as emergency rooms, where rapid decision-making is critical. The structured reflection required by the canvas is better suited to settings where clinicians have the opportunity to engage in more deliberate decision-making processes. Its design allows clinicians to document their reflections and decisions, providing a valuable record that can be referenced later or used in training.

In its current state, the advanced prototype of the PGHD trust canvas allows clinicians to enter their thoughts, considerations, and reflections on the different aspects of the PGHD at hand. Clinicians can use a printed or an online version of the tool. At the time of writing this document, the latest iteration of the PGHD trust canvas could be found in the following link: https://trustedhealthdata.web.app

7.2.4 Research objective 4

The fourth research objective was *to "establish the validity of the tool developed in the fulfilment of O3 for clinicians deciding whether to use PGHD as part of their clinical decision process."* O4 was accomplished through a qualitative validation study described in Chapter 6, where the PGHD trust canvas was tested with clinicians across various healthcare disciplines. The validation process involved semi-structured interviews in which clinicians applied the tool to simulated decision-making scenarios, assessing the usability and usefulness of the canvas. The study confirmed that the tool is particularly valuable in non-urgent care settings, where clinicians have the time to reflect on PGHD before making decisions. However, its utility was found to be limited in high-pressure environments, where rapid decision-making is essential, highlighting that the tool is best suited for slower-paced, reflective clinical settings.

7.2.4.1 Usability and Usefulness

Clinicians acknowledged the canvas's value in non-acute environments, such as nursing homes or chronic care management, where decisions are made more thoughtfully and at a slower pace. They found that the canvas provided a structured framework to reflect on the reliability and trustworthiness of PGHD, providing them with confidence at the time of deciding upon PGHD. For instance, the canvas enabled clinicians to record their reasoning when they chose to trust or dismiss PGHD, which could be invaluable for future reference or explaining decisions to

colleagues. This reflective aspect of the tool was particularly appreciated in settings where care plans are adjusted slowly over time.

One participant shared how the canvas could be useful in a hypothetical situation where they referred a patient based on PGHD from a wearable device, deviating from usual practice. If questioned later by a specialist, the clinician would likely struggle to explain the rationale behind the referral. If the PGHD trust canvas were used in this instance, the clinician could easily revisit their decision-making process to provide a confident justification.

However, participants identified the time-consuming nature of completing the canvas as a major limitation in high-pressure environments, such as emergency rooms or acute care settings. Clinicians felt that in these contexts, they did not have the time to thoroughly engage with the tool.

As one participant pointed out:

> *"Realistically, as a clinician, having time to open an application and fill it in regularly is kind of unrealistic"*

This feedback underscored the need for the tool to be used primarily in slower-paced, reflective clinical environments, where decisions about PGHD are less urgent. That is not to say that a fast-paced discipline would have no use for the tool. In areas like the emergency department, or in pre-hospital care, high level decisions like the review of clinical practice guidelines or general advice on concurrent examples of PGHD, could benefit from this tool.

7.2.4.2 Educational Potential

Beyond its primary function as a decision-support tool, clinicians also recognized the educational potential of the PGHD trust canvas. Seven participants noted that the tool could be particularly useful in training both new and experienced clinicians, helping them develop clinical reasoning skills. By documenting each step in the decision-making process, the canvas could teach clinicians how to systematically evaluate PGHD, offering a clear structure for reflection.

One clinician remarked:

> *"When you're trying to help people develop those kinds of clinical reasoning skills... you do use frameworks or you kind of lay it all out".*

The ability to save and review past decisions was also seen as a way to promote continuous learning and improvement, by allowing clinicians to reflect and communicate their reasoning process.

7.3 Chapter summary

This chapter provided a detailed discussion of how the research addressed the key question of assisting clinicians in deciding whether to trust or distrust PGHD in clinical decision-making. Through a structured response to the sub-research questions, the chapter highlighted the identification of key trust factors—data quality, provenance, governance, risk, and necessity—and their integration into the PGHD Trust Canvas. Additionally, the research objectives were fulfilled by developing and validating the PGHD Trust Canvas through co-development and qualitative feedback from clinicians. The chapter underscored the tool's usefulness in non-urgent, reflective clinical settings while acknowledging its limitations in high-pressure environments. Ultimately, the findings contribute to advancing trust frameworks in PGHD and open avenues for future research and application in various healthcare contexts.

Chapter 8. Conclusion

This thesis contributes to the growing body of research on clinician trust in PGHD through two main contributions. First, it developed and validated the PGHD Trust Canvas, a structured decision-support tool designed to assist clinicians in making informed decisions about whether to trust or distrust PGHD. By doing so, this research addresses critical gaps in the literature related to the adoption of PGHD in clinical decision making, particularly the challenges posed by the clinicians' lack of training, experience and ability to decide whether to trust or distrust PGHD.

Additionally, a minor yet significant contribution of this thesis lies in the knowledge gained in Study 1 (Chapter 4), where in-depth insights were gathered from clinicians regarding their perspectives on trust in PGHD. This understanding of clinicians' concerns and decision-making processes provides a foundation not only for the development of the PGHD trust canvas but also for other approaches aimed at facilitating the integration of PGHD into healthcare. These insights can inform the design of EHR systems**,** clinical decision-support tools**,** and training programs that address the specific challenges clinicians face. Furthermore, this knowledge can contribute to the development of policies and standards that ensure PGHD is used safely and effectively in clinical decision-making, promoting trust in the data and improving patient outcomes.

8.1 Key Takeaways

The key findings of this research highlight the cautious approach clinicians take when presented with PGHD, often due to concerns about data quality and the risks associated with integrating unverified data into clinical decision-making. However, the development of the PGHD Trust Canvas offers a practical solution to these challenges, enabling clinicians to assess data across key dimensions and ultimately make more informed decisions.

The validation of the tool demonstrated its usability and usefulness in non-urgent care settings, where clinicians have more time to reflect on the data. Clinicians appreciated the structured approach the canvas provided, particularly in guiding them through the complex process of evaluating data quality and relevance.

8.2 Significance of the Research

The significance of this research lies in its practical contribution to the safe and effective integration of PGHD into clinical care. By developing a tool that directly addresses clinicians' concerns around trust, this research has the potential to improve both patient outcomes and the quality of clinical decision-making. The PGHD Trust Canvas provides a structured framework that clinicians can use to assess PGHD, reducing the risk of relying on untrustworthy data and promoting patient safety.

Furthermore, this research contributes to the broader field of digital health by advancing the conversation on the role of PGHD in healthcare and the importance of developing tools to assist clinicians in navigating this new landscape. The additional knowledge gained from clinicians' perspectives in Chapter 4 further strengthens the understanding of how trust is developed and maintained in the use of patient-generated data.

8.3 Recommendations for Practice

To support the integration of PGHD into clinical workflows, healthcare institutions should consider incorporating tools like the PGHD Trust Canvas into their systems. This would not only improve clinician confidence in PGHD but also streamline the decision-making process, reducing

the cognitive burden on clinicians. Additionally, regulatory bodies should work toward developing specific standards for PGHD, ensuring that data meets the necessary quality and provenance criteria for use in clinical care.

8.4 Limitations

The justification for the choice of a qualitative approach lies in the depth and flexibility of the approach in dealing with vague, ambiguous and dynamic topics. The details of this decision is detailed in 3.2. This approach inherently has its limitations:

8.4.1 Sample Size and Representativeness:

The qualitative interviews conducted with 13 clinicians in Study 1 (see Chapter 4) provide valuable insights into the trust issues surrounding PGHD, but the small sample size limits the generalizability of the findings. The perspectives gathered are not necessarily representative of all healthcare providers across different specialties, geographic locations, or healthcare systems. This restricts the extent to which the findings can be applied to a broader clinical context at this point.

8.4.2 Context-Specific Validation:

The PGHD trust canvas was validated mainly in non-urgent care settings (Study 3 reported in Chapter 6), such as nursing homes and chronic care environments. While these environments allow for reflective decision-making, the tool was not validated for high-pressure, time-sensitive environments (e.g., emergency departments). As a result, the usability and effectiveness of the tool may be limited in clinical settings where rapid decision-making is crucial.

8.4.3 Reliance on Self-Reported Data:

The validation of the PGHD trust canvas in Study 3 (reported in Chapter 6) and the insights gained from clinicians' trust perspectives in Study 1 (reported in Chapter 4) were derived from interviews and self-reported feedback. Self-reported data can be subject to biases, such as clinicians presenting socially desirable answers or overestimating the practicality of the tool in actual clinical use. Further testing in real-world settings may be needed to validate these perspectives.

8.4.4 Qualitative Focus:

While the in-depth qualitative approach of Study 1 (Chapter 4) provides a rich understanding of the factors influencing clinician trust in PGHD, it may not capture the full range of challenges, especially those that could be identified through quantitative methods. For example, quantitative data could provide statistical insights into the broader clinician population's perspectives, offering a more generalizable view of the challenges in integrating PGHD into clinical workflows.

8.4.5 Technology-Specific Factors:

The focus of this research is primarily on clinicians' perspectives, especially on trust, governance, and data quality, while technology-specific factors such as the technical reliability of PGHD-generating devices, data security, or system integration with EHRs were not explored in depth. The exclusion of these technology-related concerns limits the scope of the findings and may overlook important factors that affect the safe and effective integration of PGHD into clinical care.

8.4.6 Iterative Development Process:

The development of the PGHD Trust Canvas followed an iterative, co-development process involving clinicians, which ensured that the tool was user-centered. However, the testing and validation in Chapter 6 were limited to simulated decision-making scenarios rather than real-world clinical settings. While the tool was well-received in these scenarios, its effectiveness in live clinical decision-making processes, particularly over time, remains to be fully explored.

8.5 Final Thoughts and Future Directions

The future of PGHD in healthcare holds immense potential, but its successful integration into clinical practice will depend on the development of tools and frameworks that address clinicians' concerns around trust. The PGHD Trust Canvas is a significant step in this direction, but further research is needed to validate its use across different healthcare contexts and refine its functionality.

As healthcare continues to evolve with the rise of digital health technologies, the development of regulatory frameworks and clinician training programs will be essential in ensuring that PGHD can be safely and effectively integrated into clinical decision-making. This thesis provides a foundation for these future developments, and it is hoped that the insights gained from this research will contribute to the ongoing advancement of digital health.

Chapter 9. References

Abdolkhani, R. *et al.* (2019) 'Patient-generated health data management and quality challenges in remote patient monitoring', *JAMIA Open*. Oxford University Press (OUP). doi: 10.1093/jamiaopen/ooz036.

Abdolkhani, R. *et al.* (2020) 'Quality assurance of health wearables data: Participatory workshop on barriers, solutions, and expectations', *JMIR mHealth and uHealth*. JMIR Publications, 8(1). doi: 10.2196/15329.

Abdolkhani, R., Borda, A. and Gray, K. (2018) 'Quality Management of Patient Generated Health Data in Remote Patient Monitoring Using Medical Wearables - A Systematic Review...Health Informatics Conference, Sydney Australia, 2018', *Studies in Health Technology & Informatics*, 252(January), pp. 1–7. doi: 10.3233/978-1-61499-890-7-1.

Acemyan, C. Z. and Kortum, P. (2012) 'The Relationship Between Trust and Usability in Systems', *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. SAGE PublicationsSage CA: Los Angeles, CA, 56(1), pp. 1842–1846. doi: 10.1177/1071181312561371.

Acquisti, A. and Grossklags, J. (2005) 'Privacy and rationality in individual decision making', *IEEE Security and Privacy*, 3(1), pp. 26–33. doi: 10.1109/MSP.2005.22.

AG, S. (no date) *Business Model Canvas – Download the Official Template*. Available at: https://www.strategyzer.com/canvas/business-model-canvas (Accessed: 12 April 2023).

Akbar, S., Coiera, E. and Magrabi, F. (2020) 'Review Safety concerns with consumer-facing mobile health applications and their consequences : a scoping review', *Jounral of the American Medical Informatics Association*, 27(2), pp. 330–340. doi: 10.1093/jamia/ocz175.

Aleem, I. S., Schemitsch, E. H. and Hanson, B. P. (2008) 'What is a clinical decision analysis study?', *Indian Journal of Orthopaedics*. Indian Orthopaedic Association, 42(2), p. 137. doi: 10.4103/0019-5413.40248.

Alós-Ferrer, C. and Farolfi, F. (2019) 'Trust Games and Beyond', *Frontiers in Neuroscience*. Frontiers Media SA, 13, p. 887. doi: 10.3389/FNINS.2019.00887.

Alyami, M. *et al.* (2017) 'Social anxiety apps: A systematic review and assessment of app descriptors across mobile store platforms', *Evidence-Based Mental Health*, 20(3), pp. 65–70. doi: 10.1136/eb-2017-102664.

AMA (2020) 'Medical Records and Patient Privacy Meeting Type : Interim', (5), p. 967.

American Society for Healthcare Risk Management (2009) *Risk management handbook for health care organizations*. John Wiley & Sons.

Andersen, T. O. *et al.* (2018) *Aligning Concerns in Telecare: Three Concepts to Guide the Design of Patient-Centred E-Health*, *Computer Supported Cooperative Work: CSCW: An International Journal*. Computer Supported Cooperative Work (CSCW). doi: 10.1007/s10606-018-9309-1.

Anderson, R. (2020) *Security Engineering*. Wiley. doi: 10.1002/9781119644682.

Archer, N. *et al.* (2011) 'Personal health records: a scoping review', *Journal of the American Medical Informatics Association : JAMIA*. Oxford University Press, 18(4), p. 515. doi: 10.1136/AMIAJNL-2011-000105.

Azodo, I. *et al.* (2020) 'Opportunities and challenges surrounding the use of data from wearable sensor devices in healthcare: a qualitative study (Preprint)', *Journal of Medical Internet*

Research, 22. doi: 10.2196/19542.

Bate, L. *et al.* (2012) 'How clinical decisions are made', *British Journal of Clinical Pharmacology*, 74(4), pp. 614–620. doi: 10.1111/j.1365-2125.2012.04366.x.

Bender, J. L. *et al.* (2013) 'A Lot of Action , But Not in the Right Direction : Systematic Review and Content Analysis of Smartphone Applications for the Prevention , Detection , and Management of Cancer Corresponding Author ':, *Journal of Medical Internet Research*, 15(12), pp. 1–12. doi: 10.2196/jmir.2661.

Berg, J., Dickhaut, J. and McCabe, K. (1995) 'Trust, Reciprocity, and Social History', *Games and Economic Behavior*. Academic Press, 10(1), pp. 122–142. doi: 10.1006/GAME.1995.1027.

Berg, M. (1999) 'Patient care information systems and health care work: a sociotechnical approach', *International Journal of Medical Informatics*. Elsevier, 55(2), pp. 87–101. doi: 10.1016/S1386-5056(99)00011-8.

Berry, D. L. (2011) 'Patient-reported symptoms and quality of life integrated into clinical cancer care', *Seminars in Oncology Nursing*. NIH Public Access, 27(3), pp. 203–210. doi: 10.1016/j.soncn.2011.04.005.

Bertino, E. *et al.* (2008) 'High-assurance integrity techniques for databases', in *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*, pp. 244–256. doi: 10.1007/978-3-540-70504-8_26.

Bettman, J. R., Johnson, E. J. and Payne, J. W. (1993) *The Adaptive Decision Maker*. Cambridge: Cambridge University Press. doi: DOI: 10.1017/CBO9781139173933.

Bickmore, T. and Cassell, J. (2001) 'Relational agents: a model and implementation of building user trust', in *Proceedings of the SIGCHI conference on Human factors in computing systems*, pp. 396–403.

Bierbrier, R., Lo, V. and Wu, R. C. (2014) 'Evaluation of the Accuracy of Smartphone Medical Calculation Apps Corresponding', *Journal of Medical Internet Research*, 16(2). doi: 10.2196/jmir.3062.

Billman, G. E. (2011) 'Heart rate variability - a historical perspective', *Frontiers in physiology*. Front Physiol, 2. doi: 10.3389/FPHYS.2011.00086.

Birks, M. and Mills, J. (2015) *Grounded theory: A practical guide*. Sage.

Boocock, M. and Grahame, D. (2003) 'Qualitative Interview Studies: Learning Through Experience', *Venture Capital, Islamic Finance and SMEs*. Routledge, pp. 67–84. doi: 10.4324/9781410609373-8.

Bouayad, L., Ialynytchev, A. and Padmanabhan, B. (2017) 'Patient health record systems scope and functionalities: Literature review and future directions', *Journal of Medical Internet Research*, 19(11). doi: 10.2196/jmir.8073.

Boyne, J. J. J. *et al.* (2012) 'Tailored telemonitoring in patients with heart failure: Results of a multicentre randomized controlled trial', *European Journal of Heart Failure*, 14(7), pp. 791–801. doi: 10.1093/eurjhf/hfs058.

Braga, F. and Panteghini, M. (2018) 'Defining permissible limits for the combined uncertainty budget in the implementation of metrological traceability', *Clinical Biochemistry*. Elsevier, 57, pp. 7–11. doi: 10.1016/J.CLINBIOCHEM.2018.03.007.

Brant, J. M. *et al.* (2015) 'Understanding and Evaluating Survey Research', *Journal of the*

Advanced Practitioner in Oncology. Harborside Press, 6(2), p. 168. doi: 10.6004/jadpro.2015.6.2.9.

Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology', *Qualitative research in psychology*. Taylor & Francis, 3(2), pp. 77–101.

Browne, K. (2007) 'Snowball sampling: using social networks to research non-heterosexual women', *https://doi.org/10.1080/13645570320000816 63*. Taylor & Francis Group Ltd , 8(1), pp. 47–60. doi: 10.1080/1364557032000081663.

Burka, J. F. *et al.* (2005) 'Defining the Personal Health Record', *Defining the Personal Health Record / AHIMA, American Health Information Management Association*. American Health Information Management Association, 13(3), pp. 379–388. Available at: http://library.ahima.org/doc?oid=59377 (Accessed: 5 December 2023).

