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Patient-Generated Health Data in Primary Care for the Treatment of Depression

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Preface

Research, like building a structure, is a process of piecing together many small successes, one upon the other, brick by brick. Even as a young boy, I dreamed of becoming a scientist. Back then, however, I would have preferred to see myself in a white coat at a table with test tubes.

This dissertation reflects the finished structure, but such an undertaking also requires a supporting structure of effort, guidance, and insight from colleagues, mentors, participants, and family who helped shape this work. The road has not always been easy, but each step has reinforced my commitment to contributing something meaningful, brick by brick.

First and foremost, I am deeply grateful to my supervisor, Professor Dr. Dr. h.c. Helmut Krcmar. You enabled me to work on such a fascinating project and always pushed me to new achievements. After my bachelor's thesis defense, you inspired me to continue working on scientific topics, ultimately leading me to pursue this path.

In addition, I would like to thank Dr. Barbara Prommegger for your support and guidance in academia. Your valuable advice, constructive feedback, and constant motivation contributed significantly to this dissertation project's successful completion.

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A big thank you to my family for your unfailing support. Your unconditional love and wisdom have carried me throughout my life and made me the person I am.

Lastly, I would like to thank my wife, Patricia. You are the love of my life and support me in everything I do. Your love, patience, and strength were an anchor for me during this journey. I am eternally grateful to you, as I would never have gotten this far without you.

Garching, October 2024 Philipp Reindl-Spanner

Abstract

Problem Statement: The number of people suffering from depression is steadily increasing. However, the number of therapy spots and specialized doctors for treatment is scarce. To ensure these patients receive timely help and therapy, it is essential to empower general practitioners (GPs) to treat mild and moderate depression effectively, making it necessary to equip GPs with new technologies to support their treatment efforts.

Research Design: This thesis considers how patient-generated health data (PGHD) can support GPs in treating depression. Research question one shows the possibilities and barriers of PGHD in a healthcare setting and how these can be addressed. In research question two, we identify the requirements of doctors and patients for a patient-clinician platform that uses PGHD to treat depression. In research question 3, we address the design elements needed to implement patient-clinician platforms that use PGHD to treat depression so that they can be used in primary care. We have chosen a design science research approach to address all aspects of the research questions.

Results: The results of research question one demonstrate the possibilities and barriers to using PGHD in healthcare. We show these in three dimensions. We discuss the collection of PGHD by patients, the integration of PGHD into clinical workflows, and how the use of PGHD influences the patient-clinician interaction. Finally, we provide an overview of the problems and possibilities and show how these can be overcome or utilized.

Research question 2 demonstrates the requirements for patient-clinician platforms that use PGHD to treat depression. We show which types of PGHD are relevant for use in treating depression from the point of view of GPs and which types are appropriate and acceptable from the point of view of patients. In addition, we discuss how the kinds of PGHD should be presented and how they should be incorporated into clinical workflows. From a patient perspective, we also address how the PGHD should be collected and how feedback on the data should be provided to patients. Based on these requirements, we formulate design guidelines that can be used to design such platforms.

In the third research question, we address how the software artifact can be implemented based on the requirements and design guidelines developed in research question 2. Here, we address the specific design elements and constructs that can be used to implement a patient-clinician platform to support data-based clinical decision-making.

Finally, we summarize our results, synthesize the results of the research questions, and explain how they are interrelated.

Contribution: Due to the interdisciplinary nature of this dissertation, it combines existing information systems (IS) and health management theories. We provide practical implications for developers and healthcare professionals who want to improve the treatment of depression for GPs. We show how PGHD can be integrated into clinical workflows, which data should be considered when creating technologies for depression care, and how shared decision-making can be implemented based on these technologies. In terms of theoretical contribution, this dissertation broadens our understanding of how objective patient data can be used to care for chronic diseases. In addition, we expand existing knowledge on using PGHD in clinical practice.

Limitations: The limitations of this work are three-dimensional. First, we are aware that the scope of this dissertation and the research questions chosen may have led us to overlook essential topics and influences of mental health care in the treatment of depression in the context of GPs. Second, we may not have covered all possible aspects through our choice of research methods. The analysis of the results relies on semi-structured expert interviews and focus groups, focusing on a limited number of organizations and sectors, mainly large organizations. Consequently, the results may not be generalizable. Although various measures were taken to address concerns about validity and reliability, not all results were tested by quantitative experiments or studies, so they may have been influenced by the subjective interpretations of the respondents or the researcher's judgment. Third, our data collection took place primarily in the context of German healthcare. This national influence may have influenced our results.

Future Research: Based on our results and limitations, this work opens several possibilities for future research. This includes a quantitative review of the results based purely on qualitative data collection. Furthermore, it is desirable to evaluate the software artifact we have developed in a clinical study for use in GP practices to treat depression and to adjust based on this, which will enable this technology to be used in GP practices.

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Note on wording: While this dissertation is an individual contribution, the "we" form is used here, as it is common practice in academic writing and enhances readability.

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List of Abbreviations

CCM	Chronic Care Model
EHR	Electronic Health Records
DiGA	Digitale Gesundheitsanwendung
GP	General Practitioner
PCF	Primary Care Facility
PGD	Patient-Generated Data
PGHD	Patient-Generated Health Data
PROs	Patient-Reported Outcomes
SDM	Shared Decision-Making
WHO	World Health Organization

1 Introduction

During the COVID-19 pandemic, mental illnesses increased significantly in the world population. For example, the prevalence of depression in the general population rose to around 25% worldwide (Bueno-Notivol et al., 2021; Ettman et al., 2020). Social isolation, stress, and uncertainty during the pandemic were identified as the main factors influencing the increase in mental health issues (Ganesan et al., 2021). However, even before and after the COVID-19 pandemic, depression is a widespread mental illness that affects a significant proportion of the population. In Germany, an estimated 5.3 million adults aged 18 to 79 suffer from unipolar or persistent depressive disorders every year, which corresponds to 8.2% of the adult population in this age group (Jacobi et al., 2016). Throughout a lifetime, almost one in six adults will suffer from depression (Jacobi et al., 2014). Therefore, the provision of effective treatment for depression is of paramount importance.