Burnett, D. (2003) *ISO 15189:2003-FROM THEORY IN TO PRACTICE*.

Byabazaire, J., O'hare, G. and Delaney, D. (2020) 'Data Quality and Trust : A Perception from Shared Data in IoT', *Electronics (Switzerland)*, 9(12), pp. 1–22. doi: 10.3390/electronics9122083.

Byambasuren, O. *et al.* (2018) 'Prescribable mHealth apps identified from an overview of systematic reviews', *npj Digital Medicine 2018 1:1*. Nature Publishing Group, 1(1), pp. 1–12. doi: 10.1038/s41746-018-0021-9.

Cahill, J. (2020) 'The Specification of a "Human Factors and Ethics" Canvas for Socio-technical Systems', pp. 1–18. Available at: https://www.researchgate.net/publication/340512203_The_Human_Factors_Ethics_Canvas_A_White_Paper.

Canadian Institute for Health Information (2017) *CIHI's Information Quality Framework*. Available at: www.cihi.cacopyright@cihi.ca (Accessed: 30 June 2020).

Carroll, J. K. *et al.* (2017) 'Who uses mobile phone health apps and does use matter? A secondary data analytics approach', *Journal of Medical Internet Research*. Journal of Medical Internet Research, 19(4). doi: 10.2196/jmir.5604.

Cash, P., Stanković, T. and Štorga, M. (2016) 'Experimental design research: Approaches, perspectives, applications', *Experimental Design Research: Approaches, Perspectives, Applications*. Springer International Publishing, pp. 1–270. doi: 10.1007/978-3-319-33781-4/COVER.

Charmaz, K. (2001) 'Grounded Theory: Methodology and Theory Construction', *International Encyclopedia of the Social & Behavioral Sciences*. Pergamon, pp. 6396–6399. doi: 10.1016/B0-08-043076-7/00775-0.

Charmaz, K. (2014) *Constructing grounded theory*. sage.

Chen, Y. R. R. and Schulz, P. J. (2016) 'The Effect of Information Communication Technology Interventions on Reducing Social Isolation in the Elderly: A Systematic Review', *Journal of medical Internet research*, 18(1), p. e18. doi: 10.2196/jmir.4596.

Cheng, K. G. *et al.* (2015) 'Challenges of integrating patient-centered data into clinical workflow for care of high-risk infants', *Personal and Ubiquitous Computing*, 19(1), pp. 45–57. doi: 10.1007/s00779-014-0807-y.

Chung, A. E. and Basch, E. M. (2015) 'Potential and Challenges of Patient-Generated Health Data for High-Quality Cancer Care', *Journal of Oncology Practice*, 11(3). doi: 10.1200/jop.2015.003715.

Cochrane, A. L. (1972) *Effectiveness and efficiency: random reflections on health services*.

Cohen, D. J. *et al.* (2016) 'Integrating Patient-Generated Health Data Into Clinical Care Settings or Clinical Decision-Making: Lessons Learned From Project HealthDesign', *JMIR Human Factors*. JMIR Publications Inc., 3(2), p. e26. doi: 10.2196/humanfactors.5919.

Collard, D. (1989) *Trust: Making and Breaking Cooperative Relations*. Oxford University Press Oxford, UK.

Cresswell, K. M. *et al.* (2017) 'Workarounds to hospital electronic prescribing systems: A qualitative study in English hospitals', *BMJ Quality and Safety*, 26(7), pp. 542–551. doi: 10.1136/bmjqs-2015-005149.

Cresswell, K. M. *et al.* (2018) 'Five key strategic priorities of integrating patient generated health data into United Kingdom electronic health records', *Journal of Innovation in Health Informatics*. doi: 10.14236/jhi.v25i4.1068.

Dadayan, L. and Ferro, E. (2005) 'When technology meets the mind: A comparative study of the technology acceptance model', in *Lecture Notes in Computer Science*. Springer Verlag, pp. 137–144. doi: 10.1007/11545156_13.

Damen, D. J. *et al.* (2022) 'Patients Managing Their Medical Data in Personal Electronic Health Records: Scoping Review', *Journal of Medical Internet Research*. JMIR Publications Inc., 24(12). doi: 10.2196/37783.

Davidoff, F. *et al.* (1995) 'Evidence based medicine', *BMJ*. British Medical Journal Publishing Group, 310(6987), p. 1085. doi: 10.1136/bmj.310.6987.1085.

Davis, F. (1989) 'Perceived usefulness, perceived ease of use, and user acceptance of information technology', *MIS Quarterly: Management Information Systems*, 13(3), pp. 319–339. doi: 10.2307/249008.

Davis, F. D., Bagozzi, R. P. and Warshaw, P. R. (1989) 'User acceptance of computer technology: A comparison of two theoretical models', *Management science*. INFORMS, 35(8), pp. 982–1003.

Demiris, G. *et al.* (2019) 'Patient generated health data use in clinical practice: A systematic review', *Nursing Outlook*. Elsevier Inc., 67(4), pp. 311–330. doi: 10.1016/j.outlook.2019.04.005.

Djulbegovic, B. *et al.* (1999) 'Acceptable regret in medical decision making', *Medical Hypotheses*, 53(3), pp. 253–259. doi: 10.1054/mehy.1998.0020.

Downing, J., Bollyky, J. and Schneider, J. (2017) 'Use of a connected glucose meter and certified diabetes educator coaching to decrease the likelihood of abnormal blood glucose excursions: The livongo for diabetes program', *Journal of Medical Internet Research*. JMIR Publications Inc., 19(7), p. e6659. doi: 10.2196/jmir.6659.

Emmott, N. *et al.* (2024) *Regulatory Fit-for-Purpose Considerations for Patient-Generated Health Data*.

European Statistical System (2011) *Quality Assurance Framework of the European Statistical System*.

Evans, A. M. and Krueger, J. I. (2017) 'Ambiguity and expectation-neglect in dilemmas of interpersonal trust', *Judgment and Decision Making*. Cambridge University Press, 12(6), pp. 584–595.

Ferguson, T. (2000) 'Online patient-helpers and physicians working together: A new partnership for high quality health care', *British Medical Journal*. BMJ Publishing Group, 321(7269), pp.

1129–1132. doi: 10.1136/bmj.321.7269.1129.

Fiore-Gartland, B. and Neff, G. (2015) 'Communication, mediation, and the expectations of data: Data valences across health and wellness communities', *International Journal of Communication*, 9, pp. 1466–1484.

Fletcher, G. S. (2019) *Clinical epidemiology: the essentials*. Lippincott Williams & Wilkins.

Fox, M. S. and Huang, J. (2005) 'Knowledge provenance in enterprise information', *International Journal of Production Research*, 43(20), pp. 4471–4492. doi: 10.1080/00207540500142415.

Freeman, K. *et al.* (2020) 'Algorithm based smartphone apps to assess risk of skin cancer in adults : systematic review of diagnostic accuracy studies'. doi: 10.1136/bmj.m127.

Fresques, H. and Marco, M. (2019) *"Your Default Position Should Be Skepticism" and Other Advice for Data Journalists From Hadley Wickham — ProPublica*, *ProPublica*. Available at: https://www.propublica.org/nerds/hadley-wickham-your-default-position-should-be-skepticism-and-other-advice-for-data-journalists (Accessed: 28 July 2023).

Fromm, E. (1956) *The art of Loving*, *World Perspectives*. Available at: https://medium.com/@arifwicaksanaa/pengertian-use-case-a7e576e1b6bf.

Fukuyama, F. (1996) *Trust: The social virtues and the creation of prosperity*. Simon and Schuster.

Gagnon, M. P. *et al.* (2016) 'Adoption of electronic personal health records in Canada: Perceptions of stakeholders', *International Journal of Health Policy and Management*. Kerman University of Medical Sciences, 5(7), pp. 425–433. doi: 10.15171/ijhpm.2016.36.

Gambetta, D. (2000) 'Can We Trust Trust?', in *Trust: Making and Breaking Cooperative Relations*, pp. 213–237. Available at: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.24.5695&rep=rep1&type=pdf.

Gambetta, D. and Badcock, C. (1990) 'Trust: Making and Breaking Cooperative Relations', *The British Journal of Sociology*, p. 128. doi: 10.2307/591021.

Garfinkel, S. (2000) *Database Nation: The Death of Privacy in the 21st Century*. 1st edn. O'Reilly. Available at: https://books.google.com/books/about/Database_Nation.html?id=vZyFAAAAMAAJ (Accessed: 1 August 2023).

Glaser, B. and Strauss, A. (2017) *Discovery of grounded theory: Strategies for qualitative research*. Routledge.

Glaser, B. and Strauss, A. L. (1999) *The discovery of grounded theory: Strstegies for qualitative research*. 1st edn. London: Aldine Transaction. doi: https://doi.org/10.4324/9780203793206.

Glasser, B. G. and Strauss, A. L. (1999) *The discovery of grounded theory: Strstegies for qualitative research*. 1st edn. London: Aldine Transaction. doi: https://doi.org/10.4324/9780203793206.

Goranson, H. T. *et al.* (2003) 'A Merged Future for Knowledge Management and Enterprise Modeling', in *Enterprise Inter- and Intra-Organizational Integration*. Springer US, pp. 37–50. doi: 10.1007/978-0-387-35621-1_5.

Greenhalgh, T. (2010) *How to Read a Paper: The Basics of Evidence-Based Medicine*. Wiley. Available at: https://books.google.ie/books?id=q-92iFMFJGwC.

Greenwood, D. A. *et al.* (2017) 'A Systematic Review of Reviews Evaluating Technology-Enabled Diabetes Self-Management Education and Support', *Journal of Diabetes Science and Technology*.

SAGE Publications Inc., 11(5), pp. 1015–1027. doi: 10.1177/1932296817713506.

Groth, P., Luck, M. and Moreau, L. (2004) 'Formalising a protocol for recording provenance in Grids', *Proceedings of the UK OST e-Science Second All Hands Meeting 2004 (AHM'04)*.

Grubbs, F. E. (1969) 'Procedures for Detecting Outlying Observations in Samples', *Technometrics*. JSTOR, 11(1), p. 1. doi: 10.2307/1266761.

Gupta, A. (2009) 'Data Provenance', in LIU, L. and ÖZSU, M. T. (eds) *Encyclopedia of Database Systems*. Boston, MA: Springer US, p. 608. doi: 10.1007/978-0-387-39940-9_1305.

Guyatt, G. *et al.* (2011) 'GRADE guidelines: 1. Introduction - GRADE evidence profiles and summary of findings tables', *Journal of Clinical Epidemiology*, 64(4), pp. 383–394. doi: 10.1016/J.JCLINEPI.2010.04.026.

Guyatt, G. *et al.* (2015) *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice, 3rd ed*, *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice, 3rd ed*. New York, NY: McGraw-Hill Education. Available at: http://jamaevidence.mhmedical.com/content.aspx?aid=1147669501.

Guyatt, G. H. and Rennie, D. (1993) 'Users' Guides to the Medical Literature', *JAMA: The Journal of the American Medical Association*. American Medical Association, 270(17), pp. 2096–2097. doi: 10.1001/jama.1993.03510170086037.

Han, P. K. J., Klein, W. M. P. and Arora, N. K. (2011) 'Varieties of Uncertainty in Health Care: A Conceptual Taxonomy', *Medical Decision Making*, 31(6), pp. 828–838. doi: 10.1177/0272989x11393976.

Haynes, B. and Haines, A. (1996) 'Barriers and bridges to evidence based clinical practice', *British Medical Journal*. BMJ Publishing Group, p. 2. doi: 10.1136/bmj.317.7153.273.

Hederman, L., Berry, D. and Ormazabal, A. (2023) 'Clinician's perspective on trusting Patient Generated Health Data for use in clinical decision-making: A qualitative interview study', in *2023 IEEE 36th International Symposium on Computer-Based Medical Systems (CBMS)*. IEEE, pp. 252–256.

HIQA (2018) *Guidance on a data quality framework for health and social care Health Information and Quality Authority*.

Hofmann, H., Wickham, H. and Kafadar, K. (2017) 'Letter-Value Plots: Boxplots for Large Data', *Journal of Computational and Graphical Statistics*, 26(3), pp. 469–477. doi: 10.1080/10618600.2017.1305277.

HPRA (2017) *HPRA Guide to Placing Medical Device Standalone Software on the Market*.

Hsueh, P. Y. S. *et al.* (2017) 'Making sense of patient-generated health data for interpretable patient-centered care: The transition from "More" to "Better"', *Studies in Health Technology and Informatics*, 245, pp. 113–117. doi: 10.3233/978-1-61499-830-3-113.

Huang, J. and Fox, M. S. (2006) 'An ontology of trust - Formal semantics and transitivity', *ACM International Conference Proceeding Series*, (January), pp. 259–270. doi: 10.1145/1151454.1151499.

Huba, N. and Zhang, Y. (2012) 'Designing patient-centered personal health records (PHRs): Health care professionals' perspective on patient-generated data', *Journal of Medical Systems*, 36(6), pp. 3893–3905. doi: 10.1007/s10916-012-9861-z.

Hussein, R. *et al.* (2021) 'Patient-Generated Health Data (PGHD) Interoperability: An Integrative

Perspective', *Studies in health technology and informatics*. Stud Health Technol Inform, 281, pp. 228–232. doi: 10.3233/SHTI210154.

ISO (1995) *Guıde To The Expressıon Of Uncertaınty In Measurement*.

ISO (2021) *CEN ISO TS82304-2-2021*, *ISO*. doi: 10.7551/mitpress/7803.003.0005.

Jacobs, M. L., Clawson, J. and Mynatt, E. D. (2015) 'Comparing Health Information Sharing Preferences of Cancer Patients, Doctors, and Navigators', in *Proceedings of the 18th ACM Conference on Computer Supported Cooperative Work & Social Computing - CSCW '15*. New York, New York, USA: ACM Press, pp. 808–818. doi: 10.1145/2675133.2675252.

Jim, H. S. L. *et al.* (2020) 'Innovations in research and clinical care using patient-generated health data', *CA: A Cancer Journal for Clinicians*. Wiley, 70(3), pp. 182–199. doi: 10.3322/caac.21608.

Jo Deering, M. (2013) 'Patient-Generated Health Data and Health IT'. Available at: https://www.healthit.gov/sites/default/files/pghd_brief_final122013.pdf.

Joice, M. (2018) 'Screening for atrial fibrillation with a wearable patch: Seek and ye shall find … and then what? |', *Health News Review*. Available at: https://www.healthnewsreview.org/2018/07/atrial-fibrillation-screening-wearable/ (Accessed: 20 July 2022).

Kay, J. A. (John A. and King, M. A. (2020) *Radical uncertainty : decision-making beyond the numbers*.

Kearney, R. C. and Hays, S. W. (2019) 'Labor-Management Relations and Participative Decision Making : Toward a New Paradigm Published by : Wiley on behalf of the American Society for Public Administration Stable URL : https://www.jstor.org/stable/976497 Linked references are available on JSTOR', 54(1), pp. 44–51.

Keeney, R. L. and Keeney, R. L. (2009) *Value-focused thinking: A path to creative decisionmaking*. Harvard University Press.

Khereldeen, M. and Baazeem, M. (2021) 'Excessive Utilization of Laboratory Investigations and its Relationship with Defensive Medicine Practice: A Saudi Arabia Perspective', *International Journal of Medical Reviews*. Baqiyatallah University of Medical Sciences, 8(2), pp. 87–98. doi: 10.30491/IJMR.2020.248448.1145.

Kim, K. and Lee, Y. M. (2018) 'Understanding uncertainty in medicine: concepts and implications in medical education', *Korean Journal of Medical Education*. Korean Society of Medical Education, 30(3), p. 181. doi: 10.3946/KJME.2018.92.

King, M. and Kay, J. (2020) *Radical uncertainty: Decision-making for an unknowable future*. Hachette UK.

Knight, F. (1921) *Risk, Uncertainty, and Profit*, *Die 100 wichtigsten Werke der Ökonomie*. doi: 10.34156/9783791046006-108.

Kramer, R. M. and Tyler, T. R. (1996) *Trust in organizations: Frontiers of theory and research*. Sage.

Kreps, D. M. (1990) 'Corporate culture and economic theory', *Perspectives on positive political economy*. Cambridge, MA, 90(109–110), p. 8.

Kvedar, J., Coye, M. J. and Everett, W. (2014) 'Connected health: A review of technologies and strategies to improve patient care with telemedicine and telehealth', *Health Affairs*, 33(2), pp. 194–199. doi: 10.1377/hlthaff.2013.0992.

Lai, A. M. *et al.* (2017) 'Present and Future Trends in Consumer Health Informatics and Patient-Generated Health Data', *Yearbook of medical informatics*, pp. 152–159. doi: 10.15265/IY-2017-016.

LaRosa, E. and Danks, D. (2018) *Impacts on Trust of Healthcare AI*, *AIES 2018 - Proceedings of the 2018 AAAI/ACM Conference on AI, Ethics, and Society*. Association for Computing Machinery, Inc. doi: 10.1145/3278721.3278771.

Lawler, E. E. (1995) 'The Ultimate Advantage: Creating the High-Involvement Organization.', *Industrial and Commercial Training*, 27(6). doi: 10.5465/ame.1993.9409142063.

Lee, A. L. and Mohamed, N. N. E. (2022) 'Application of Patient-Generated Health Data in Managing Chronic Conditions in Hospital Kuala Lumpur: A Qualitative Study', *The Malaysian Journal of Medical Sciences : MJMS*. School of Medical Sciences, Universiti Sains Malaysia, 29(3), p. 99. doi: 10.21315/MJMS2022.29.3.10.

Lenaerts, G. *et al.* (2021) 'A tool to assess the trustworthiness of evidence-based point-of-care information for health care professionals (CAPOCI): Design and validation study', *Journal of Medical Internet Research*, 23(10). doi: 10.2196/27174.

Lewicki, R. J., Tomlinson, E. C. and Gillespie, N. (2006) 'Models of Interpersonal Trust Development: Theoretical Approaches, Empirical Evidence, and Future Directions', *Journal of Management*. Sage PublicationsSage CA: Thousand Oaks, CA, 32(6), pp. 991–1022. doi: 10.1177/0149206306294405.

Li, C., Turmunkh, U. and Wakker, P. P. (2019) 'Trust as a decision under ambiguity', *Experimental Economics*. Springer New York LLC, 22(1), pp. 51–75. doi: 10.1007/S10683-018-9582-3/FIGURES/6.

Lintern, G. and Motavalli, A. (2018) 'Healthcare information systems: the cognitive challenge', *BMC medical informatics and decision making*. Springer, 18, pp. 1–10.

Lordon, R. J. *et al.* (2020) 'How patient-generated health data and patient-reported outcomes affect patient–clinician relationships: A systematic review', *Health Informatics Journal*. SAGE Publications Ltd, 26(4), pp. 2689–2706. doi: 10.1177/1460458220928184.

De Lusignan, S. *et al.* (2014) 'Patients' online access to their electronic health records and linked online services: A systematic interpretative review', *BMJ Open*. BMJ Publishing Group, 4(9), p. e006021. doi: 10.1136/BMJOPEN-2014-006021/-/DC1.

Lyles, C. R. *et al.* (2020) 'Using Electronic Health Record Portals to Improve Patient Engagement: Research Priorities and Best Practices', *Annals of internal medicine*. NIH Public Access, 172(11 Suppl), p. S123. doi: 10.7326/M19-0876.

Magrabi, F. *et al.* (2019) 'Why is it so difficult to govern mobile apps in healthcare ?', pp. 1–5. doi: 10.1136/bmjhci-2019-100006.

Marcus, G. and Davis, E. (2019) *Rebooting AI: Building artificial intelligence we can trust*. Vintage.

Mayer, R. C., Davis, J. H. and David Schoorman, F. (1995) 'An Integrative Model of Organizational Trust', 20(3), pp. 709–734.

Melnyk, B. M. (2004) 'Integrating Levels of Evidence into Clinical Decision Making', *Pediatric Nursing*, 30(4), p. 323. Available at: https://search.proquest.com/docview/199394549?pq-origsite=gscholar&fromopenview=true (Accessed: 1 September 2020).

Melnyk, B. M. and Fineout-Overholt, E. (2010) 'Evidence-based practice in nursing & healthcare : a guide to best practice / edited by , .', pp. 0–2.

Metzer, R. (2018) *Are diagnostic health apps accurate? Researchers say there's no way to tell*, *Fierce Healthcare*. Available at: https://www.fiercehealthcare.com/tech/are-diagnostic-health-apps-accurate-analysts-say-there-s-no-way-to-tell.

Mill, J. S. (2013) *A System Of Logic, Ratiocinative And Inductive: Being a Connected View of the Principles of Evidence, and the Methods of Scientific Investigation*. Harper and Brothers, Publishers.

Miller, S. J. (2015) *Benford's law*. Princeton University Press.

Miyaji, T. *et al.* (2020) 'Patient-generated health data collection using a wearable activity tracker in cancer patients—a feasibility study', *Supportive Care in Cancer*. Springer, pp. 1–9. doi: 10.1007/s00520-020-05395-z.

Naumann, F. and Rolker, C. (2005) 'Assessment methods for information quality criteria'. Humboldt-Universität zu Berlin, Mathematisch-Naturwissenschaftliche Fakultät …, 465(October 2000). Available at: http://library1.nida.ac.th/termpaper6/sd/2554/19755.pdf.

Nazi, K. M., Newton, T. and Armstrong, C. M. (2024) 'Unleashing the Potential for Patient-Generated Health Data (PGHD)', *Journal of General Internal Medicine*. Springer, 39(Suppl 1), pp. 9–13.

Newton, N. *et al.* (2023) 'Methods used to evaluate clinicians' acceptance and use of clinical decision support systems over time: a systematic review', *Digital Health Week*, 2(1).

Nittas, V. *et al.* (2018) 'Electronic patient-generated health data to facilitate prevention and health promotion: A scoping review protocol', *BMJ Open*. BMJ Publishing Group. doi: 10.1136/bmjopen-2017-021245.

Nundy, S. *et al.* (2014) 'Using patient-generated health data from mobile technologies for diabetes self-management support: Provider perspectives from an academic medical center', *Journal of Diabetes Science and Technology*. Diabetes Technology Society, 8(1), pp. 74–82. doi: 10.1177/1932296813511727.

O'Neill, O. (2018) 'Linking Trust to Trustworthiness', *International Journal of Philosophical Studies*. Routledge, 26(2), pp. 293–300. doi: 10.1080/09672559.2018.1454637.

O'Rourke, K. (2017) 'Patient Generated Health Data in Ireland: A Study of the Patient Perspective', p. 126. Available at: https://scss.tcd.ie/publications/theses/diss/2017/TCD-SCSS-DISSERTATION-2017-012.pdf.

Or, C. and Tao, D. (2012) 'Usability study of a computer-based self-management system for older adults with chronic diseases', *Journal of Medical Internet Research*, 14(6). doi: 10.2196/resprot.2184.

Ortega Egea, J. M. and Román González, M. V. (2010) 'Explaining physicians' acceptance of EHCR systems: An extension of TAM with trust and risk factors'. doi: 10.1016/j.chb.2010.08.010.

Osterwalder, A. and Pigneur, Y. (2010) *Business model generation: a handbook for visionaries, game changers, and challengers*. John Wiley & Sons.

Pais, S., Parry, D. and Huang, Y. (2017) 'Suitability of Fast Healthcare Interoperability Resources (FHIR) for Wellness Data', in *Proceedings of the 50th Hawaii International Conference on System Sciences | 2017*, pp. 3499–3505. Available at: http://hdl.handle.net/10125/41581 (Accessed: 15 October 2019).

Panteghini, M. (2010) 'Application of traceability concepts to analytical quality control may reconcile total error with uncertainty of measurement', *Clinical Chemistry and Laboratory*

Medicine, 48(1), pp. 7–10. doi: 10.1515/CCLM.2010.020.

Papautsky, E. L. and Panganiban, A. R. (2018) 'Implications of Trust on Patient Generated Health Data', *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. Human Factors and Ergonomics Society Inc., 62(1), pp. 550–550. doi: 10.1177/1541931218621125.

Park, Y. R. *et al.* (2018) 'Managing Patient-Generated Health Data Through Mobile Personal Health Records: Analysis of Usage Data', *JMIR mHealth and uHealth*. JMIR Publications Inc., 6(4), p. e89. doi: 10.2196/mhealth.9620.

Patel, M. S., Asch, D. A. and Volpp, K. G. (2015) 'Wearable Devices as Facilitators, Not Drivers, of Health Behavior Change', *JAMA*. American Medical Association, 313(5), pp. 459–460. doi: 10.1001/JAMA.2014.14781.

Pearson, K. (2009) 'X. On the criterion that a given system of deviations from the probable in the case of a correlated system of variables is such that it can be reasonably supposed to have arisen from random sampling', *https://doi.org/10.1080/14786440009463897*. Taylor & Francis Group, 50(302), pp. 157–175. doi: 10.1080/14786440009463897.

Perez, M. V. *et al.* (2019) 'Large-scale assessment of a smartwatch to identify atrial fibrillation', *New England Journal of Medicine*, 381(20), pp. 1909–1917. doi: 10.1056/NEJMoa1901183.

Petersen, C. and DeMuro, A. (2015) 'Legal and regulatory considerations associated with use of patient-generated health data from social media and mobile health (mHealth) devices', *Applied Clinical Informatics*. Schattauer GmbH, 6(1), pp. 16–26. doi: 10.4338/ACI-2014-09-R-0082.

Pikulev, A. (no date) *Team Trust Canvas – 'In Team We Trust'*, *inteamwetrust.com*. Available at: https://inteamwetrust.com/team-trust-toolbox/team-trust-canvas/ (Accessed: 27 May 2023).

Plastiras, P. and O'Sullivan, D. (2018) 'Exchanging personal health data with electronic health records: A standardized information model for patient generated health data and observations of daily living', *International Journal of Medical Informatics*. doi: 10.1016/j.ijmedinf.2018.10.006.

Plastiras, P., O'Sullivan, D. and Weller, P. (2014) 'An Ontology-Driven Information Model for Interoperability of Personal and Electronic Health Records', in *The Sixth International Conference on eHealth, Telemedicine, and Social Medicine*, pp. 130–133.

Plays-In-Business (no date) *Team Trust Canvas — How to Create Trust in Your Team*, *Plays-In-Business.com*. Available at: https://www.plays-in-business.com/team-trust-canvas-how-to-create-trust-in-your-team/ (Accessed: 16 April 2023).

Pratt, J. W., Raiffa, H. and Schlaifer, R. (1995) *Introduction to statistical decision theory*. MIT press.

Priya, A. (2020) 'Case Study Methodology of Qualitative Research: Key Attributes and Navigating the Conundrums in Its Application', *https://doi.org/10.1177/0038022920970318*. SAGE PublicationsSage India: New Delhi, India, 70(1), pp. 94–110. doi: 10.1177/0038022920970318.

Products Regulatory Authority, H. (2009) *Guide to Classification of a Medical Device HPRA*.

Proesmans, T. *et al.* (2019) 'Mobile phone-based use of the photoplethysmography technique to detect atrial fibrillation in primary care: Diagnostic accuracy study of the FibriCheck App', *Journal of Medical Internet Research*. Journal of Medical Internet Research, 21(3), p. e12284. doi: 10.2196/12284.

Raeve, L. De and Ba, R. G. N. (2002) 'Trust and trustworthiness in nurse – patient relationships', *Nursing Philosophy*. John Wiley & Sons, Ltd, 3(2), pp. 152–162. doi: 10.1046/J.1466-769X.2002.00090.X.

Rajendran, R. and Rayman, G. (2014) 'Point-of-Care Blood Glucose Testing for Diabetes Care in Hospitalized Patients: An Evidence-Based Review', *Journal of Diabetes Science and Technology*. Diabetes Technology Society, 8(6), p. 1081. doi: 10.1177/1932296814538940.

Reading, M. J. and Merrill, J. A. (2018) 'Converging and diverging needs between patients and providers who are collecting and using patient-generated health data: An integrative review', *Journal of the American Medical Informatics Association*. Oxford University Press, 25(6), pp. 759–771. doi: 10.1093/jamia/ocy006.

Roehrs, A. *et al.* (2017) 'Personal health records: A systematic literature review', *Journal of Medical Internet Research*. Journal of Medical Internet Research, 19(1). doi: 10.2196/jmir.5876.

Rosner, B. I., Kvedar, J. C. and Adler-Milstein, J. (2021) 'Patient-generated health data earn a seat at the table: clinical adoption during the COVID-19 transition to telemedicine', *JAMIA Open*. Oxford Academic, 4(4). doi: 10.1093/JAMIAOPEN/OOAB097.

Rousseau, D. M. *et al.* (1998) 'Not so different after all: A cross-discipline view of trust', *Academy of Management Review*. Academy of Management Briarcliff Manor, NY 10510, 23(3), pp. 393–404. doi: 10.5465/AMR.1998.926617.

Sackett, D. L. *et al.* (1996) 'Evidence based medicine: what it is and what it isn't', *BMY*, 312, pp. 71–72.

Sackett, D. L. (2000) *Evidence-based Medicine: How to Practice and Teach EBM*. Churchill Livingstone (Churchill Livingstone). Available at: https://books.google.ie/books?id=oYJrAAAAMAAJ.

Sands, D. Z. and Wald, J. S. (2014) 'Transforming health care delivery through consumer engagement, health data transparency, and patient-generated health information', *Yearbook of medical informatics*, pp. 170–176. doi: 10.15265/IY-2014-0017.

Sanger, P. C. *et al.* (2016) 'A patient-centered system in a providercentered world: Challenges of incorporating post-discharge wound data into practice', *Journal of the American Medical Informatics Association*. Oxford University Press, 23(3), pp. 514–525. doi: 10.1093/jamia/ocv183.

Scanlon, M. C., Karsh, B.-T. and Saran, K. A. (2008) *Risk-Based Patient Safety Metrics*, *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment)*. Agency for Healthcare Research and Quality. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21249862 (Accessed: 7 July 2020).

Schroeder, J. *et al.* (2017) 'Supporting patient-provider collaboration to identify individual triggers using food and symptom journals', in *Proceedings of the ACM Conference on Computer Supported Cooperative Work, CSCW*. doi: 10.1145/2998181.2998276.

Schwartz, J. M. *et al.* (2022) 'Factors influencing clinician trust in predictive clinical decision support systems for in-hospital deterioration: qualitative descriptive study', *JMIR Human Factors*. JMIR Publications Toronto, Canada, 9(2), p. e33960.

Shapiro, M. *et al.* (2012) *Patient-Generated Health Data*.

Shorten, A. and Smith, J. (2017) 'Mixed methods research: expanding the evidence base', *Evidence-Based Nursing*. Royal College of Nursing, 20(3), pp. 74–75. doi: 10.1136/EB-2017-102699.

Siminerio, L. *et al.* (2014) 'Telemedicine for Reach, Education, Access, and Treatment (TREAT): Linking Telemedicine With Diabetes Self-management Education to Improve Care in Rural Communities', *The Diabetes Educator*, 40(6), pp. 797–805. doi: 10.1177/0145721714551993.

Simon, H. A. (1979) 'Rational Decision Making in Business Organizations on JSTOR', *The american economic rebiew*, 69(4), pp. 493–813. Available at: https://www.jstor.org/stable/1808698 (Accessed: 7 August 2022).

Simpkin, A. L. and Schwartzstein, R. M. (2016) 'Tolerating uncertainty - The Next medical revolution?', *New England Journal of Medicine*. Massachussetts Medical Society, pp. 1713–1715. doi: 10.1056/NEJMp1606402.

Slevin, M. L. *et al.* (1988) 'Who should measure quality of life, the doctor or the patient?', *British Journal of Cancer*. Br J Cancer, 57(1), pp. 109–112. doi: 10.1038/bjc.1988.20.

Söderström, E. (2009) 'Trust Types: An Overview', in *Discourses in security assurance and privacy*. Available at: www.security-conference.org (Accessed: 21 July 2022).

Söderström, E., Eriksson, N. and Åhlfeldt, R.-M. (2016) 'Managing healthcare information: analyzing trust', *International Journal of Health Care Quality Assurance2*, 29(7), pp. 786–800. doi: 10.1108/IJHCQA-11-2015-0136.

Strauss, A. and Corbin, J. (1998) 'Basics of qualitative research techniques'. Thousand oaks, CA: Sage publications.

Swendeman, D. *et al.* (2018) 'Longitudinal Validity and Reliability of Brief Smartphone Self-Monitoring of Diet , Stress , and Physical Activity in a Diverse Sample of Mothers Corresponding Author ':, 6. doi: 10.2196/mhealth.9378.

Taleb, N. (2015) 'The black swan: The impact of the highly improbable', *Victoria*, 250, pp. 595–7955.

Tarassenko, L. and Greenhalgh, T. (2020) *Question: Should smartphone apps be used clinically as oximeters? Answer: No.*, *Centre for Evidence Based Medicine*. Available at: https://www.cebm.net/covid-19/question-should-smartphone-apps-be-used-as-oximeters-answer-no/.

Telemonitoring Study - for Chronic Myeloid Leukemia (CML) (2018). Available at: https://beta.clinicaltrials.gov/study/NCT01490983 (Accessed: 19 June 2023).

The Ethics Canvas (no date). Available at: https://www.ethicscanvas.org/ (Accessed: 27 May 2023).

Tiase, V. L. (2017) 'Navigating the patient-generated health data deluge', *Nursing Informatics*, (December), pp. 7–8.

Tiase, Victoria L *et al.* (2021) 'Patient-generated health data and electronic health record integration: a scoping review', *JAMIA Open*. Oxford Academic, 3(4), pp. 619–627. doi: 10.1093/JAMIAOPEN/OOAA052.

Tiase, Victoria L. *et al.* (2021) 'Patient-Generated Health Data in Pediatric Asthma: Exploratory Study of Providers' Information Needs', *JMIR Pediatrics and Parenting*. JMIR Publications Inc., 4(1). doi: 10.2196/25413.

Timnit Gebru (2020) 'Race and Gender', in *The Oxford Handbook of Ethics of AI*. Available at: https://books.google.ie/books?hl=en&lr=&id=8vQTEAAAQBAJ&oi=fnd&pg=PA253&dq=Timnit+Gebru+trust&ots=JkrFycNAA8&sig=ubTvAcBCvaG2fRITfLI2UMhTj38&redir_esc=y#v=onepage&q&f=false (Accessed: 1 August 2023).

Topol, E. (2015) *The patient will see you now: the future of medicine is in your hands*. Basic Books.

Valentin Fuster (2019) ‘Dr. Valentin Fuster on the Apple Heart Study - ACC 2019 Wrap-Up - YouTube’, in *ACC 2019*. Available at: https://www.youtube.com/watch?v=VQ2K_Kfq3TQ (Accessed: 7 July 2022).

Venkatesh *et al.* (2003) ‘User Acceptance of Information Technology: Toward a Unified View’, *MIS Quarterly*. Management Information Systems Research Center, 27(3), p. 425. doi: 10.2307/30036540.

Vogiatzaki, E., Rodríguez, J. M. and Conejero-Lara, F. (2022) ‘Personal Health Record’, *Cyberphysical Systems for Epilepsy and Related Brain Disorders: Multi-Parametric Monitoring and Analysis for Diagnosis and Optimal Disease Management*. StatPearls Publishing, pp. 205–238. doi: 10.1007/978-3-319-20049-1_11.