General practitioners (GPs) are usually responsible for the initial diagnosis of depression and provide treatment for patients, especially for mild to moderate disorders, which means that they play an essential role in the care of depressed patients (Ferenchick et al., 2019). Given the limited availability of specialized therapy, GPs are often responsible for assessing and initiating treatment for depression (Gensichen et al., 2022). As part of this process, doctors usually use validated screening tools such as the Patient Health Questionnaire (PHQ) (Kroenke & Spitzer, 2002) to make a diagnosis and monitor patient progress during treatment. Patients usually must recall past experiences (e.g., the PHQ-9 questionnaire refers to the past two weeks) and complete questionnaires with their treating clinician (or therapist) during in-person patient-clinician sessions. Despite the recognized validity of these instruments, the reliance on retrospective recall may cause patients to misrepresent or forget important information (Sandstrom et al., 2016). Furthermore, this traditional method of questionnaire administration using pen and paper can be burdensome and disruptive for patients (Depp et al., 2012). In addition to such validated questionnaires, clinical interviews have also established themselves as valuable tools for diagnosing depression (Goldman et al., 1999). These interviews are primarily based on classification systems such as the Diagnostic and Statistical Manual of Mental Disorders (DSM) (American Psychiatric Association & American Psychiatric Association, 2013). In addition, symptom-oriented self-report tests are essential to detect depression, including assessments such as the General Health Questionnaire or the Beck Depression Inventory (Goldman et al., 1999). However, these approaches rely heavily on patient self-report, and symptom severity assessment is subject to clinician judgment (Goldman et al., 1999). Both methods are established for the diagnosis and monitoring of depression in today's care but have the disadvantage that they only provide a subjective insight of the patients into the past. Hence, strategies aimed at enhancing care and diagnosis for patients exhibiting mild to moderate depression symptoms involve optimizing depression care within the context of GPs (Unützer & Park, 2012).

Therefore, strategies are needed to support GPs in the treatment of depression. Patient-Generated Health Data (PGHD) enabled by digital applications can help meaningfully support healthcare professionals in diagnosing and treating depression. One way to support doctors in treating depression is to use PGHD. PGHD refers to health-related information created, recorded, and collected by patients, including medical history, symptoms, lifestyle habits, and other relevant data (Shapiro et al., 2012). PGHD has been used in healthcare for several decades (Ziegler et al., 1989). Historically, these data have been collected for specific diseases using specialized, often hardware-based devices (Cahn et al., 2018), with typical examples of use including managing diabetes and high blood pressure (Shah & Garg, 2015; Turner et al., 2021). For the generation of PGHD, smartphone apps in combination with wearables are most used. The PGHD generated by these applications can detect problems early, monitor progress (e.g., through mental health monitoring systems), and improve communication between patients and GPs (Tiase et al., 2019). Furthermore, PGHD actively engages patients, which makes them take more responsibility, leading to a sense of control and autonomy during the treatment process (Jørgensen & Rendtorff, 2018). To advance the treatment of such conditions, the integration of patient-generated health data (PGHD) into clinical workflows is proving to be one possible way to improve the diagnosis and treatment of depression. Furthermore, new technologies such as smartphones and wearables have extended the scope of personalized treatment to a broader range of conditions, including mental disorders (Burgermaster et al., 2020; Danis, 2016; Hartmann et al., 2019). Consequently, the role of PGHD in clinical contexts is highly relevant and timely. To explore the potential of PGHD in depression treatment, it is crucial to examine its applicability in the treatment of mental disorders and to identify the types of PGHD that patients can collect.

Incorporating PGHD into primary care workflows can be beneficial because encouraging the patient to participate in his treatment can prove crucial (Danis, 2016). Nowadays, PGHD is already being used in isolated cases not only to treat or monitor chronic diseases such as hypertension and diabetes. Through digital applications, new data collection and incorporation methods have been explored to enable the support of patients for a broader range of diseases. In the case of obesity, fitness trackers and smartwatches allow the patient and clinician to track physical activity and support weight management (E. Austin et al., 2020). While some of this data is already being used, PGHD collected through digital apps has the potential to revolutionize primary care. However, mixed opinions exist on its integration (Cohen et al., 2016). Healthcare professionals acknowledge the potential value of PGHD in clinical care, but its usefulness depends on patients collecting data that is clinically relevant and valuable to healthcare professionals. Integrating PGHD into existing clinical infrastructure is preferred by healthcare professionals, but data storage, privacy, and clinic workflow concerns exist (Cohen et al., 2016). Overall, collecting and using PGHD in health care is effective, but more research is needed to determine the best implementation strategies and consider the ethical implications of these strategies (Cohen et al., 2016). PGHD can improve patient-clinician communication and provide additional context to improve clinician awareness of patient health between clinical encounters (Lordon et al., 2020). Patients desire their clinicians to be involved with their PGHD during clinic visits, but clinicians have difficulty accommodating these requests (Lordon et al., 2020). However, healthcare providers are concerned about information overload and must determine the frequency of readings and critical alert parameters. Data can often be irrelevant and taken out of context since context always matters regarding medical data (West et al., 2018).

In addition to its potential to improve disease treatment, PGHD introduces an overlooked facet: active patient involvement and engagement in the treatment process. Medical research, including studies on the chronic care model (CCM) (Wagner et al., 1996), underscores the benefits of involving patients in diagnosing and treating their conditions, promoting self-management skills and tools for symptom monitoring. Encouraging self-monitoring helps mitigate an excessive fixation on negative aspects, which can contribute to patient anxiety (Purtzer & Hermansen-Kobulnicky, 2016). PGHD empowers patients to play a more active role in their treatment and contribute to their well-being. Following the principles of the CCM, clinicians, and patients establish a value co-creation environment to identify the most suitable therapy through SDM facilitated by PGHD (Kim & Lee, 2017).

1.1 Research Questions

This dissertation was inspired by the realization that there is a critical opportunity to improve the diagnosis and treatment of depression in primary care through the use of PGHD. Although depressive disorders are becoming increasingly common and therapy in the context of primary care is often difficult, the inclusion of technical solutions based on PGHD could represent a promising new option in the long term. Integrating PGHD into primary care practice presents healthcare providers with new opportunities, significant challenges, and barriers. These require a thorough understanding of the obstacles and enabling factors to overcome them. There is also an urgent need to investigate the specific needs of clinicians and patients for a platform that allows the effective collection and analysis of treatment-related PGHD.

To address the identified research gaps, this thesis employs an empirically grounded research design that complements the existing literature on the role of PGHD in primary care and mental health treatment with qualitative and quantitative data from patients and healthcare professionals.

Therefore, we aim to answer the following research questions with this dissertation:

RQ1: What are the opportunities and barriers for PGHD in diagnosing and treating primary care patients with depression?

Current research suggests that PGHD, including data from sensors and smartphones, such as physical activity, heart rate, and sleep patterns, can be relevant to mental health (Ng et al., 2019). Integrating PGHD into clinical workflows could potentially enhance the diagnosis and treatment of depression in primary care. However, several barriers need to be overcome to support clinicians in the treatment of these patients effectively (West et al., 2018), and there is a need to explore specific opportunities and challenges associated with treating patients with depression. To successfully integrate PGHD into clinical workflows, solutions must address the goals of both clinicians and patients (Chung et al., 2016). Thus, our objective is to investigate the potential opportunities and barriers to using PGHD in clinical workflows, considering the perspectives of both patients and clinicians.

RQ2: What are clinicians' and patients' requirements for a platform for collecting and analyzing therapy-relevant PGHD?

To improve depression treatment in primary care, supporting patients and clinicians in managing PGHD is crucial. Defining requirements from the perspectives of both groups is essential for implementing IT-based solutions in this area (Chung et al., 2016). Mental health apps and smart sensors can be user-friendly, but issues can still arise in their usage, and data privacy is a top concern (Anderson & Agarwal, 2011). Additionally, it is essential to motivate patients to collect their data (West et al., 2018). Given the interdisciplinary nature of this topic (information systems (IS), healthcare) and the various stakeholders involved, gathering requirements based on users' preferences and fears for an IT-based solution is vital. This process helps identify potential conflicts and challenges early in development, leading to more effective problem-solving and a successful outcome. The platform aims to create an everyday basis for doctors and patients treating depression.

RQ3: What are the design elements and constructs of a patient-clinician platform based on PGHD to support clinical decision-making for depression care in primary care?

With the widespread use of technology, including smartphones and related wearable devices, an abundance of PGHD can be collected. Using RQ2, we identified which forms of PGHD are relevant for clinicians to treat and equally acceptable for patients to collect. In this research question, we focus on the design elements that must be implemented in such a patient-clinician platform so that both sides can use it without any problems. On the one hand, we look at how the data can be easily collected from patients using a smartphone application and how it can be incorporated into the clinical process. On the other hand, we look at how the data can be prepared for the GPs and made available at the workplace for use during treatment. The aim is to implement the relevant design elements in a prototype application and evaluate it with the intended user groups.

1.2 Structure

This dissertation is structured as follows: First, we discuss the theoretical background of this work and present the most important related topics. This section also explains the most important underlying concepts for this work. The following section presents the research methodology based on the work. Here, we present the research methods used in this dissertation and the underlying design science research methodology. Figure 1 provides an overview of the structure and context of the dissertation.