Wallis, J. C. *et al.* (2007) ‘Know thy sensor: Trust, data quality, and data integrity in scientific digital libraries’, in *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*. Springer Verlag, pp. 380–391. doi: 10.1007/978-3-540-74851-9_32.

Wang, R. Y. and Strong, D. M. (2015) ‘Beyond Accuracy: What Data Quality Means to Data Consumers’, *https://doi.org/10.1080/07421222.1996.11518099*. Routledge, 12(4), pp. 5–34. doi: 10.1080/07421222.1996.11518099.

Wattanapisit, A. *et al.* (2020) ‘Can mobile health apps replace GPs? A scoping review of comparisons between mobile apps and GP tasks’, *BMC Medical Informatics and Decision Making*. BioMed Central Ltd, 20(1), p. 5. doi: 10.1186/s12911-019-1016-4.

West, P. *et al.* (2017) ‘Information Quality Challenges of Patient-Generated Data in Clinical Practice’, *Frontiers in Public Health*, 5(November 2017). doi: 10.3389/fpubh.2017.00284.

West, P. *et al.* (2018) ‘Common Barriers to the Use of Patient-Generated Data Across Clinical Settings’. doi: 10.1145/3173574.3174058.

Whiting, P. *et al.* (2003) ‘The development of QUADAS: A tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews’, *BMC Medical Research Methodology*. BioMed Central Ltd., 3(1), pp. 1–13. doi: 10.1186/1471-2288-3-25/TABLES/1.

Whiting, P. F. *et al.* (2011) ‘QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies’, *Annals of internal medicine*. American College of Physicians, 155(8), pp. 529–536.

Wiley (2000) *Cochrane Reviews | Cochrane Library*, *Cochrane*. Available at: https://www.cochranelibrary.com/ (Accessed: 11 December 2023).

Winter, J. S. and Davidson, E. (2021) ‘Harmonizing regulatory regimes for the governance of patient-generated health data’, *Telecommunications Policy*. Pergamon, p. 102285. doi: 10.1016/j.telpol.2021.102285.

Wood, W. A., Bennett, A. V and Basch, E. (2015) ‘Emerging uses of patient generated health data in clinical research’, *Molecular Oncology*, 9, pp. 1018–1024. doi: 10.1016/j.molonc.2014.08.006.

Woods, S. S., Evans, N. C. and Frisbee, K. L. (2016) ‘Integrating patient voices into health information for self-care and patient-clinician partnerships: Veterans Affairs design recommendations for patient-generated data applications’, *Journal of the American Medical Informatics Association*, 23(3), pp. 491–495. doi: 10.1093/jamia/ocv199.

Woolever, D. (2008) *The Art and Science of Clinical Decision Making*, *Family Practice Management*. Available at: www.aafp.org/fpm. (Accessed: 2 September 2020).

Wuetherick, B. (2010) 'Basics of qualitative research: Techniques and procedures for developing grounded theory', *Canadian Journal of University Continuing Education*, 36(2).

Ye, J. (2021) 'The impact of electronic health record-integrated patient-generated health data on clinician burnout', *Journal of the American Medical Informatics Association : JAMIA*, 28(5), pp. 1051–1056. doi: 10.1093/jamia/ocab017.

Zadeh, L. A. (1965) 'Fuzzy sets', *Information and control*. Elsevier, 8(3), pp. 338–353.

Zerilli, J. *et al.* (2018) 'Transparency in Algorithmic and Human Decision-Making: Is There a Double Standard?', *Philosophy and Technology*. Springer, 32(4), pp. 661–683. doi: 10.1007/S13347-018-0330-6/METRICS.

Chapter 10. Appendix

10.1 Study 1 Research ethics application

School of Computer Science & Statistics
Research Ethics Application

Part A

Project Title: Identifying key aspects of quality, provenance and risk that influence clinician trust in PGHD for clinical decision making.

Name of Lead Researcher (student in case of project work): .... Alfredo Ormazabal..... Name of Supervisor: ....Lucy Hederman.....

TCD E-mail: …ormazaba@tcd.ie..... Contact Tel No.: …….0868664748.....

Course Name and Code (if applicable): …PhD in Computer Science..... Estimated start date of survey/research: …August 2022..... I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs

- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- If the study involves participants viewing video displays then I will verify that they understand that if they or anyone in their family has a history of epilepsy then the participant is proceeding at their own risk
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Signed: ..... Date: .....14/07/2022.....

Lead Researcher/student in case of project work

Part B

Please answer the following questions.		***Yes/No***
Has this research application or any application of a similar nature connected to this research project been refused ethical approval by another review committee of the College (or at the institutions of any collaborators)?		NO
Will your project involve photographing participants or electronic audio or video recordings?		YES
Will your project deliberately involve misleading participants in any way?		NO
Does this study contain commercially sensitive material?		NO
Is there a risk of participants experiencing either physical or psychological distress or discomfort? If yes, give details on a separate sheet and state what you will tell them to do if they should experience any such problems (e.g. who they can contact for help).		NO
Does your study involve any of the following?	Children (under 18 years of age)	NO
	People with intellectual or communication difficulties	NO
	Patients	NO

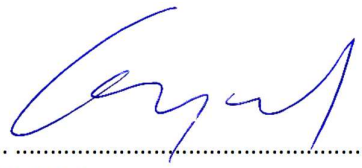
School of Computer Science and Statistics Research Ethical Application Form

Details of the Research Project Proposal must be submitted as a separate document to include the following information:

1. Title of project
2. Purpose of project including academic rationale
3. Brief description of methods and measurements to be used
4. Participants - recruitment methods, number, age, gender, exclusion/inclusion criteria, including statistical justification for numbers of participants
5. Debriefing arrangements
6. A clear concise statement of the ethical considerations raised by the project and how you intend to deal with them
7. Cite any relevant legislation relevant to the project with the method of compliance e.g. Data Protection Act etc.

Part C

I confirm that the materials I have submitted provided a complete and accurate account of the research I propose to conduct in this context, including my assessment of the ethical ramifications.



Signed: .... Date:

.....14/07/2022.....

Lead Researcher/student in case of project work

There is an obligation on the lead researcher to bring to the attention of the SCSS Research Ethics Committee any issues with ethical implications not clearly covered above.

Part D

If external or other TCD Ethics Committee approval has been received, please complete below.

External/TCD ethical approval has been received and no further ethical approval is required from the School's Research Ethical Committee. I have attached a copy of the external ethical approval for the School's Research Unit.

Signed: ..... Date: .....

Lead Researcher/student in case of project work

Part E

If the research is proposed by an undergraduate or postgraduate student, please have the below section completed.

I confirm, as an academic supervisor of this proposed research that the documents at hand are complete (i.e. each item on

the submission checklist is accounted for) and are in a form that is suitable for review by the SCSS Research Ethics Committ

Signed: ..... Date: .....

.....

Supervisor

Completed application forms together with supporting documentation should be submitted electronically to the online ethics system - https://webhost.tchpc.tcd.ie/research_ethics/ When your application has been reviewed and approved by the Ethics committee, hardcopies with original signatures should be submitted to the School of Computer Science & Statistics, Room 104, Lloyd Building, Trinity College, Dublin 2.

CHECKLIST

Please ensure that you have submitted the following documents with your application:

1.	• SCSS Ethical **Application Form**	✓
2.	• **Participant's Information Sheet** must include the following: *a) Declarations from Part A of the application form;* b) Details provided to participants about how they were selected to participate; c) Declaration of all conflicts of interest.	✓
3.	• **Participant's Consent Form** must include the following: *a) Declarations from Part A of the application form;* **b)** Researchers contact details provided for counter-signature (your participant will keep one copy of the signed consent form and return a copy to you).	✓
4.	• **Research Project Proposal** must include the following: *a) You must inform the Ethics Committee **who** your intended participants are* i.e. are they your work colleagues, class mates etc. b) How will you recruit the participants i.e. **how** do you intend asking people to take part in your research? For example, will you stand on Pearse Street asking passers-by? c) If your participants are under the age of 18, you must seek both parental/guardian AND child consent.	✓
5.	• Intended **questionnaire**/survey/interview protocol/screen shots/representative materials (as appropriate)	✓
6.	• **URL** to intended on-line survey (as appropriate)	✓

Notes on Conflict of Interest

1. If your intended participants are work colleagues, you must declare a potential conflict of interest: you are taking advantage of your existing relationships in order to make progress in your research. It is best to acknowledge this in your invitation to participants.

2. If your research is also intended to direct commercial or other exploitation, this must be declared. For example, *"Please be advised that this research is being conducted by an employee of the company that supplies the product or service which form an object of study within the research."*

Notes for questionnaires and interviews

1. If your questionnaire is **paper based**, you must have the following **opt-out** clause on the top of each page of the questionnaire: *"Each question is optional. Feel free to omit a response to any question; however the researcher would be grateful if all questions are responded to."*

*If you questionnaire is **on-line**, the first page of your questionnaire must repeat the content of the information sheet. This must be followed by the consent form. If the participant does not agree to the consent, they must automatically be exited from the questionnaire.*

2. Each question must be **optional**.
3. The participant must have the option to '**not submit, exit without submitting'** at the final submission point on your questionnaire.

5. If you have open-ended questions on your questionnaire you must warn the participant against naming **third parties**: "*Please do not name third parties in any open text field of the questionnaire. Any such replies will be anonymised."*

6. You must inform your participants regarding **illicit activity**: "*In the extremely unlikely event that illicit activity is reported I will be obliged to report it to appropriate authorities."*

SCSS Research Project Proposal

PI: Alfredo Ormazabal

Supervisors: Lucy Hederman and Damon Berry.

SECTION 1 – Project Description

Identifying key aspects of quality, provenance and risk that influence clinician trust in PGHD for clinical decision making

Commencement of study: August 2022
Duration: 12 Months

Overview

Patient Generated Health Data (PGHD) is considered to have the potential to enable personalised healthcare and promise to enable healthcare to further address patients' needs that traditionally seemed out of reach. The adoption of PGHD in clinical decision-making is slow and clinicians seem to resist the incorporation of PGHD into their process of clinical decision-making. Patients, however, want the data that they generate to be considered in clinical decisions about them (Reading and Merrill, 2018).

Lessons learned from the painful process of adoption of Electronic Health Records (EHR)(Ortega Egea and Román González, 2010) tell us that trust plays a significant role in these innovations and the similarity with the process of adoption of PGHD calls for research in the topic.

Informal conversations with clinicians and key informants revealed that lack of understanding of the quality assurance processes behind PGHD-generating technologies; lack of familiarity with the institutions behind these technologies; and the risk of harming patients due to the inclusion of unsuitable data in the clinical decision-making process, may be key aspects to clinician trust in PGHD.

Furthermore, limitations in quality assurance(Abdolkhani, Borda and Gray, 2018)(West *et al.*, 2018), governance frameworks(Cresswell *et al.*, 2018) and general trustworthiness(West *et al.*, 2017) have been identified as common barriers to the adoption of PGHD for clinical decision-making.

The topic of clinician trust in patient's information is little discussed in the literature (Papautsky and Panganiban, 2018), particularly when addressing possibly disruptive digital interventions. This may be an indication that the topic is complex, but also that it is of a somewhat sensitive nature to clinicians since they might be reluctant to admit that their trust in patients is limited, presenting a conflict with bioethics principles. It can also be an indication that a large proportion of clinicians are simply not interested in the psychosocial aspects of their trust in PGHD.

This study proposes one explorative and informative round of interviews to understand the main barriers to trust in the adoption of PGHD for clinical decision-making. These interviews will also inform the development of an artifact (like a tool, framework, guideline, checklist, algorithm etc.) that would aid clinicians in deciding and at least partially justifying whether to include or exclude a source of PGHD for certain clinical decisions. Qualitative methods of analysis will be used to convert the interview data into knowledge.

The artifact:

An artifact to help deciding whether to include or exclude a source of PGHD will be created with the knowledge gathered in the interviews.

A secondary objective of these interviews is to determine what type of artifact is best suited, based on the nature of the interactions between quality, risk and provenance and their influence on clinician trust of PGHD for clinical decision-making. In decision science, the uncertainty element of the problem at hand can determine the most appropriate approach to decision-making (Kay and King, 2020). Particularly in healthcare, where uncertainty sides closer to the radical end of the resolvable-radical uncertainty continuum (Han, Klein and Arora, 2011), the best type of artifact can be determined by aspects like ambiguity and vagueness, non-stationary and non-ergodic nature of the problem.

Recruitment

Participants will be recruited using Snowball sampling (Browne, 2007) with one participant identified due to their interest and experience working at a management level in an Irish hospital.

Exponential snowball sampling interview study can address the difficulties in recruiting participants with an interest in the topic, and that have invested some time in considering their stance on trusting patients generated information. Participants will be asked to propose at least one main referral and one backup if possible. They in turn will be asked for referrals of clinicians who also have an opinion on PGHD and/or some involvement in projects regarding new ways to deliver healthcare. These can include nurses, physicians and other clinical staff that may have seen examples of PGHD in their practice. Each referring participant will need to consent that their name is mentioned only for the purpose of contacting the referred participant. 15 to 20 participants will be recruited for this study

Inclusion criteria:

Participants will be clinicians who have been exposed to or presented with some form of PGHD in their practice and will have formed an opinion on whether PGHD should be included in their clinical decision process.

Procedures of the study

The study will consist of semi-structured interviews lasting between 20 and 40 minutes. Each participant will be informed in advance of the topics to be discussed to make the best use of the time allocated. The interviews will be audio recorded, and the recordings will be transcribed a posteriori. Participants will be made aware of their right to decline at any point before, during or after the interview. They will also be made aware of their right to decline referring further participants.

Debriefing arrangements following the study.

Participants whose quotations are included in any publication will be contacted in advance and given the opportunity to correct or contextualize their statements. They will also be given the opportunity to participate in further studies by the researcher if they wish so.

Participants will also be forwarded the transcripts of their interview to have the opportunity to correct and contextualize their responses.

Interview protocol

Participants will be given the choice of declaring their professional status and will be asked if their responses could be used in direct quotation without mentioning their identity or any other identifiable details. At the end of each interview, they will be asked for one referral to the next participant and one referral to a backup participant.

1.

Patient Generated Health Data (PGHD) is any data related to a patient's health that has been recorded, gathered, or inferred by the patient or on their behalf. The main difference between PGHD and clinical data is that it is the patient who is responsible for, and in control of the data. Have you ever used PGHD to inform a clinical decision?	
YES	NO
Can you share some information about the context and results of that decision?	Have you ever encountered PGHD in a clinical setting?
What gave you the confidence that you could use this data to help making the decision? • Would you say you trusted the source enough in this case? • Why?	What stopped you from including that data in your decision-making process? • What would it take for you to feel confident using PGHD? • Why?
Would you do it again in similar circumstances? • Why? • What would make PGHD more trustworthy in this case?	Do you think there is a place for PGHD in clinical decision-making? • What would make PGHD closer to being trustworthy?

	• Are there any circumstances where hypothetically PGHD can be used in your opinion?
How likely are you to try or become familiar with other sources of PGHD? • Why? • What would be the main things you would be looking for in a source of PGHD to even consider using it in clinical decision?	What do you think could be the negative consequences of you including PGHD in your clinical decision-making process? • What are the main barriers for clinicians to adoption of PGHD for decision-making in your opinion?
Do you know of any explicit or implicit guidance in your institution regarding the use of PGHD?	
If you were in a situation where the only data you have at hand is generated by the patient and a decision can't be delayed, would you say that it would justify using PGHD alone?	

SECTION 2 – Ethical Concerns

Ethical concerns regarding this study are low. There is a possibility that participants' opinions regarding the possible lack of trust in patients' information for the use in clinical decisions may be somewhat sensitive. This is since a clinician expressing distrust in the patient's information may be understood as patronising toward the patient. It will be made clear that participants can decline to answer any question at any point. Participation in these studies is completely voluntary.

Participants are only being benefitted by being able to voice their opinions on the use of PGHD in clinical decision-making. Since there is a slight possibility that their opinion on distrusting patients may be seen as less than ethically optimal there is a slight risk. This is being mitigated by maintaining confidentiality and anonymity.

There are no conflicts of interest to declare.

SECTION 3 – CONFIDENTIALITY AND DATA PROTECTION

Note that it is up to the researcher (and their supervisor if relevant) to discharge their own professional and legal obligations with respect to the handling of personal data. Please consult the College Data Protection Officer (DPO) if in any doubt regarding your obligations.

3.1 Does this study involve collecting, using, accessing or sharing personal data[1]?

1 Personal data is information which can identify a person. In particular: a name, address, email, telephone number, an identification number, location data, an online identifier, an IP address, a code key linking back to identifiable data etc. Please note that pseudonymised data is personal data under GDPR. Pseudonymised data means data which cannot be attributed to an individual without the use of additional information which is kept separately.

Yes [X] No [ ]

If **NO**, please go to section 4.
If **YES,** please list[2] all categories of personal data.
Please see checklist on secure storage available here.

Type of Data	**Justification:** **Why do you need the data?**	**Data Format**	**Technical and Organisational Controls**	**Identifiable coded, or anonymised**
Email address	*Contact to organise interviews*	*Excel spreadsheet*	*OneDrive in encrypted format, on local machine which is encrypted.* *Accessible to PI only.*	*Identifiable*
Participant name	*Contact to organise interviews*	*Excel spreadsheet*	*OneDrive in encrypted format, on local machine which is encrypted.* *Accessible to PI only.*	*Identifiable*
Participant clinical area	*To prepare for the interview and understand the clinical context of the interview*	*Excel spreadsheet*	*OneDrive in encrypted format, on local machine which is encrypted.* *Accessible to PI only.*	*Identifiable*
Consent form	*Evidence of consent from an ethical perspective*	*Hard copy form*	*Stored in locked cabinet, in locked office with access limited to PI.*	*Identifiable*
Electronic consent form	*Evidence of consent from an ethical perspective*	*MS Forms*	*OneDrive in encrypted format, on local*	*Identifiable*

(i.e. a key) . It is sometimes referred to as 'coded data'. Please note that in order to be considered personal data in our hands, Trinity must hold the key.

[2] If using Personal data. Records must be kept pursuant to Article 30, GDPR; https://gdpr-info.eu/art-30-gdpr/

			machine which is encrypted. *Accessible to PI only.*	
Referred participant name	*To communicate at the referral process between participants.*	*Excel spreadsheet*	*OneDrive in encrypted format, on local machine which is encrypted.* *Accessible to PI only.*	*Identifiable*
Referred participant email address	*To communicate at the referral process between participants.*	*Excel spreadsheet*	*OneDrive in encrypted format, on local machine which is encrypted.* *Accessible to PI only.*	*Identifiable*
Interview voice recordings	*For transcription purposes and to keep the original record since any identifiable information revealed in the recording will be left out of the transcription.*	*Audio file*	*OneDrive in encrypted format, on local machine which is encrypted.* *Accessible to PI only.*	*Identifiable*
Interview transcripts	*To anonymize the interviews*	*MS word file*	*OneDrive in encrypted format, on local machine which is encrypted.* *Accessible to PI only.*	*Pseudonymized (code given to each individual). PI has the key*
Coding Key (3 copies)	*To ensure a method for withdrawal for participants*	*Excel Spreadsheet*	*3 USB drives in a locked storage in the home of the PI*	*Identifiable*

3.2

Does the study involve collecting, using, accessing or sharing sensitive data[3]?

Yes ☐ No ☒ X

If **NO,** please go to question 3. 3.

3 Sensitive personal data means personal data, which poses a higher risk to the individual. It includes personal data revealing racial and ethnic origin, political opinions, religious or ideological convictions, trade union membership, criminal convictions and offences, genetic, biometric (photos, videos, audio etc.) data concerning physical or mental well-being , information relating to education, professional training employment and career history, questionnaires, Information relating to the family of the individual and the individual's lifestyle and social circumstances.

If **YES**, please list all categories of the sensitive data collected.

Please see checklist on secure storage available here.

Type of Data	Justification: Why you need the data?	Data Format	Technical and Organisational Controls	Identifiable coded, or anonymised
EXAMPLE: *Interview sheet*	*Method of research*	*Hard copy form*	*Stored in encrypted format on local machine which is also encrypted*	*Pseudonymized (code given to each individual). PI has the key*

3.3 Who determines how and why the personal and/or sensitive data is used?

(Data Controller[4] or Joint Data Controllers**)**

Decisions about the handling of personal and/or personal data is made by Alfredo Ormazabal in consultation with his academic supervisor.

3.4 Will the personal and/or sensitive personal data be shared with any third parties[5]?

If **YES,** provide details including information on the contractual arrangements in place.

If **NO**, please go to question 3.5

This list should include all Data Processing Agreements with external laboratories, Cloud-based Solutions Agreements etc., and any and Data Sharing Agreements with Collaborators.

Please contact researchDPO@tcd.ie if you need assistance with agreements and/or for any transfer outside EEA (including England, Wales, Scotland or Northern Ireland).

With the participant's consent, upon contacting referred participants the name of the person that referred them will be mentioned. This is to make it possible the snowball recruiting process.

3.5 How long will you retain the personal data?

Please see good research practice guide for guidance on retention of research data. Your school should be able to advice on best practice.

The data will be retained for a period of 10 years as per good research practice guide.

[4] *Employees and students of TCD are not data controllers. TCD is the data controller for the institution. However, if other institutes jointly decide how and why the data will be used, they should also be noted as controllers here.*

[5] Third parties could be collaborators (institutes/industry) or service providers (transcribers, cloud storage etc.)

3. 6 Will the personal data be fully anonymised or deleted after it is no longer necessary?

See advice on secure data disposal Provide Details: The data gathered will be retained for 10 years, after which the encryption key will expire, and the data be rendered impossible to access.

3.7 How will you inform participants of their rights under GDPR[6]:

Participants' rights under GDPR will be expressed in the participant information sheet and their consent form.

Please note that the DPO's contact details must be included on any information leaflet or privacy notice if you are using personal data for your research.

Email: dataprotection@tcd.ie
Post: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland

6 Under GDPR, these include:

- right of access;
- right to rectification;
- right to erasure;
- right to object to processing based on legitimate or public interest;
- right to data portability;
- right to object to profiling or making decisions about individuals by automated means?

TRINITY COLLEGE DUBLIN

INFORMED CONSENT FORM

LEAD RESEARCHERS: Alfredo Ormazabal

You will be asked a series of semi-structured questions and you will be given the possibility to express your opinion on PGHD and the possibility of using it for clinical decisions. At the end of the interview, you will be asked to provide a referral to a colleague or contact in your network with interest or experience in the topic. The interviews will be audio recorded and later transcribed. Any information in the recording that identifies you will be omitted from the transcription or changed to preserve your anonymity. You will be provided with a copy of the transcript of the interview so you can request any part to be omitted or correct any misinterpretation of your ideas. Your comments may be included in publications as direct quotations if no identifiable data is disclosed. Before doing this the researcher will contact you to give you the opportunity to refuse this. At the end of this interview, you will be asked to propose one or more participants.

With your consent, we will contact them and mention that you gave us their name as referral. You may refuse to do this.

We do not anticipate any risks to you. While participation will not benefit you directly, the research will support the development of better tools for understanding issues with clinician trust in PGHD for clinical decision-making, which will benefit the healthcare system as a whole.

PUBLICATION: It is intended that the results of this study are compiled, analysed, and published as an article in a scientific journal or conference. Any such publication/s shall be on open access basis and if you wish, you can request the researcher to notify you when the results are published.

CONFLICTS OF INTEREST: The researchers have no conflict of interest to declare.

Electronic form of this document will be made available for participants in remote interviews. Link to electronic consent form: https://forms.office.com/r/zVkCnGNu5j

DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- **I understand that if the results of the research have been published, then it will no longer be possible to withdraw.**
- **I understand that I may stop electronic recordings at any time, and that I may at any time, even subsequent to my participation have such recordings and corresponding transcripts destroyed (except in situations such as above).**
- I understand that the research team will remove such recordings and transcripts, where possible, but if the transcripts have been published or made publicly available, with my original consent, then this will no longer be possible.
- I understand that, except in the case of reporting illicit activities to the authorities, no recordings will be replayed in any public forum or made available to any audience other than the current researchers /research team.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation.
- I have received a copy of this agreement.

By signing this document, I consent to participate in this study, and consent to the data processing necessary to enable my participation and to achieve the research goals of this study.

PARTICIPANT'S NAME:

PARTICIPANT'S SIGNATURE:

Date:

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHERS CONTACT DETAILS: ormazaba@tcd.ie

RESEARCHER'S SIGNATURE:

Date:

TRINITY COLLEGE DUBLIN

INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS

You have been invited to participate in a study on the influence of quality, provenance, and risk on clinician trust of Patient Generated Health Data for clinical decisions.

The topic of Patient Generated Health Data (PGHD) is any data related to a patient's health that has been recorded, gathered, or inferred by the patient or on their behalf. It is considered to have the potential to enable personalized healthcare and promise to enable healthcare to further address patients' needs that traditionally seemed out of reach. The adoption of PGHD in clinical decision-making seems slow and clinicians seem to resist the incorporation of PGHD into their process of clinical decision-making. According to current literature, the uncertain nature, and unfamiliar sources of these data may be partially responsible for PGHD to be considered as less than trustworthy for its use in clinical decision-making. Patients, however, want the data that they generate to be considered when making clinical decisions.

You have been invited to participate in this study on the influence of quality, provenance and risk, on clinician trust in PGHD for clinical decision-making. The aim of these interviews is to guide our researchers to develop an artifact that will help deciding whether a source of PGHD is appropriate for use in clinical decisions-making or not.

This study is being carried out by Mr. Alfredo Ormazabal as part of his PhD in the School of Computer Science at Trinity College Dublin. Alfredo is currently in the second year of his PhD, which is supported by the Science Foundation of Ireland through the SFI Centre for Research Training in Digitally-Enhanced Reality.

We are recruiting clinicians who have encountered patients bringing their PGHD to the consultation or who have been considering the possibility to use PGHD in clinical decision-making.

You will be asked a series of semi-structured questions and you will be given the possibility to express your opinion on PGHD and the possibility of using it on clinical decisions. At the end of the interview, you will be asked to provide a referral to one or more colleagues or contacts in your network with interest or experience in the topic. The interviews will be sound recorded and later transcribed. Any information in the recording that identifies you will be omitted from the transcription or changed to preserve your anonymity.

With your prior consent, your comments may be included in publications as direct quotations if no identifiable data is disclosed. In such case, you will be contacted to reconfirm your consent and in relation to the context in which you will be quoted. You will have an opportunity to deny permission.

We will record the interview using a portable audio recorder, and afterwards transfer it to a secure server in the School of Computer Science and Statistics, at which point it will be deleted from the portable recorder. The interview will then be transcribed, and personal details removed. The transcripts of the interviews, any contact information, record of your consent as well as the recordings of your interview, will be stored in an encrypted drive and will be only accessible by the principal investigator, Alfredo Ormazabal and his academic supervisors. The researcher will send you a copy of the transcripts for you to check and see if you would like to remove or change any part of it.

The data gathered will be retained for 10 years, after which the encryption key will expire, and the data be rendered impossible to access.

We will be storing and processing this data to conduct research (this is the legal basis).

We expect that the interview will take approximately 30 minutes.

We do not anticipate any risks to you. While participation will not benefit you directly, the research will support the development of better tools for understanding issues with clinician trust in PGHD for clinical decision-making, which will benefit the healthcare system.

Your participation is entirely voluntary, and you can withdraw at any time up to publication of results without penalty. To withdraw, simply email the researcher giving the email you used to sign up with, indicating that you wish to withdraw. For obvious reasons withdrawal after publication of the results is impracticable.

Each question is optional. Feel free to omit a response to any question; however, the researcher would be grateful if all questions are responded to.

As the methodology of the participant recruitment is "exponential snowball sampling", your referral of at least one other participant is appreciated. Note that your name will be mentioned when contacting your referred participant.

Any publication as a result of the study shall be on open access basis. If you wish, you can request the researcher to notify you when the results are published.

The data will be analysed to understand clinician trust in PGHD for clinical decision purposes. We plan to publish the results of our research in open access academic journals and conference proceedings. We will do this in a way which does not identify you, or any other individual participant. No audio or video recordings will be made available to anyone other than the researcher and his supervisors, nor will any such recordings be replayed in any public forum or presentation of the research.

While it is unlikely that illicit activities would be disclosed, if you do so, we would be obliged report them to the appropriate authorities.

The researcher has no conflicts of interest to declare.

If you have any queries, feel free to contact Alfredo Ormazabal at ormazaba@tcd.ie, and we will be happy to answer questions about the experiment.

Data Controllers: Trinity College Dublin

Data Protection Officer: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2 - dataprotection@tcd.ie

Abdolkhani, R. *et al.* (2019) 'Patient-generated health data management and quality challenges in remote patient monitoring', *JAMIA Open*. Oxford University Press (OUP). doi: 10.1093/jamiaopen/ooz036.

Abdolkhani, R. *et al.* (2020) 'Quality assurance of health wearables data: Participatory workshop on barriers, solutions, and expectations', *JMIR mHealth and uHealth*. JMIR Publications, 8(1). doi: 10.2196/15329.

Abdolkhani, R., Borda, A. and Gray, K. (2018) 'Quality Management of Patient Generated Health Data in Remote Patient Monitoring Using Medical Wearables - A Systematic Review...Health Informatics Conference, Sydney Australia, 2018', *Studies in Health Technology & Informatics*, 252(January), pp. 1–7. doi: 10.3233/978-1-61499-890-7-1.

Acemyan, C. Z. and Kortum, P. (2012) 'The Relationship Between Trust and Usability in Systems', *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. SAGE PublicationsSage CA: Los Angeles, CA, 56(1), pp. 1842–1846. doi: 10.1177/1071181312561371.

Acquisti, A. and Grossklags, J. (2005) 'Privacy and rationality in individual decision making', *IEEE Security and Privacy*, 3(1), pp. 26–33. doi: 10.1109/MSP.2005.22.

AG, S. (no date) *Business Model Canvas – Download the Official Template*. Available at: https://www.strategyzer.com/canvas/business-model-canvas (Accessed: 12 April 2023).

Akbar, S., Coiera, E. and Magrabi, F. (2020) 'Review Safety concerns with consumer-facing mobile health applications and their consequences : a scoping review', *Jounral of the American Medical Informatics Association*, 27(2), pp. 330–340. doi: 10.1093/jamia/ocz175.

Aleem, I. S., Schemitsch, E. H. and Hanson, B. P. (2008) 'What is a clinical decision analysis study?', *Indian Journal of Orthopaedics*. Indian Orthopaedic Association, 42(2), p. 137. doi: 10.4103/0019-5413.40248.

Alós-Ferrer, C. and Farolfi, F. (2019) 'Trust Games and Beyond', *Frontiers in Neuroscience*. Frontiers Media SA, 13, p. 887. doi: 10.3389/FNINS.2019.00887.

Alyami, M. *et al.* (2017) 'Social anxiety apps: A systematic review and assessment of app descriptors across mobile store platforms', *Evidence-Based Mental Health*, 20(3), pp. 65–70. doi: 10.1136/eb-2017-102664.

AMA (2020) 'Medical Records and Patient Privacy Meeting Type : Interim', (5), p. 967.

American Society for Healthcare Risk Management (2009) *Risk management handbook for health care organizations*. John Wiley & Sons.

Andersen, T. O. *et al.* (2018) *Aligning Concerns in Telecare: Three Concepts to Guide the Design of Patient-Centred E-Health*, *Computer Supported Cooperative Work: CSCW: An International Journal*. Computer Supported Cooperative Work (CSCW). doi: 10.1007/s10606-018-9309-1.

Anderson, R. (2020) *Security Engineering*. Wiley. doi: 10.1002/9781119644682.

Archer, N. *et al.* (2011) 'Personal health records: a scoping review', *Journal of the American Medical Informatics Association : JAMIA*. Oxford University Press, 18(4), p. 515. doi: 10.1136/AMIAJNL-2011-000105.

Azodo, I. *et al.* (2020) 'Opportunities and challenges surrounding the use of data from wearable sensor devices in healthcare: a qualitative study (Preprint)', *Journal of Medical Internet Research*, 22. doi: 10.2196/19542.

Bate, L. *et al.* (2012) 'How clinical decisions are made', *British Journal of Clinical Pharmacology*, 74(4), pp. 614–620. doi: 10.1111/j.1365-2125.2012.04366.x.

Bender, J. L. *et al.* (2013) 'A Lot of Action , But Not in the Right Direction : Systematic Review and Content Analysis of Smartphone Applications for the Prevention , Detection , and Management of Cancer Corresponding Author ':, *Journal of Medical Internet Research*, 15(12), pp. 1–12. doi: 10.2196/jmir.2661.

Berg, J., Dickhaut, J. and McCabe, K. (1995) 'Trust, Reciprocity, and Social History', *Games and Economic Behavior*. Academic Press, 10(1), pp. 122–142. doi: 10.1006/GAME.1995.1027.

Berg, M. (1999) 'Patient care information systems and health care work: a sociotechnical approach', *International Journal of Medical Informatics*. Elsevier, 55(2), pp. 87–101. doi: 10.1016/S1386-5056(99)00011-8.

Berry, D. L. (2011) 'Patient-reported symptoms and quality of life integrated into clinical cancer care', *Seminars in Oncology Nursing*. NIH Public Access, 27(3), pp. 203–210. doi: 10.1016/j.soncn.2011.04.005.

Bertino, E. *et al.* (2008) 'High-assurance integrity techniques for databases', in *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*, pp. 244–256. doi: 10.1007/978-3-540-70504-8_26.

Bettman, J. R., Johnson, E. J. and Payne, J. W. (1993) *The Adaptive Decision Maker*. Cambridge: Cambridge University Press. doi: DOI: 10.1017/CBO9781139173933.

Bickmore, T. and Cassell, J. (2001) 'Relational agents: a model and implementation of building user trust', in *Proceedings of the SIGCHI conference on Human factors in computing systems*, pp. 396–403.

Bierbrier, R., Lo, V. and Wu, R. C. (2014) 'Evaluation of the Accuracy of Smartphone Medical Calculation Apps Corresponding', *Journal of Medical Internet Research*, 16(2). doi: 10.2196/jmir.3062.

Billman, G. E. (2011) 'Heart rate variability - a historical perspective', *Frontiers in physiology*. Front Physiol, 2. doi: 10.3389/FPHYS.2011.00086.

Birks, M. and Mills, J. (2015) *Grounded theory: A practical guide*. Sage.

Boocock, M. and Grahame, D. (2003) 'Qualitative Interview Studies: Learning Through Experience', *Venture Capital, Islamic Finance and SMEs*. Routledge, pp. 67–84. doi: 10.4324/9781410609373-8.

Bouayad, L., Ialynytchev, A. and Padmanabhan, B. (2017) 'Patient health record systems

scope and functionalities: Literature review and future directions', *Journal of Medical Internet Research*, 19(11). doi: 10.2196/jmir.8073.

Boyne, J. J. J. *et al.* (2012) 'Tailored telemonitoring in patients with heart failure: Results of a multicentre randomized controlled trial', *European Journal of Heart Failure*, 14(7), pp. 791–801. doi: 10.1093/eurjhf/hfs058.

Braga, F. and Panteghini, M. (2018) 'Defining permissible limits for the combined uncertainty budget in the implementation of metrological traceability', *Clinical Biochemistry*. Elsevier, 57, pp. 7–11. doi: 10.1016/J.CLINBIOCHEM.2018.03.007.