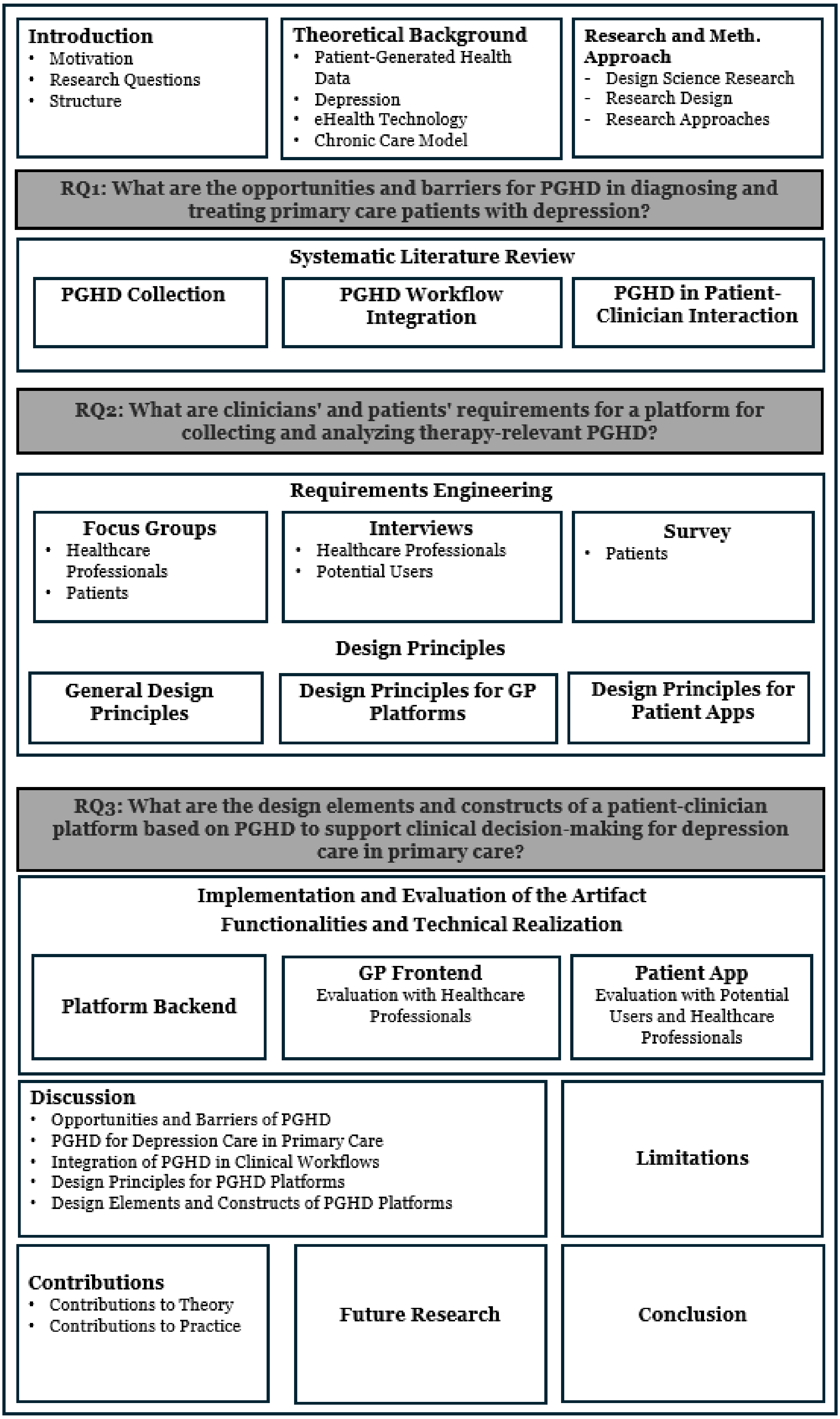
In the following section, we present the process and results of our extensive literature review on the opportunities and obstacles of PGHD in healthcare. We describe our chosen literature review design, which defines the scope, conceptualizes the topic, and presents our search process. We then present our results, which include the methods for capturing PGHD, the integration of PGHD into medical workflows, and the interaction between clinician and patient with PGHD. Finally, we provide an overview of the results and their implications.

In the next chapter, we present the results of our requirements analysis for PGHD platforms in depression care. Here, we address clinicians' requirements and thoroughly examine PGHD types, collection, presentation, and integration into workflows and utilization. We then address patient requirements, similarly addressing PGHD collection, types, communication of PGHD, concerns, and functionalities of PGHD apps. We also discuss the recognized PGHD types and patients' concerns regarding PGHD. Based on the results of doctors and patients, we postulate design principles for the implementation and use of PGHD patient-clinician platforms in depression care, which we divide into general, GP, and patient principles.

The following chapter is dedicated to the practical implementation of our patient-clinician platform, “POKALConnect.” We first present the platform's architecture and stack and then discuss the functionalities and technical aspects of the backend, the clinician front end, and the patient app. We conclude the chapter with an overview of the platform's evaluation by clinicians and potential users.

In the next section, we discuss this study's results. First, we highlight the key findings and present our theoretical and practical contributions. Finally, we identify our study's limitations and suggest avenues for future research.

Figure 1: Structure of Dissertation (own illustration)



RQ1: What are the opportunities and barriers for PGHD in diagnosing and treating primary care patients with depression?

RQ2: What are clinicians' and patients' requirements for a platform for collecting and analyzing therapy-relevant PGHD?

RQ3: What are the design elements and constructs of a patient-clinician platform based on PGHD to support clinical decision-making for depression care in primary care?

2 Background

The following chapter presents the research background, including the theoretical foundations. First, we examine the concept of PGHD and discuss its use in the context of depression and shared decision-making (SDM). We then provide a detailed insight into depression and discuss its diagnosis and treatment. Next, we look at mental health monitoring, which provides critical insights into using mental health apps and eHealth technologies. Following this, we present the concept of Digital Health Apps. Finally, we present the theoretical framework of the CCM.

2.1 Patient-Generated Health Data

Precision healthcare requires collecting and analyzing large amounts of data to capture an individual's unique behavior, lifestyle, genetic characteristics, and environmental context to enable personalized healthcare (Akdis & Ballas, 2016). Due to technological advances, individuals can now easily collect data about themselves anytime and anywhere using smartphones and wearables with portable sensors. This data can also include data about the health of the person collecting it. This introduction of digital tools has led to a significant increase in so-called PGHD (Demiris et al., 2019). PGHD is data that reflects patients' everyday behaviors, including but not limited to physical data, psychological data, behavioral data, and (disease) symptoms (Choe et al., 2018). A general definition of PGHD has been given by Shapiro et al. (2012):. A general definition of PGHD has been given by Shapiro et al. (2012):

„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 directly share or distribute these data to healthcare providers and other stakeholders. In these ways, PGHD complements provider-directed capture and flow of health-related data across the healthcare system. PGHD is not new; many patients record and share information on their health and wellness with care providers. However, the proliferation of Smartphones, remote monitoring devices, application development platforms (e.g., iPhone and iPad apps), and ubiquitous networks are enabling massive growth of PGHD. Increasingly, PGHD will be created, recorded, and shared electronically."

According to this definition, PGHD differs in two ways from data collected in clinical settings and encounters with healthcare providers (Chung & Basch, 2015):

1. Patients, rather than healthcare professionals, record and capture the data.
2. The patient decides how and with whom the data is shared and distributed.

With these distinctions to data collected in clinical settings, PGHD can extend the traditional question-and-answer process during patient-clinician interactions by generating data outside clinical settings. (Lindroth et al., 2018). Moreover, patient data is collected continuously so that no information is lost (Ng et al., 2019). PGHD from patient tracking complements the clinical data collected through testing or in the patient-clinician conversation. This improved insight into the patient's symptoms, life, and personality can help the doctor in several ways (Burgermaster et al., 2020). First, GPs can improve the diagnosis of diseases through deeper insights (Zhang et al., 2019). Second, disease management can be personalized (Cahn et al., 2018), and counseling and treatment planning can be improved by avoiding unnecessary consultations (Burns et al., 2019). This approach can enable better clinical decisions jointly with the patient (Shapiro et al., 2012).

PGHD can be collected in different ways. These approaches to collecting data from patients have advantages and disadvantages. Most data types can be collected actively, passively, or semi-actively.

- Active Data Collection:

  Active data collection involves the deliberate efforts of individuals to record health-related information. Traditionally, active health data recording refers to measuring and documenting the results of these measurements or keeping disease logs (Nittas et al., 2019). Data measured in this traditional way includes blood pressure measurements (Turner et al., 2021) or manual measurement of blood glucose levels (Saudek, 1989; Ziegler et al., 1989). Modern technologies can facilitate these processes by providing applications for these tasks or eliminating the need for active patient participation through automation, allowing this data to be collected passively (blood glucose levels, through automated measurements). Today, data that can be actively collected in the context of PGHD includes manually entering data into mobile health apps, answering questionnaires, and keeping diaries or logs, symptoms, medication intake, or mood (Demiris et al., 2019). In contrast to passive data collection, active data collection relies on patient engagement and self-disclosure and provides insights into patient experiences, perceptions, and outcomes that are not easily captured by automated means (Nittas et al., 2019). This approach offers valuable context to the health data and enriches understanding of health behaviors and outcomes.

- Passive Data Collection:

  Passive collection of PGHD refers to the automatic collection of health-related data without their active contribution or effort. This type of data collection is made possible using modern digital devices. This usually involves wearable devices, smart sensors, and mobile health applications (Nittas et al., 2019). In addition to smartphones, which can be used to track data such as activity through the number of steps taken or, for example, location data via GPS, these include newer sensors such as smartwatches or smart rings (Heintzman & Kleinberg, 2016; Ng et al., 2019). In addition to these devices, which are often marketed as lifestyle products, dedicated medical products that enable even more precise data collection can also be used. These devices can record health data such as physical activity, heart rate, sleep patterns, and blood sugar levels. These advanced technologies facilitate continuous data collection and provide a comprehensive and objective overview of a patient's health status over time, which can be essential for personalized healthcare and disease management.

- Semi-Active Data Collection:

  PGHD's semi-active data collection bridges the gap between active and passive methods by combining automatic data collection and user engagement. This approach could include smart devices or applications that automatically collect health data (e.g., steps taken or heart rate) and then ask users for contextual information or subjective feedback (depression or mood questionnaire) at specific intervals (Nittas et al., 2019). For example, a wearable device can passively record physical activity throughout the day and then ask the user to rate their perceived exertion or mood. This hybrid method enriches quantitative data with qualitative insights and provides a more nuanced view of the patient's health and behavior without requiring constant active input from the user (Nittas et al., 2019).

SDM improves the diagnosis and treatment of many diseases and has other positive aspects in patient therapy. The first important aspect is the patient's active participation in the treatment process. By using PGHD in therapy, patients are more involved in their treatment and can actively contribute to their health. With PGHD-supported therapy, doctors and patients create an environment of shared value creation to find the best therapy based on joint decisions (L. Austin et al., 2020; Kim & Lee, 2017). In addition, the data collected provides valuable insights into the patient's condition and treatment progress. An appropriate data perspective involves integrating relevant types of PGHD into the treatment process. The second important aspect is the patient-clinician relationship (Wu et al., 2020). Considering patients' experiences and optimizing their care promotes better relationships and communication with health teams and supports SDM (Bourke et al., 2020). Finally, another significant benefit is that important therapy decisions supported by PGHD lead to more data-driven clinical decisions. PGHD can facilitate data-based discussions and focused conversations (L. Austin et al., 2020; Bourke et al., 2020; Zhang et al., 2019).

While PGHD offers excellent potential for added value in healthcare, several obstacles may arise. On the one hand, the problem is that patients can collect all kinds of data about themselves by using smartphones. However, not all the data the patient can collect is relevant to the diagnosis or treatment of their condition. As a result, excessive data can flood doctors with information and lead to problems such as technostress (Ye, 2021) or information overload (Rodriguez et al., 2019). On the other hand, the PGHD collection can sometimes burden patients (e.g., paper questionnaires on mental health) (Piras, 2019). Mentally ill patients pose a particular challenge regarding active monitoring because they tend to deviate from guidelines and do not cooperate sufficiently (Porras-Segovia et al., 2020). Therefore, it is crucial to integrate only relevant and easy-to-collect types of PGHD into depression treatment to reduce the burden on patients. Furthermore, these laborious data collection methods may make patients more prone to errors in data collection. This addresses the problem that patients need to be motivated to collect data so that there are no missing measurements or poor patient adherence (West et al., 2018). However, in contrast, less error-prone automated data collection methods often lead to concerns about patient privacy (Ng et al., 2019). Data collected by digital devices often contains large amounts of personal and sensitive information that users want to keep private and over which they want more control over who has access to it (Karim & Talhouk, 2021).