Brant, J. M. *et al.* (2015) 'Understanding and Evaluating Survey Research', *Journal of the Advanced Practitioner in Oncology*. Harborside Press, 6(2), p. 168. doi: 10.6004/jadpro.2015.6.2.9.

Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology', *Qualitative research in psychology*. Taylor & Francis, 3(2), pp. 77–101.

Browne, K. (2007) 'Snowball sampling: using social networks to research non-heterosexual women', *https://doi.org/10.1080/1364557032000081663*. Taylor & Francis Group Ltd , 8(1), pp. 47–60. doi: 10.1080/1364557032000081663.

Burka, J. F. *et al.* (2005) 'Defining the Personal Health Record', *Defining the Personal Health Record / AHIMA, American Health Information Management Association*. American Health Information Management Association, 13(3), pp. 379–388. Available at: http://library.ahima.org/doc?oid=59377 (Accessed: 5 December 2023).

Burnett, D. (2003) *ISO 15189:2003-FROM THEORY IN TO PRACTICE*.

Byabazaire, J., O'hare, G. and Delaney, D. (2020) 'Data Quality and Trust : A Perception from Shared Data in IoT', *Electronics (Switzerland)*, 9(12), pp. 1–22. doi: 10.3390/electronics9122083.

Byambasuren, O. *et al.* (2018) 'Prescribable mHealth apps identified from an overview of systematic reviews', *npj Digital Medicine 2018 1:1*. Nature Publishing Group, 1(1), pp. 1–12. doi: 10.1038/s41746-018-0021-9.

Cahill, J. (2020) 'The Specification of a "Human Factors and Ethics" Canvas for Socio-technical Systems', pp. 1–18. Available at: https://www.researchgate.net/publication/340512203_The_Human_Factors_Ethics_Canvas_A_White_Paper.

Canadian Institute for Health Information (2017) *CIHI's Information Quality Framework*. Available at: www.cihi.cacopyright@cihi.ca (Accessed: 30 June 2020).

Carroll, J. K. *et al.* (2017) 'Who uses mobile phone health apps and does use matter? A secondary data analytics approach', *Journal of Medical Internet Research*. Journal of Medical Internet Research, 19(4). doi: 10.2196/jmir.5604.

Cash, P., Stanković, T. and Štorga, M. (2016) 'Experimental design research: Approaches, perspectives, applications', *Experimental Design Research: Approaches, Perspectives, Applications*. Springer International Publishing, pp. 1–270. doi: 10.1007/978-3-319-33781-4/COVER.

Charmaz, K. (2001) ‘Grounded Theory: Methodology and Theory Construction’, *International Encyclopedia of the Social & Behavioral Sciences*. Pergamon, pp. 6396–6399. doi: 10.1016/B0-08-043076-7/00775-0.

Charmaz, K. (2014) *Constructing grounded theory*. sage.

Chen, Y. R. R. and Schulz, P. J. (2016) ‘The Effect of Information Communication Technology Interventions on Reducing Social Isolation in the Elderly: A Systematic Review’, *Journal of medical Internet research*, 18(1), p. e18. doi: 10.2196/jmir.4596.

Cheng, K. G. *et al.* (2015) ‘Challenges of integrating patient-centered data into clinical workflow for care of high-risk infants’, *Personal and Ubiquitous Computing*, 19(1), pp. 45–57. doi: 10.1007/s00779-014-0807-y.

Chung, A. E. and Basch, E. M. (2015) ‘Potential and Challenges of Patient-Generated Health Data for High-Quality Cancer Care’, *Journal of Oncology Practice*, 11(3). doi: 10.1200/jop.2015.003715.

Cochrane, A. L. (1972) *Effectiveness and efficiency: random reflections on health services*.

Cohen, D. J. *et al.* (2016) ‘Integrating Patient-Generated Health Data Into Clinical Care Settings or Clinical Decision-Making: Lessons Learned From Project HealthDesign’, *JMIR Human Factors*. JMIR Publications Inc., 3(2), p. e26. doi: 10.2196/humanfactors.5919.

Collard, D. (1989) *Trust: Making and Breaking Cooperative Relations*. Oxford University Press Oxford, UK.

Cresswell, K. M. *et al.* (2017) ‘Workarounds to hospital electronic prescribing systems: A qualitative study in English hospitals’, *BMJ Quality and Safety*, 26(7), pp. 542–551. doi: 10.1136/bmjqs-2015-005149.

Cresswell, K. M. *et al.* (2018) ‘Five key strategic priorities of integrating patient generated health data into United Kingdom electronic health records’, *Journal of Innovation in Health Informatics*. doi: 10.14236/jhi.v25i4.1068.

Dadayan, L. and Ferro, E. (2005) ‘When technology meets the mind: A comparative study of the technology acceptance model’, in *Lecture Notes in Computer Science*. Springer Verlag, pp. 137–144. doi: 10.1007/11545156_13.

Damen, D. J. *et al.* (2022) ‘Patients Managing Their Medical Data in Personal Electronic Health Records: Scoping Review’, *Journal of Medical Internet Research*. JMIR Publications Inc., 24(12). doi: 10.2196/37783.

Davidoff, F. *et al.* (1995) ‘Evidence based medicine’, *BMJ*. British Medical Journal Publishing Group, 310(6987), p. 1085. doi: 10.1136/bmj.310.6987.1085.

Davis, F. (1989) ‘Perceived usefulness, perceived ease of use, and user acceptance of information technology’, *MIS Quarterly: Management Information Systems*, 13(3), pp. 319–339. doi: 10.2307/249008.

Davis, F. D., Bagozzi, R. P. and Warshaw, P. R. (1989) ‘User acceptance of computer technology: A comparison of two theoretical models’, *Management science*. INFORMS, 35(8), pp. 982–1003.

Demiris, G. *et al.* (2019) 'Patient generated health data use in clinical practice: A systematic review', *Nursing Outlook*. Elsevier Inc., 67(4), pp. 311–330. doi: 10.1016/j.outlook.2019.04.005.

Djulbegovic, B. *et al.* (1999) 'Acceptable regret in medical decision making', *Medical Hypotheses*, 53(3), pp. 253–259. doi: 10.1054/mehy.1998.0020.

Downing, J., Bollyky, J. and Schneider, J. (2017) 'Use of a connected glucose meter and certified diabetes educator coaching to decrease the likelihood of abnormal blood glucose excursions: The livongo for diabetes program', *Journal of Medical Internet Research*. JMIR Publications Inc., 19(7), p. e6659. doi: 10.2196/jmir.6659.

Emmott, N. *et al.* (2024) *Regulatory Fit-for-Purpose Considerations for Patient-Generated Health Data*.

European Statistical System (2011) *Quality Assurance Framework of the European Statistical System*.

Evans, A. M. and Krueger, J. I. (2017) 'Ambiguity and expectation-neglect in dilemmas of interpersonal trust', *Judgment and Decision Making*. Cambridge University Press, 12(6), pp. 584–595.

Ferguson, T. (2000) 'Online patient-helpers and physicians working together: A new partnership for high quality health care', *British Medical Journal*. BMJ Publishing Group, 321(7269), pp. 1129–1132. doi: 10.1136/bmj.321.7269.1129.

Fiore-Gartland, B. and Neff, G. (2015) 'Communication, mediation, and the expectations of data: Data valences across health and wellness communities', *International Journal of Communication*, 9, pp. 1466–1484.

Fletcher, G. S. (2019) *Clinical epidemiology: the essentials*. Lippincott Williams & Wilkins.

Fox, M. S. and Huang, J. (2005) 'Knowledge provenance in enterprise information', *International Journal of Production Research*, 43(20), pp. 4471–4492. doi: 10.1080/00207540500142415.

Freeman, K. *et al.* (2020) 'Algorithm based smartphone apps to assess risk of skin cancer in adults : systematic review of diagnostic accuracy studies'. doi: 10.1136/bmj.m127.

Fresques, H. and Marco, M. (2019) *"Your Default Position Should Be Skepticism" and Other Advice for Data Journalists From Hadley Wickham — ProPublica*, *ProPublica*. Available at: https://www.propublica.org/nerds/hadley-wickham-your-default-position-should-be-skepticism-and-other-advice-for-data-journalists (Accessed: 28 July 2023).

Fromm, E. (1956) *The art of Loving*, *World Perspectives*. Available at: https://medium.com/@arifwicaksanaa/pengertian-use-case-a7e576e1b6bf.

Fukuyama, F. (1996) *Trust: The social virtues and the creation of prosperity*. Simon and Schuster.

Gagnon, M. P. *et al.* (2016) 'Adoption of electronic personal health records in Canada: Perceptions of stakeholders', *International Journal of Health Policy and Management*. Kerman University of Medical Sciences, 5(7), pp. 425–433. doi: 10.15171/ijhpm.2016.36.

Gambetta, D. (2000) 'Can We Trust Trust?', in *Trust: Making and Breaking Cooperative Relations*, pp. 213–237. Available at: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.24.5695&rep=rep1&type=pdf.

Gambetta, D. and Badcock, C. (1990) 'Trust: Making and Breaking Cooperative Relations', *The British Journal of Sociology*, p. 128. doi: 10.2307/591021.

Garfinkel, S. (2000) *Database Nation: The Death of Privacy in the 21st Century*. 1st edn. O'Reilly. Available at: https://books.google.com/books/about/Database_Nation.html?id=vZyFAAAAMAAJ (Accessed: 1 August 2023).

Glaser, B. and Strauss, A. (2017) *Discovery of grounded theory: Strategies for qualitative research*. Routledge.

Glaser, B. and Strauss, A. L. (1999) *The discovery of grounded theory: Strstegies for qualitative research*. 1st edn. London: Aldine Transaction. doi: https://doi.org/10.4324/9780203793206.

Glasser, B. G. and Strauss, A. L. (1999) *The discovery of grounded theory: Strstegies for qualitative research*. 1st edn. London: Aldine Transaction. doi: https://doi.org/10.4324/9780203793206.

Goranson, H. T. *et al.* (2003) 'A Merged Future for Knowledge Management and Enterprise Modeling', in *Enterprise Inter- and Intra-Organizational Integration*. Springer US, pp. 37–50. doi: 10.1007/978-0-387-35621-1_5.

Greenhalgh, T. (2010) *How to Read a Paper: The Basics of Evidence-Based Medicine*. Wiley. Available at: https://books.google.ie/books?id=q-92iFMFJGwC.

Greenwood, D. A. *et al.* (2017) 'A Systematic Review of Reviews Evaluating Technology-Enabled Diabetes Self-Management Education and Support', *Journal of Diabetes Science and Technology*. SAGE Publications Inc., 11(5), pp. 1015–1027. doi: 10.1177/1932296817713506.

Groth, P., Luck, M. and Moreau, L. (2004) 'Formalising a protocol for recording provenance in Grids', *Proceedings of the UK OST e-Science Second All Hands Meeting 2004 (AHM'04)*.

Grubbs, F. E. (1969) 'Procedures for Detecting Outlying Observations in Samples', *Technometrics*. JSTOR, 11(1), p. 1. doi: 10.2307/1266761.

Gupta, A. (2009) 'Data Provenance', in LIU, L. and ÖZSU, M. T. (eds) *Encyclopedia of Database Systems*. Boston, MA: Springer US, p. 608. doi: 10.1007/978-0-387-39940-9_1305.

Guyatt, G. *et al.* (2011) 'GRADE guidelines: 1. Introduction - GRADE evidence profiles and summary of findings tables', *Journal of Clinical Epidemiology*, 64(4), pp. 383–394. doi: 10.1016/J.JCLINEPI.2010.04.026.

Guyatt, G. *et al.* (2015) *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice, 3rd ed*, *Users' Guides to the Medical Literature: A Manual for*

Evidence-Based Clinical Practice, 3rd ed. New York, NY: McGraw-Hill Education. Available at: http://jamaevidence.mhmedical.com/content.aspx?aid=1147669501.

Guyatt, G. H. and Rennie, D. (1993) 'Users' Guides to the Medical Literature', *JAMA: The Journal of the American Medical Association*. American Medical Association, 270(17), pp. 2096–2097. doi: 10.1001/jama.1993.03510170086037.

Han, P. K. J., Klein, W. M. P. and Arora, N. K. (2011) 'Varieties of Uncertainty in Health Care: A Conceptual Taxonomy', *Medical Decision Making*, 31(6), pp. 828–838. doi: 10.1177/0272989x11393976.

Haynes, B. and Haines, A. (1996) 'Barriers and bridges to evidence based clinical practice', *British Medical Journal*. BMJ Publishing Group, p. 2. doi: 10.1136/bmj.317.7153.273.

Hederman, L., Berry, D. and Ormazabal, A. (2023) 'Clinician's perspective on trusting Patient Generated Health Data for use in clinical decision-making: A qualitative interview study', in *2023 IEEE 36th International Symposium on Computer-Based Medical Systems (CBMS)*. IEEE, pp. 252–256.

HIQA (2018) *Guidance on a data quality framework for health and social care Health Information and Quality Authority*.

Hofmann, H., Wickham, H. and Kafadar, K. (2017) 'Letter-Value Plots: Boxplots for Large Data', *Journal of Computational and Graphical Statistics*, 26(3), pp. 469–477. doi: 10.1080/10618600.2017.1305277.

HPRA (2017) *HPRA Guide to Placing Medical Device Standalone Software on the Market*.

Hsueh, P. Y. S. *et al.* (2017) 'Making sense of patient-generated health data for interpretable patient-centered care: The transition from "More" to "Better"', *Studies in Health Technology and Informatics*, 245, pp. 113–117. doi: 10.3233/978-1-61499-830-3-113.

Huang, J. and Fox, M. S. (2006) 'An ontology of trust - Formal semantics and transitivity', *ACM International Conference Proceeding Series*, (January), pp. 259–270. doi: 10.1145/1151454.1151499.

Huba, N. and Zhang, Y. (2012) 'Designing patient-centered personal health records (PHRs): Health care professionals' perspective on patient-generated data', *Journal of Medical Systems*, 36(6), pp. 3893–3905. doi: 10.1007/s10916-012-9861-z.

Hussein, R. *et al.* (2021) 'Patient-Generated Health Data (PGHD) Interoperability: An Integrative Perspective', *Studies in health technology and informatics*. Stud Health Technol Inform, 281, pp. 228–232. doi: 10.3233/SHTI210154.

ISO (1995) *Guıde To The Expressıon Of Uncertaınty In Measurement*.

ISO (2021) *CEN ISO TS82304-2-2021*, *ISO*. doi: 10.7551/mitpress/7803.003.0005.

Jacobs, M. L., Clawson, J. and Mynatt, E. D. (2015) 'Comparing Health Information Sharing Preferences of Cancer Patients, Doctors, and Navigators', in *Proceedings of the 18th ACM Conference on Computer Supported Cooperative Work & Social Computing -*

CSCW '15. New York, New York, USA: ACM Press, pp. 808–818. doi: 10.1145/2675133.2675252.

Jim, H. S. L. *et al.* (2020) 'Innovations in research and clinical care using patient-generated health data', *CA: A Cancer Journal for Clinicians*. Wiley, 70(3), pp. 182–199. doi: 10.3322/caac.21608.

Jo Deering, M. (2013) 'Patient-Generated Health Data and Health IT'. Available at: https://www.healthit.gov/sites/default/files/pghd_brief_final122013.pdf.

Joice, M. (2018) 'Screening for atrial fibrillation with a wearable patch: Seek and ye shall find … and then what? |', *Health News Review*. Available at: https://www.healthnewsreview.org/2018/07/atrial-fibrillation-screening-wearable/ (Accessed: 20 July 2022).

Kay, J. A. (John A. and King, M. A. (2020) *Radical uncertainty : decision-making beyond the numbers*.

Kearney, R. C. and Hays, S. W. (2019) 'Labor-Management Relations and Participative Decision Making : Toward a New Paradigm Published by : Wiley on behalf of the American Society for Public Administration Stable URL : https://www.jstor.org/stable/976497 Linked references are available on JSTOR', 54(1), pp. 44–51.

Keeney, R. L. and Keeney, R. L. (2009) *Value-focused thinking: A path to creative decisionmaking*. Harvard University Press.

Khereldeen, M. and Baazeem, M. (2021) 'Excessive Utilization of Laboratory Investigations and its Relationship with Defensive Medicine Practice: A Saudi Arabia Perspective', *International Journal of Medical Reviews*. Baqiyatallah University of Medical Sciences, 8(2), pp. 87–98. doi: 10.30491/IJMR.2020.248448.1145.

Kim, K. and Lee, Y. M. (2018) 'Understanding uncertainty in medicine: concepts and implications in medical education', *Korean Journal of Medical Education*. Korean Society of Medical Education, 30(3), p. 181. doi: 10.3946/KJME.2018.92.

King, M. and Kay, J. (2020) *Radical uncertainty: Decision-making for an unknowable future*. Hachette UK.

Knight, F. (1921) *Risk, Uncertainty, and Profit*, *Die 100 wichtigsten Werke der Ökonomie*. doi: 10.34156/9783791046006-108.

Kramer, R. M. and Tyler, T. R. (1996) *Trust in organizations: Frontiers of theory and research*. Sage.

Kreps, D. M. (1990) 'Corporate culture and economic theory', *Perspectives on positive political economy*. Cambridge, MA, 90(109–110), p. 8.

Kvedar, J., Coye, M. J. and Everett, W. (2014) 'Connected health: A review of technologies and strategies to improve patient care with telemedicine and telehealth', *Health Affairs*, 33(2), pp. 194–199. doi: 10.1377/hlthaff.2013.0992.

Lai, A. M. *et al.* (2017) 'Present and Future Trends in Consumer Health Informatics and

Patient-Generated Health Data', *Yearbook of medical informatics*, pp. 152–159. doi: 10.15265/IY-2017-016.

LaRosa, E. and Danks, D. (2018) *Impacts on Trust of Healthcare AI*, *AIES 2018 - Proceedings of the 2018 AAAI/ACM Conference on AI, Ethics, and Society*. Association for Computing Machinery, Inc. doi: 10.1145/3278721.3278771.