The use of PGHD in clinical settings can be roughly divided into three distinct phases: (1) the collection of PGHD, (2) the integration of PGHD into clinical workflows, and (3) the use of PGHD in patient-clinician interactions (Reindl-Spanner et al., 2022). The first phase includes all aspects associated with the collection of PGHD. This consists of the active and passive data collection by patients and the aggregation of data on the end devices of the collecting patients. The second phase includes all steps to make the data collected in phase one available to doctors and healthcare professionals. This can be done by sending the data to the doctor or by entering the data into electronic health records (EHR). This also includes the analysis and evaluation of the PGHD in a clinical context so that doctors can use it for treatment. The third phase covers all aspects of using PGHD in patient-clinician interactions. This can be during the patient-clinician consultation and outside of office hours when an alarming value triggers a notification to the doctor. As described above, PGHD offers many advantages for diagnosing and treating many diseases. Still, when using PGHD to treat patients, many challenges must be overcome in all three phases of PGHD use (West et al., 2018).

2.1.1 Patient-Generated Health Data in Depression Care

The diagnosis, treatment, and prevention of mental, emotional, and behavioral disorders have traditionally relied on patient data collected in clinical settings (American Psychiatric Association, 2023). However, since the 1960s, the value of patients' perspectives, such as health-related quality of life, has been increasingly recognized. This perspective provides insights into symptoms, side effects of treatments, and the physical, social, and psychological condition of patients (Revicki et al., 2014). Such insights come from patient-reported outcomes (PROs), which are valuable but often limited by standardized questionnaires and not continuously collected (Cella et al., 2015; Wu et al., 2020).

The growing demand for mental healthcare requires more efficient and accurate approaches. Information technology offers scalable solutions and enables more comprehensive data collection through wearable sensors, mobile apps, and smart devices. These technologies allow active and passive data collection for PGHD (Wang et al., 2018). PGHD can be helpful not only in the treatment of physical illnesses but also in the treatment of mental illnesses such as depression (Rosenbloom, 2016).

The use of PGHD in depression care is more complex than in other, primarily physical, conditions for several reasons. First, depression is a multifaceted condition with many different symptoms that impact the emotional, cognitive, and physical aspects of a person's life (Wirz-Justice, 2008). Therefore, various types of PGHD from all three aspects can help manage depression, not only to assist the treating clinician during therapy but also to support the patient in monitoring their illness. This data falls into several categories. On the one hand, “physical health” data provides information about the patient's vital functions. This includes, among other things, heart rate (Ng et al., 2019), blood pressure (Turner et al., 2021), and data about patients' medication (Park et al., 2019). The second group of PGHD for treating depression is behavioral and lifestyle data. This includes, among other things, the patient's activity (Kim et al., 2017) or data on sleep (sleep duration and quality) (Ng et al., 2019; Tsuno et al., 2005). Finally, other relevant data is not health-related but contextual and provides further insights into the patient's environment (Shapiro et al., 2012). This includes, for example, weather data (Brazienė et al., 2022).

Furthermore, when working with depressed patients, the first challenges arise when collecting the data needed to improve the patient's treatment. As described above, the collection methods can be divided into active and passive groups. In contrast, active data collection methods have been around for longer; with the introduction of smartphones, smart sensors, and wearables (e.g., smart watches), there has been a shift towards passive data collection methods. While data collection using active data collection methods was initially rather time-consuming and resource-intensive for patients (Piras, 2019), the modern technologies mentioned above enable the collection of large amounts of data without the active participation of patients. Active monitoring poses a challenge for patients with mental illnesses because the psychiatric population has high rates of non-adherence and lack of cooperation (Porras-Segovia et al., 2020). Furthermore, it is possible that active monitoring causes stress in patients who are already unstable, causing them to drop out of follow-up (Porras-Segovia et al., 2020; Wu et al., 2020). Nevertheless, active monitoring methods through mental health questionnaires (Nittas et al., 2019) or active patient involvement (E. Austin et al., 2020) still have their place. On the other hand, passive monitoring involves collecting data from the devices' native sensors without user intervention. Although current passive sensing methods do not provide direct insight into mental states such as anxiety or mood, other parameters relevant to physical and psychological health can be tracked (Jayakody et al., 2014; Ng et al., 2019). These include smartphone usage patterns, mobility, physical activity, sleep quality, and sleep habits (Borghouts et al., 2021). In addition to the ability to collect patient data almost continuously, it reduces memory errors and provides a more valid ecological environment (Porras-Segovia et al., 2020).

PGHD offers significant opportunities for adoption in depression treatment. However, there is currently a lack of research on the use of PGHD in depression treatment. Therefore, PGHD offers opportunities to improve treatment decisions by systematically tracking symptoms and patients. Further studies suggest that patients collect PGHD, which is then discussed in counseling sessions. This procedure has improved therapeutic feedback (Meng et al., 2018). Other ideas for using PGHD in depression treatment include using the data collected as predictors of depression (Hallgren et al., 2017; Saeb et al., 2015). In this context, the collected data is used to create comparative values based on established and validated questionnaires, which are then used to predict clinical risks. Furthermore, this prediction has the potential to identify patients who are not responding well to treatment or who are not engaged, leading to timely clinical intervention when needed (Hallgren et al., 2017).