Lawler, E. E. (1995) 'The Ultimate Advantage: Creating the High-Involvement Organization.', *Industrial and Commercial Training*, 27(6). doi: 10.5465/ame.1993.9409142063.

Lee, A. L. and Mohamed, N. N. E. (2022) 'Application of Patient-Generated Health Data in Managing Chronic Conditions in Hospital Kuala Lumpur: A Qualitative Study', *The Malaysian Journal of Medical Sciences : MJMS*. School of Medical Sciences, Universiti Sains Malaysia, 29(3), p. 99. doi: 10.21315/MJMS2022.29.3.10.

Lenaerts, G. *et al.* (2021) 'A tool to assess the trustworthiness of evidence-based point-of-care information for health care professionals (CAPOCI): Design and validation study', *Journal of Medical Internet Research*, 23(10). doi: 10.2196/27174.

Lewicki, R. J., Tomlinson, E. C. and Gillespie, N. (2006) 'Models of Interpersonal Trust Development: Theoretical Approaches, Empirical Evidence, and Future Directions', *Journal of Management*. Sage PublicationsSage CA: Thousand Oaks, CA, 32(6), pp. 991–1022. doi: 10.1177/0149206306294405.

Li, C., Turmunkh, U. and Wakker, P. P. (2019) 'Trust as a decision under ambiguity', *Experimental Economics*. Springer New York LLC, 22(1), pp. 51–75. doi: 10.1007/S10683-018-9582-3/FIGURES/6.

Lintern, G. and Motavalli, A. (2018) 'Healthcare information systems: the cognitive challenge', *BMC medical informatics and decision making*. Springer, 18, pp. 1–10.

Lordon, R. J. *et al.* (2020) 'How patient-generated health data and patient-reported outcomes affect patient–clinician relationships: A systematic review', *Health Informatics Journal*. SAGE Publications Ltd, 26(4), pp. 2689–2706. doi: 10.1177/1460458220928184.

De Lusignan, S. *et al.* (2014) 'Patients' online access to their electronic health records and linked online services: A systematic interpretative review', *BMJ Open*. BMJ Publishing Group, 4(9), p. e006021. doi: 10.1136/BMJOPEN-2014-006021/-/DC1.

Lyles, C. R. *et al.* (2020) 'Using Electronic Health Record Portals to Improve Patient Engagement: Research Priorities and Best Practices', *Annals of internal medicine*. NIH Public Access, 172(11 Suppl), p. S123. doi: 10.7326/M19-0876.

Magrabi, F. *et al.* (2019) 'Why is it so difficult to govern mobile apps in healthcare ?', pp. 1–5. doi: 10.1136/bmjhci-2019-100006.

Marcus, G. and Davis, E. (2019) *Rebooting AI: Building artificial intelligence we can trust*. Vintage.

Mayer, R. C., Davis, J. H. and David Schoorman, F. (1995) 'An Integrative Model of Organizational Trust', 20(3), pp. 709–734.

Melnyk, B. M. (2004) 'Integrating Levels of Evidence into Clinical Decision Making', *Pediatric Nursing*, 30(4), p. 323. Available at: https://search.proquest.com/docview/199394549?pq-origsite=gscholar&fromopenview=true (Accessed: 1 September 2020).

Melnyk, B. M. and Fineout-Overholt, E. (2010) 'Evidence-based practice in nursing & healthcare : a guide to best practice / edited by , .', pp. 0–2.

Metzer, R. (2018) *Are diagnostic health apps accurate? Researchers say there's no way to tell*, *Fierce Healthcare*. Available at: https://www.fiercehealthcare.com/tech/are-diagnostic-health-apps-accurate-analysts-say-there-s-no-way-to-tell.

Mill, J. S. (2013) *A System Of Logic, Ratiocinative And Inductive: Being a Connected View of the Principles of Evidence, and the Methods of Scientific Investigation*. Harper and Brothers, Publishers.

Miller, S. J. (2015) *Benford's law*. Princeton University Press.

Miyaji, T. *et al.* (2020) 'Patient-generated health data collection using a wearable activity tracker in cancer patients—a feasibility study', *Supportive Care in Cancer*. Springer, pp. 1–9. doi: 10.1007/s00520-020-05395-z.

Naumann, F. and Rolker, C. (2005) 'Assessment methods for information quality criteria'. Humboldt-Universität zu Berlin, Mathematisch-Naturwissenschaftliche Fakultät …, 465(October 2000). Available at: http://library1.nida.ac.th/termpaper6/sd/2554/19755.pdf.

Nazi, K. M., Newton, T. and Armstrong, C. M. (2024) 'Unleashing the Potential for Patient-Generated Health Data (PGHD)', *Journal of General Internal Medicine*. Springer, 39(Suppl 1), pp. 9–13.

Newton, N. *et al.* (2023) 'Methods used to evaluate clinicians' acceptance and use of clinical decision support systems over time: a systematic review', *Digital Health Week*, 2(1).

Nittas, V. *et al.* (2018) 'Electronic patient-generated health data to facilitate prevention and health promotion: A scoping review protocol', *BMJ Open*. BMJ Publishing Group. doi: 10.1136/bmjopen-2017-021245.

Nundy, S. *et al.* (2014) 'Using patient-generated health data from mobile technologies for diabetes self-management support: Provider perspectives from an academic medical center', *Journal of Diabetes Science and Technology*. Diabetes Technology Society, 8(1), pp. 74–82. doi: 10.1177/1932296813511727.

O'Neill, O. (2018) 'Linking Trust to Trustworthiness', *International Journal of Philosophical Studies*. Routledge, 26(2), pp. 293–300. doi: 10.1080/09672559.2018.1454637.

O'Rourke, K. (2017) 'Patient Generated Health Data in Ireland: A Study of the Patient Perspective', p. 126. Available at: https://scss.tcd.ie/publications/theses/diss/2017/TCD-SCSS-DISSERTATION-2017-012.pdf.

Or, C. and Tao, D. (2012) 'Usability study of a computer-based self-management system

for older adults with chronic diseases', *Journal of Medical Internet Research*, 14(6). doi: 10.2196/resprot.2184.

Ortega Egea, J. M. and Román González, M. V. (2010) 'Explaining physicians' acceptance of EHCR systems: An extension of TAM with trust and risk factors'. doi: 10.1016/j.chb.2010.08.010.

Osterwalder, A. and Pigneur, Y. (2010) *Business model generation: a handbook for visionaries, game changers, and challengers*. John Wiley & Sons.

Pais, S., Parry, D. and Huang, Y. (2017) 'Suitability of Fast Healthcare Interoperability Resources (FHIR) for Wellness Data', in *Proceedings of the 50th Hawaii International Conference on System Sciences | 2017*, pp. 3499–3505. Available at: http://hdl.handle.net/10125/41581 (Accessed: 15 October 2019).

Panteghini, M. (2010) 'Application of traceability concepts to analytical quality control may reconcile total error with uncertainty of measurement', *Clinical Chemistry and Laboratory Medicine*, 48(1), pp. 7–10. doi: 10.1515/CCLM.2010.020.

Papautsky, E. L. and Panganiban, A. R. (2018) 'Implications of Trust on Patient Generated Health Data', *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. Human Factors and Ergonomics Society Inc., 62(1), pp. 550–550. doi: 10.1177/1541931218621125.

Park, Y. R. *et al.* (2018) 'Managing Patient-Generated Health Data Through Mobile Personal Health Records: Analysis of Usage Data', *JMIR mHealth and uHealth*. JMIR Publications Inc., 6(4), p. e89. doi: 10.2196/mhealth.9620.

Patel, M. S., Asch, D. A. and Volpp, K. G. (2015) 'Wearable Devices as Facilitators, Not Drivers, of Health Behavior Change', *JAMA*. American Medical Association, 313(5), pp. 459–460. doi: 10.1001/JAMA.2014.14781.

Pearson, K. (2009) 'X. On the criterion that a given system of deviations from the probable in the case of a correlated system of variables is such that it can be reasonably supposed to have arisen from random sampling', *https://doi.org/10.1080/14786440009463897*. Taylor & Francis Group, 50(302), pp. 157–175. doi: 10.1080/14786440009463897.

Perez, M. V. *et al.* (2019) 'Large-scale assessment of a smartwatch to identify atrial fibrillation', *New England Journal of Medicine*, 381(20), pp. 1909–1917. doi: 10.1056/NEJMoa1901183.

Petersen, C. and DeMuro, A. (2015) 'Legal and regulatory considerations associated with use of patient-generated health data from social media and mobile health (mHealth) devices', *Applied Clinical Informatics*. Schattauer GmbH, 6(1), pp. 16–26. doi: 10.4338/ACI-2014-09-R-0082.

Pikulev, A. (no date) *Team Trust Canvas – 'In Team We Trust'*, *inteamwetrust.com*. Available at: https://inteamwetrust.com/team-trust-toolbox/team-trust-canvas/ (Accessed: 27 May 2023).

Plastiras, P. and O'Sullivan, D. (2018) 'Exchanging personal health data with electronic health records: A standardized information model for patient generated health data and

observations of daily living', *International Journal of Medical Informatics*. doi: 10.1016/j.ijmedinf.2018.10.006.

Plastiras, P., O'Sullivan, D. and Weller, P. (2014) 'An Ontology-Driven Information Model for Interoperability of Personal and Electronic Health Records', in *The Sixth International Conference on eHealth, Telemedicine, and Social Medicine*, pp. 130–133.

Plays-In-Business (no date) *Team Trust Canvas — How to Create Trust in Your Team*, *Plays-In-Business.com*. Available at: https://www.plays-in-business.com/team-trust-canvas-how-to-create-trust-in-your-team/ (Accessed: 16 April 2023).

Pratt, J. W., Raiffa, H. and Schlaifer, R. (1995) *Introduction to statistical decision theory*. MIT press.

Priya, A. (2020) 'Case Study Methodology of Qualitative Research: Key Attributes and Navigating the Conundrums in Its Application', *https://doi.org/10.1177/0038022920970318*. SAGE PublicationsSage India: New Delhi, India, 70(1), pp. 94–110. doi: 10.1177/0038022920970318.

Products Regulatory Authority, H. (2009) *Guide to Classification of a Medical Device HPRA*.

Proesmans, T. *et al.* (2019) 'Mobile phone-based use of the photoplethysmography technique to detect atrial fibrillation in primary care: Diagnostic accuracy study of the FibriCheck App', *Journal of Medical Internet Research*. Journal of Medical Internet Research, 21(3), p. e12284. doi: 10.2196/12284.

Raeve, L. De and Ba, R. G. N. (2002) 'Trust and trustworthiness in nurse – patient relationships', *Nursing Philosophy*. John Wiley & Sons, Ltd, 3(2), pp. 152–162. doi: 10.1046/J.1466-769X.2002.00090.X.

Rajendran, R. and Rayman, G. (2014) 'Point-of-Care Blood Glucose Testing for Diabetes Care in Hospitalized Patients: An Evidence-Based Review', *Journal of Diabetes Science and Technology*. Diabetes Technology Society, 8(6), p. 1081. doi: 10.1177/1932296814538940.

Reading, M. J. and Merrill, J. A. (2018) 'Converging and diverging needs between patients and providers who are collecting and using patient-generated health data: An integrative review', *Journal of the American Medical Informatics Association*. Oxford University Press, 25(6), pp. 759–771. doi: 10.1093/jamia/ocy006.

Roehrs, A. *et al.* (2017) 'Personal health records: A systematic literature review', *Journal of Medical Internet Research*. Journal of Medical Internet Research, 19(1). doi: 10.2196/jmir.5876.

Rosner, B. I., Kvedar, J. C. and Adler-Milstein, J. (2021) 'Patient-generated health data earn a seat at the table: clinical adoption during the COVID-19 transition to telemedicine', *JAMIA Open*. Oxford Academic, 4(4). doi: 10.1093/JAMIAOPEN/OOAB097.

Rousseau, D. M. *et al.* (1998) 'Not so different after all: A cross-discipline view of trust', *Academy of Management Review*. Academy of Management Briarcliff Manor, NY 10510, 23(3), pp. 393–404. doi: 10.5465/AMR.1998.926617.

Sackett, D. L. *et al.* (1996) 'Evidence based medicine: what it is and what it isn't', *BMY*, 312, pp. 71–72.

Sackett, D. L. (2000) *Evidence-based Medicine: How to Practice and Teach EBM*. Churchill Livingstone (Churchill Livingstone). Available at: https://books.google.ie/books?id=oYJrAAAAMAAJ.

Sands, D. Z. and Wald, J. S. (2014) 'Transforming health care delivery through consumer engagement, health data transparency, and patient-generated health information', *Yearbook of medical informatics*, pp. 170–176. doi: 10.15265/IY-2014-0017.

Sanger, P. C. *et al.* (2016) 'A patient-centered system in a providercentered world: Challenges of incorporating post-discharge wound data into practice', *Journal of the American Medical Informatics Association*. Oxford University Press, 23(3), pp. 514–525. doi: 10.1093/jamia/ocv183.

Scanlon, M. C., Karsh, B.-T. and Saran, K. A. (2008) *Risk-Based Patient Safety Metrics*, *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment)*. Agency for Healthcare Research and Quality. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21249862 (Accessed: 7 July 2020).

Schroeder, J. *et al.* (2017) 'Supporting patient-provider collaboration to identify individual triggers using food and symptom journals', in *Proceedings of the ACM Conference on Computer Supported Cooperative Work, CSCW*. doi: 10.1145/2998181.2998276.

Schwartz, J. M. *et al.* (2022) 'Factors influencing clinician trust in predictive clinical decision support systems for in-hospital deterioration: qualitative descriptive study', *JMIR Human Factors*. JMIR Publications Toronto, Canada, 9(2), p. e33960.

Shapiro, M. *et al.* (2012) *Patient-Generated Health Data*.

Shorten, A. and Smith, J. (2017) 'Mixed methods research: expanding the evidence base', *Evidence-Based Nursing*. Royal College of Nursing, 20(3), pp. 74–75. doi: 10.1136/EB-2017-102699.

Siminerio, L. *et al.* (2014) 'Telemedicine for Reach, Education, Access, and Treatment (TREAT): Linking Telemedicine With Diabetes Self-management Education to Improve Care in Rural Communities', *The Diabetes Educator*, 40(6), pp. 797–805. doi: 10.1177/0145721714551993.

Simon, H. A. (1979) 'Rational Decision Making in Business Organizations on JSTOR', *The american economic rebiew*, 69(4), pp. 493–813. Available at: https://www.jstor.org/stable/1808698 (Accessed: 7 August 2022).

Simpkin, A. L. and Schwartzstein, R. M. (2016) 'Tolerating uncertainty - The Next medical revolution?', *New England Journal of Medicine*. Massachussetts Medical Society, pp. 1713–1715. doi: 10.1056/NEJMp1606402.

Slevin, M. L. *et al.* (1988) 'Who should measure quality of life, the doctor or the patient?', *British Journal of Cancer*. Br J Cancer, 57(1), pp. 109–112. doi: 10.1038/bjc.1988.20.

Söderström, E. (2009) 'Trust Types: An Overview', in *Discourses in security assurance and privacy*. Available at: www.security-conference.org (Accessed: 21 July 2022).

Söderström, E., Eriksson, N. and Åhlfeldt, R.-M. (2016) 'Managing healthcare information: analyzing trust', *International Journal of Health Care Quality Assurance2*, 29(7), pp. 786–800. doi: 10.1108/IJHCQA-11-2015-0136.

Strauss, A. and Corbin, J. (1998) 'Basics of qualitative research techniques'. Thousand oaks, CA: Sage publications.

Swendeman, D. *et al.* (2018) 'Longitudinal Validity and Reliability of Brief Smartphone Self-Monitoring of Diet , Stress , and Physical Activity in a Diverse Sample of Mothers Corresponding Author ':, 6. doi: 10.2196/mhealth.9378.

Taleb, N. (2015) 'The black swan: The impact of the highly improbable', *Victoria*, 250, pp. 595–7955.

Tarassenko, L. and Greenhalgh, T. (2020) *Question: Should smartphone apps be used clinically as oximeters? Answer: No.*, *Centre for Evidence Based Medicine*. Available at: https://www.cebm.net/covid-19/question-should-smartphone-apps-be-used-as-oximeters-answer-no/.

Telemonitoring Study - for Chronic Myeloid Leukemia (CML) (2018). Available at: https://beta.clinicaltrials.gov/study/NCT01490983 (Accessed: 19 June 2023).

The Ethics Canvas (no date). Available at: https://www.ethicscanvas.org/ (Accessed: 27 May 2023).

Tiase, V. L. (2017) 'Navigating the patient-generated health data deluge', *Nursing Informatics*, (December), pp. 7–8.

Tiase, Victoria L *et al.* (2021) 'Patient-generated health data and electronic health record integration: a scoping review', *JAMIA Open*. Oxford Academic, 3(4), pp. 619–627. doi: 10.1093/JAMIAOPEN/OOAA052.

Tiase, Victoria L. *et al.* (2021) 'Patient-Generated Health Data in Pediatric Asthma: Exploratory Study of Providers' Information Needs', *JMIR Pediatrics and Parenting*. JMIR Publications Inc., 4(1). doi: 10.2196/25413.

Timnit Gebru (2020) 'Race and Gender', in *The Oxford Handbook of Ethics of AI*. Available at: https://books.google.ie/books?hl=en&lr=&id=8vQTEAAAQBAJ&oi=fnd&pg=PA253&dq=Timnit+Gebru+trust&ots=JkrFycNAA8&sig=ubTvAcBCvaG2fRITfLI2UMhTj38&redir_esc=y#v=onepage&q&f=false (Accessed: 1 August 2023).

Topol, E. (2015) *The patient will see you now: the future of medicine is in your hands*. Basic Books.