2.1.2 Shared Decision-Making

The integration of PGHD into psychiatric care and, in our specific case, into depression treatment opens new possibilities for patient-clinician communication, such as SDM.

SDM has been defined as an approach in which clinicians and patients share the best available evidence when making decisions. Patients are supported in exploring options to arrive at informed preferences (Elwyn et al., 2010). This definition encompasses a typical communication process in SDM: The patient, treating clinician, or healthcare professional contributes to medical decision-making in a collaborative process. It is crucial that patients actively contribute to and are included in the decision-making process (Resnicow et al., 2022).

For SDM to be effective, clear and transparent, communication is needed between patients and the healthcare provider, and patients must be fully and impartially informed about their options and the pros and cons (Elwyn et al., 2012). The various forms of treatment and therapy can then be discussed on this basis. This step then helps evaluate each option's consequences based on the patient's lifestyle and values (Légaré & Witteman, 2013). Finally, after this evaluation, a decision can be made about the form of therapy. Finally, after therapy has begun, SDM can be used to make further adjustments during treatment and to reevaluate the chosen form of therapy. This re-evaluation is then based on new information, changes in the patient's life, or changes in the patient's condition. This makes iterative, ongoing re-evaluation of the situation essential (Resnicow et al., 2022).

Although SDM offers many advantages, there are some challenges to be overcome in implementing it. The first problem arises from patients' medical understanding. Although using plain language makes it possible to involve patients in the best possible way, difficulties can still occur when communicating treatment options (Légaré et al., 2008). Other challenges include that healthcare professionals providing the service are not sufficiently trained to provide patients with the necessary information understandably. Furthermore, implementing SDM is significantly more complex than traditional methods of communication and decision-making. This results in a greater time commitment for the healthcare professional, which must be systemically compensated to create a supportive environment for SDM (Légaré et al., 2008).

However, the clear advantages of implementing SDM balance out these obstacles. In general, the active participation of patients has led to better patient treatment outcomes. In mental health, SDM has been shown to influence treatment positively (Joosten et al., 2008). Likewise, studies with depressed patients in primary care treatment show that patients highly value collaboration with doctors, especially when it comes to sharing information, but also want to have control over the decision during the decision-making process. This suggests that a safe and trusting environment for SDM can, therefore, provide a basis for better treatment of the stigmatized disease of depression in particular (Matthews et al., 2021).

2.2 **Depression**

Depression is a common and severe mood disorder that negatively impacts feelings, thoughts, and actions, leading to deep sadness or a lack of interest in activities that used to bring pleasure before the onset of the disorder. This mental illness results in various emotional and physical problems and can affect performance in both personal and professional settings. Typically, depression is treated with a combination of medication and therapy. However, issues often arise, such as frequent hospital readmissions and long periods of suffering, which can also end in suicide. Even milder forms of depression are usually associated with a significantly reduced quality of life, making everyday tasks more difficult, promoting pessimistic thought patterns, and increasing the difficulty of coping with mental and physical health problems (Sartorius, 2001).

2.2.1 **Diagnosis**

Nowadays, depression is primarily diagnosed by clinical assessment. This includes detailed interviews, patient-clinician discussions, and evaluation questionnaires to assess mental state (Goldman et al., 1999). Depression is distinct from normal sadness because of its recurrent pattern and the significant impairment it causes. The ICD-10-GM (World Health Organization, 2004) outlines the diagnosis of a depressive episode with three main symptoms (in addition to the symptoms described using ICD-10, the literature on depression is pervasive. Treatment guidelines, for example, can be found at AWMF (2022). Further overviews on the topic in Hautzinger (1993), Hautzinger (2023)and Wolfersdorf (2008)):

1. **Anhedonia**

   Anhedonia is the loss of interest or pleasure in everyday activities. This is characterized by a reduced ability to feel joy, motivation, and emotional response. It is considered an indicator of an increased risk of suicide and is associated with lower adherence to treatment. This condition is not only a core symptom of depression but also occurs in several other psychiatric disorders, including schizophrenia and bipolar disorder, indicating its wide-ranging impact on mental health. In addition, anhedonia can manifest itself socially and physically, affecting interpersonal relationships and daily functioning. Understanding and treating anhedonia is critical to improving treatment outcomes for depression and enhancing the quality of life for those affected (Craske et al., 2016; Kennedy, 2008; Loas, 1996).

2. **Depressed Mood**

   This symptom is characterized by a persistent depressed mood that generally does not adapt to changing circumstances and can vary in intensity throughout the day. It may be accompanied by irritability, increased alcohol consumption, dramatic behavior, increased phobias, obsessive-compulsive symptoms, and hypochondriacal traits that obscure mood swings. In addition, sufferers may experience sleep disturbances, changes in appetite, and significant weight fluctuations, further complicating the clinical picture. Cognitive impairments such as difficulty concentrating, making decisions, and memory difficulties are common and make everyday challenges more difficult. These multi-layered symptoms underscore the complexity of depressive disorders and require comprehensive and individualized treatment approaches to address the wide range of manifestations effectively (Wirz-Justice, 2008).

3. **Reduced Energy Levels**

   Patients often experience increased fatigue and a limited ability to perform everyday physical activities. Around 73% of patients with depression report exhaustion that occurs after the slightest exertion (Tylee et al., 1999).