Valentin Fuster (2019) 'Dr. Valentin Fuster on the Apple Heart Study - ACC 2019 Wrap-Up - YouTube', in *ACC 2019*. Available at: https://www.youtube.com/watch?v=VQ2K_Kfq3TQ (Accessed: 7 July 2022).

Venkatesh *et al.* (2003) 'User Acceptance of Information Technology: Toward a Unified

View', *MIS Quarterly*. Management Information Systems Research Center, 27(3), p. 425. doi: 10.2307/30036540.

Vogiatzaki, E., Rodríguez, J. M. and Conejero-Lara, F. (2022) 'Personal Health Record', *Cyberphysical Systems for Epilepsy and Related Brain Disorders: Multi-Parametric Monitoring and Analysis for Diagnosis and Optimal Disease Management*. StatPearls Publishing, pp. 205–238. doi: 10.1007/978-3-319-20049-1_11.

Wallis, J. C. *et al.* (2007) 'Know thy sensor: Trust, data quality, and data integrity in scientific digital libraries', in *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*. Springer Verlag, pp. 380–391. doi: 10.1007/978-3-540-74851-9_32.

Wang, R. Y. and Strong, D. M. (2015) 'Beyond Accuracy: What Data Quality Means to Data Consumers', *https://doi.org/10.1080/07421222.1996.11518099*. Routledge, 12(4), pp. 5–34. doi: 10.1080/07421222.1996.11518099.

Wattanapisit, A. *et al.* (2020) 'Can mobile health apps replace GPs? A scoping review of comparisons between mobile apps and GP tasks', *BMC Medical Informatics and Decision Making*. BioMed Central Ltd, 20(1), p. 5. doi: 10.1186/s12911-019-1016-4.

West, P. *et al.* (2017) 'Information Quality Challenges of Patient-Generated Data in Clinical Practice', *Frontiers in Public Health*, 5(November 2017). doi: 10.3389/fpubh.2017.00284.

West, P. *et al.* (2018) 'Common Barriers to the Use of Patient-Generated Data Across Clinical Settings'. doi: 10.1145/3173574.3174058.

Whiting, P. *et al.* (2003) 'The development of QUADAS: A tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews', *BMC Medical Research Methodology*. BioMed Central Ltd., 3(1), pp. 1–13. doi: 10.1186/1471-2288-3-25/TABLES/1.

Whiting, P. F. *et al.* (2011) 'QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies', *Annals of internal medicine*. American College of Physicians, 155(8), pp. 529–536.

Wiley (2000) *Cochrane Reviews | Cochrane Library*, *Cochrane*. Available at: https://www.cochranelibrary.com/ (Accessed: 11 December 2023).

Winter, J. S. and Davidson, E. (2021) 'Harmonizing regulatory regimes for the governance of patient-generated health data', *Telecommunications Policy*. Pergamon, p. 102285. doi: 10.1016/j.telpol.2021.102285.

Wood, W. A., Bennett, A. V and Basch, E. (2015) 'Emerging uses of patient generated health data in clinical research', *Molecular Oncology*, 9, pp. 1018–1024. doi: 10.1016/j.molonc.2014.08.006.

Woods, S. S., Evans, N. C. and Frisbee, K. L. (2016) 'Integrating patient voices into health information for self-care and patient-clinician partnerships: Veterans Affairs design recommendations for patient-generated data applications', *Journal of the American Medical Informatics Association*, 23(3), pp. 491–495. doi: 10.1093/jamia/ocv199.

Woolever, D. (2008) *The Art and Science of Clinical Decision Making*, *Family Practice Management*. Available at: www.aafp.org/fpm. (Accessed: 2 September 2020).

Wuetherick, B. (2010) 'Basics of qualitative research: Techniques and procedures for developing grounded theory', *Canadian Journal of University Continuing Education*, 36(2).

Ye, J. (2021) 'The impact of electronic health record-integrated patient-generated health data on clinician burnout', *Journal of the American Medical Informatics Association : JAMIA*, 28(5), pp. 1051–1056. doi: 10.1093/jamia/ocab017.

Zadeh, L. A. (1965) 'Fuzzy sets', *Information and control*. Elsevier, 8(3), pp. 338–353.

Zerilli, J. *et al.* (2018) 'Transparency in Algorithmic and Human Decision-Making: Is There a Double Standard?', *Philosophy and Technology*. Springer, 32(4), pp. 661–683. doi: 10.1007/S13347-018-0330-6/METRICS.

10.2 Study 2 Research ethics application

Applicant & Collaborators

Applicant Details

- Applicant Name : Alfredo Ormazabal

- Is applicant applying as a member of staff or a student? : Student

- School / Department : School of Computer Science & Statistics - Computer Science

- Role on the Project : Principal Investigator

- Primary Employer (if not TCD) : ADAPT Centre

- Other affiliations (if applicable) : SFI's D-Real

- Course (for student applicant only) : PhD

- Part time / full time : Full-Time

- I have read and understood Trinity policy on Good Research Practice : Yes

- I have read and completed the Integrity module : Yes

- I have read and completed the Data Protection Training module within the last 24 months : No

Trinity Collaborators

User	Role
Lucy Hederman	Primary Supervisor

Other Collaborators

Name	Email Address	User
Damon Berry	damon.berry@tudublin.ie	Professor

Project Details

Main Project Details

- Title of research :PGHD trust tool development study

- Data Collection Start Date : 13/08/2023

- Data Collection End Date : 15/10/2023

- Project End Date : 05/11/2023 12:00:00 AM

- Does the research involve :Humans (or their data)

- Does this Animal research involve :

- Is this AREC research a first application or an amendment :

- Is the research WHOLLY (i) an analysis of statutes/legal provisions AND/OR (ii) legal judgments/cases which have been made public by a judicial process? : No

- Trinity Researchers will have access ONLY to aggregate data or data that otherwise fall outside of the remit of the GDPR. : No

- Could the research have detrimental legal, economic or social consequences for either the participant or their establishments : No

- Intentions of the research: Does the research : None of the above

- State research aim(s) and objective(s), research question or hypothesis : To co-develop a tool to help clinicians understand the implications of including or excluding Patient Generated Health Data from the clinical decision process.

- Lay Summary: including background/ rationale/ justification, research approach, study design (exclude detail of measurement instruments and intervention and analysis (if applicable) (Word limit: 250 words) : Patient Generated Health Data (PGHD) has the potential to revolutionize healthcare by providing clinicians with real-time data on patients

- Identify all countries where data is collected or processed : IE

- Does the project involve :Human participants and /or their data and no biological samples

- Is the project funded : No

Details on Human Participants and their Data

- Does your research involve Mixed Methods : No

- Does the project use data from :Primary sources only

- Will you obtain Consent from participants (or in the case of children or adults at risk of vulnerability from a parent / legal guardian) for their participation and/ or the use of their data? : Yes

- Provide further information :

- Will payment be made to research participants? :No

- Provide further information :

- Is the research Health Research as defined in the Health Research Regulations? : No

- Does the research require a Consent Declaration form as defined by the Health Research Regulations 2018 and amendments 2021? : NO

- Which of the following best describes the research Secondary Data Source(s)? :

- Could any of the research data directly identify any participant? : No

- Could any of the research data indirectly identify any participant? :No

- Do you process Personal Data for study administration purposes? e.g. contacting individuals : Yes

- If yes please outline how you will store the information, keep it confidential, and destroy it in line with the data retention policy. : OneDrive in encrypted format, on local machine which is encrypted. Accessible to PI only.

- Which of the following best describes the general characteristics of the target population? :Adults currently not at risk of vulnerability

- Do any of the following further describe the characteristics of the target population? : Other

- Please describe :

- List the inclusion/ exclusion criteria for selection of research participants : Inclusion criteria: Participants will be clinicians who have been exposed to or presented with some form of PGHD in their practice and will have formed an opinion on whether PGHD should be included in their clinical decision process.

Research Sources and Sites

Name	Req
Online Interviews	REQUIRED_NOTOBTAINED

Outline of research methods

Method / Measurement
Online interviews

- Does your research use any of the following methods exclusively? : No

- Does the research include an intervention? : No

- Please select which of the following best describes the intervention :

- Other :

- Outline the intervention :

- Outline the method of analysis (Word limit :100 words) : Once the clinician expresses their opinions and/or suggests modifications to the tool, these will be considered whether: They are modifications to the wording of the tool. They are modifications to the layout of the tool. The modifications suggested have been present in previous iterations. The modifications are suggested to develop the tool towards its objectives and requirements. Version control measures will allow the clinician to show previous versions to participants who suggest backward modifications.

- What is the approximate size of the target population? : 37000

- What is the proposed sample size -how many participants are involved in the study? : 15

- What is the justification for the sample size? : It is expected that after 15 iterations of the development, no further significant modifications will be suggested.

Risk

Risk , benefit, harm to researcher

- What setting/s will be used for data collection : Online

- Other elaborate :

Type	Other Type	Impact	Probabilty	Mitigation
None				

Risk , benefit, harm to site environment or Society

Type	Impact	Probabilty	Mitigation
None			

Risk , benefit, harm to participants

- Do you or any of the research team have any dependant relationship to the participants? : : No

- Detail the role of the researcher/s, the relationship of the researcher/s to the participants normally, and how you will mitigate against coercion of participants to participate in the research or in influencing their responses :

Type	Other Type	Impact	Probabilty	Mitigation
Inconvenience		Low	Low	The interviews will be kept to a minimum time possible.

Participant Benefits

- Is it foreseeable that participants could potentially reveal information that you have a legal obligation to disclose (e.g. child protection policy, malpractice, etc.) :No

- What information may be disclosed, why, and to whom. :

- Outline any direct benefits to research participants of participation : Participant will not be directly benefited, other than knowing that they have participated in the development of a tool to help clinicians.

Conflict of Interest

- Are you aware of any Conflict of Interest from the PI or any collaborator, processor or other person involved in the conduct of the project, that could arise in the course of the project? : No

- Give details of the Conflict of Interest and what mitigation measures are in place :

Consent

Consent

- Do your participants require support to give Consent : No

- How will Assent be obtained and by whom :

- Provide Further Information :

- Do you require Assent or Proxy Consent from participants e.g. because of their vulnerability : No

- Provide Further Information :

- Are you required to have Garda Clearance : No

- What is the time interval between giving information and securing Consent : 7 or More Days

- Provide Further Information :

- Describe how you will inform participants about the use of their Personal Data : Through the participant information sheet

- Describe how participants can withdraw their Consent and/or their data : Through the participant information sheet and verbally during the interview

---

Sampling & Recruitment

Sampling and Recruitment

- Outline the sampling method : Convenience sampling Participants will be recruited from a list of clinicians who have shown interest in the subject in the past. The contact will be made through email and participation is strictly voluntary.

- Describe the time commitment of the participant : Participants will be interviewed for 15-25 minutes online.

- Will the research require/use a gatekeeper :No

- Outline the position/role of the gatekeeper within the organisation :

- Detail the role of the gatekeeper in the research :

- Is there a dependant relationship between the gatekeeper and the participants :

- Outline how this is going to be managed to mitigate against the dependencies :

- Please give a detailed step by step description of how participants will be recruited and append the recruitment material (Word limit: 100 words). : Participants will be emailed with an invitation to participate if they are interested. Once they manifest intentions to participate, the researcher will propose times available for the interview and upon agreement of a date and time, another email will provide them with a link to the participant information sheet, consent form and link to the meeting.

10.3 Study 3 Research ethics application

Applicant & Collaborators

Applicant Details

- Applicant Name : Alfredo Ormazabal

- Is applicant applying as a member of staff or a student? : Student

- School / Department : School of Computer Science & Statistics - Computer Science

- Role on the Project : Principal Investigator

- Primary Employer (if not TCD) : ADAPT Centre

- Other affiliations (if applicable) :

- Course (for student applicant only) : PhD

- Part time / full time : Full-Time

- I have read and understood Trinity policy on Good Research Practice : Yes

- I have read and completed the Integrity module : Yes

- I have read and completed the Data Protection Training module within the last 24 months : Yes

Trinity Collaborators

User	Role
Lucy Hederman	Primary Supervisor

Other Collaborators

Name	Email Address	User
Damon Berry	damon.berry@tudublin.ie	Professor

Project Details

Main Project Details

- Title of research :PGHD Trust tool validation study

- Data Collection Start Date : 01/04/2024

- Data Collection End Date : 01/05/2024

- Project End Date : 14/05/2024 12:00:00 AM

- Does the research involve :Humans (or their data)

- Does this Animal research involve :

- Is this AREC research a first application or an amendment :

- Is the research WHOLLY (i) an analysis of statutes/legal provisions AND/OR (ii) legal judgments/cases which have been made public by a judicial process? : No

- Trinity Researchers will have access ONLY to aggregate data or data that otherwise fall outside of the remit of the GDPR. : No

- Could the research have detrimental legal, economic or social consequences for either the participant or their establishments : No

- Intentions of the research: Does the research : None of the above

- State research aim(s) and objective(s), research question or hypothesis : This study aims at validating a tool to help clinicians decide whether to trust or distrust Patient Generated Health Data for clinical decision puproses

- Lay Summary: including background/ rationale/ justification, research approach, study design (exclude detail of measurement instruments and intervention and analysis (if applicable) (Word limit: 250 words) : The use of Patient Generated Health Data (PGHD) has the potential to transform healthcare, but trust in its accuracy is a concern for clinicians. This research proposes developing a validated tool to evaluate the trustworthiness of PGHD. Clinical decision-making is complex, relying on ambiguous information and clinicians

- Identify all countries where data is collected or processed : IE

- Does the project involve :Human participants and /or their data and no biological samples

- Is the project funded : No

Details on Human Participants and their Data

- Does your research involve Mixed Methods : No

- Does the project use data from :Primary sources only

- Will you obtain Consent from participants (or in the case of children or adults at risk of vulnerability from a parent / legal guardian) for their participation and/ or the use of their data? : Yes

- Provide further information :

- Will payment be made to research participants? :No

- Provide further information :

- Is the research Health Research as defined in the Health Research Regulations? : No

- Does the research require a Consent Declaration form as defined by the Health Research Regulations 2018 and amendments 2021? :

- Which of the following best describes the research Secondary Data Source(s)? :

- Could any of the research data directly identify any participant? : No

- Could any of the research data indirectly identify any participant? :No

- Do you process Personal Data for study administration purposes? e.g. contacting individuals : Yes

- If yes please outline how you will store the information, keep it confidential, and destroy it in line with the data retention policy. : OneDrive in encrypted format, on local machine which is encrypted.

- Which of the following best describes the general characteristics of the target population? :Adults currently not at risk of vulnerability

- Do any of the following further describe the characteristics of the target population? :

- Please describe :

- List the inclusion/ exclusion criteria for selection of research participants : Inclusion criteria: Participants will be clinicians who have been exposed to or presented with some form of PGHD in their practice and will have formed an opinion on whether PGHD should be included in their clinical decision process.

Research Sources and Sites

Name	Req
Online Interviews	REQUIRED_NOTOBTAINED

Outline of research methods

Method / Measurement
Interviews

- Does your research use any of the following methods exclusively? : No

- Does the research include an intervention? : No

- Please select which of the following best describes the intervention :

- Other :

- Outline the intervention :

- Outline the method of analysis (Word limit :100 words) : The data from the interviews will be analyzed using grounded theory techniques, more specifically, thematic coding.

- What is the approximate size of the target population? : 37000

- What is the proposed sample size -how many participants are involved in the study? : 15

- What is the justification for the sample size? : 15 is considered minimum appropriate number for qualitative research.

Risk

Risk , benefit, harm to researcher

- What setting/s will be used for data collection : Online

- Other elaborate :

Type	Other Type	Impact	Probabilty	Mitigation

None				

Risk , benefit, harm to site environment or Society

Type	Impact	Probabilty	Mitigation
None			

Risk , benefit, harm to participants

- Do you or any of the research team have any dependant relationship to the participants? : : No

- Detail the role of the researcher/s, the relationship of the researcher/s to the participants normally, and how you will mitigate against coercion of participants to participate in the research or in influencing their responses :

Type	Other Type	Impact	Probabilty	Mitigation
Inconvenience		Low	Low	The interviews will be kept to a minimum length.

Participant Benefits

- Is it foreseeable that participants could potentially reveal information that you have a legal obligation to disclose (e.g. child protection policy, malpractice, etc.) :No

- What information may be disclosed, why, and to whom. :

- Outline any direct benefits to research participants of participation : Participants will not be directly benefited from this research, other than knowing that they participated in the development of a tool to help clinicians.

Conflict of Interest

- Are you aware of any Conflict of Interest from the PI or any collaborator, processor or other person involved in the conduct of the project, that could arise in the course of the project? : No

- Give details of the Conflict of Interest and what mitigation measures are in place :

Consent

Consent

- Do your participants require support to give Consent : No

- How will Assent be obtained and by whom :

- Provide Further Information :

- Do you require Assent or Proxy Consent from participants e.g. because of their vulnerability : No

- Provide Further Information :

- Are you required to have Garda Clearance : No

- What is the time interval between giving information and securing Consent : 7 or More Days

- Provide Further Information :

- Describe how you will inform participants about the use of their Personal Data : Via the participant information sheet and verbally before the interview.

- Describe how participants can withdraw their Consent and/or their data : Participants can withdraw their consent simply emailing the principal researcher. The contact information will be in the participant information sheet.

Sampling & Recruitment

Sampling and Recruitment

- Outline the sampling method : Convenience Sampling

- Describe the time commitment of the participant : 25-30 minutes

- Will the research require/use a gatekeeper :No

- Outline the position/role of the gatekeeper within the organisation :

- Detail the role of the gatekeeper in the research :

- Is there a dependant relationship between the gatekeeper and the participants :

- Outline how this is going to be managed to mitigate against the dependencies :

- Please give a detailed step by step description of how participants will be recruited and append the recruitment material (Word limit: 100 words). : Participants will be invited to participate from a list of clinicians that showed interest in the topic in part interactions. First contact will be made via email.