Besides the primary symptoms of depression, there are also secondary symptoms. Secondary symptoms are additional symptoms that may arise because of the primary symptoms, including changes in social behavior, altered pain perception, and cognitive impairments, which may not be directly linked to depression's core diagnostic criteria but can significantly affect an individual's quality of life. Additional symptoms include:

1. Diminished concentration and attentiveness
2. Lowered self-esteem and feelings of worthlessness
3. Excessive guilt or self-reproach
4. Pessimistic outlook on the future
5. Suicidal ideation and behaviors, which are significant in psychiatric comorbidities like major depressive disorder (MDD), are notable causes of preventable death in mental health conditions (Orsolini et al., 2020).
6. Sleep disturbances, including insomnia or hypersomnia, often signal the onset of a depressive episode (Nutt et al., 2008).
7. Changes in appetite or weight, with individuals experiencing weight fluctuations unrelated to dieting due to significant changes in appetite (Kennedy, 2008).

The main symptoms of depression are presented in Table 1, additional symptoms in Table 2.

Table 1: Main Symptoms of Depression (World Health Organization, 2004)

Main symptoms (according to ICD-10)	
Symptoms	**Characteristics**
The main symptom is depressive/depressed mood (deep sadness) (according to ICD-10)	• Dejection, despair, insensitivity to positive and negative events, rapid irritability, feeling of being overwhelmed • Often in combination with feelings of anxiety/fear of the future and uncertainty • Change in mood from day to day regardless of life circumstances • Characteristic daily fluctuations, e.g., pronounced "morning low"
Lack of interest/joy	• No interest in and commitment to everyday activities (job, household) • No interest in and enjoyment of previous hobbies and leisure activities • Decline in the level of activity
Reduced drive/loss of energy/fatigue	• Neglect of and rapid exhaustion from simple everyday activities (household, personal hygiene) • No interest in social contacts • Social withdrawal

Table 2: Additional Symptoms of Depression (World Health Organization, 2004)

Additional symptoms (according to ICD-10)	
Symptoms	**Characteristics**
Reduced concentration and attention	• Restriction in the ability to think • Difficulty making decisions or lack of decisions • Recurring brooding, self-doubt and anxiety
Decreased self-esteem/self-confidence, feelings of guilt	• Loss of confidence in one's abilities, e.g., at work, in social contacts, in leisure activities, or in household management • Self-reproach • Unrealistic/exaggerated feelings of guilt in a professional or social context
Psychomotor agitation or inhibition	• Inner restlessness, a feeling of being driven • Fidgeting, urge to speak • Taciturnity, quiet, monotonous speech, slow speech • Delayed reactions, slow movements, reduced facial expressions
Sleeping disorders	• Insomnia • Difficulty sleeping through the night, waking early, and falling asleep • Less frequently hypersomnia: increased sleep during the day, prolonged sleep at night
Appetite disorders	• The feeling of having to force yourself to eat • Significant weight loss
Suicidal thoughts/acts	• Wish to die quickly from a terminal illness or accident • Concrete considerations for actively ending one's own life • Partly in connection with delusional symptoms and hallucinations, e.g., the conviction that only through one's death can the family be saved or an outstanding debt compensated for

The ICD-10 (World Health Organization, 2004) categorizes depressive episodes into three severity levels: mild, moderate, and severe. For diagnosis, symptoms must last at least two weeks. Distinguishing among these levels demands intricate clinical evaluation. The Hamilton Depression Rating Scale (HAMD) is often utilized to appraise depression's severity, focusing on the quantity, type, and intensity of current symptoms (Hamilton, 1960).

1. Mild Depressive Episode: Diagnosis necessitates the presence of at least two core symptoms. These symptoms are generally mild and may slightly disrupt the individual's daily activities and routines, causing stress.

2. Moderate Depressive Episode: At least four symptoms must be evident for a moderate diagnosis. Symptoms of moderate intensity considerably impair daily functioning and activities, including work.

3. Severe Depressive Episode: This level is marked by numerous symptoms, some of which are intensely distressing, notably impacting self-esteem, and may include suicidal ideation and behaviors. Functionality may be profoundly hindered. Severe episodes can manifest without or with psychotic symptoms, the latter including hallucinations, delusions, or significant psychomotor changes, severely affecting social engagement.

Depression often follows a recurrent pattern, with individuals experiencing episodic symptoms interspersed with periods of remission.

2.2.2 **Treatment**

Depression treatment predominantly involves outpatient care, including the administration of antidepressants, antipsychotics, mood stabilizers, anxiolytics, or psychotherapy (Olfson et al., 2016). Care is typically provided by professionals such as psychiatrists, neurologists, GPs, medically or psychologically trained psychotherapists, and other human service workers, often with expertise in specific syndromes (Wittchen et al., 2011). Notably, GPs are the primary care providers for most patients with depression, who are less likely than those seen by psychotherapists or psychologists to have been formally diagnosed with depression or to be prescribed antidepressants (Olfson et al., 2016).

Recent studies highlight the significant benefits of self-monitoring daily activities, including physical exercise, sleep habits, and mood, in managing depression (Porras-Segovia et al., 2020). Such practices enhance patient experiences, facilitate early intervention by healthcare teams, improve health outcomes, foster better communication between patients and clinicians, and empower patients (Rajabiyazdi et al., 2017; Wu et al., 2020). Typically, healthcare providers rely on observing patient behavior and interactions during visits, patient self-reports, and survey scores (Ng et al., 2019). Recent findings suggest that patient-generated health data constitutes a valuable fourth data stream, enriching the treatment process with information gathered outside the clinical environment (Ng et al., 2019).

2.2.3 **Primary Care Facilities**

While the concept of Primary Care Facilities (PCFs) differs from country to country, general concepts are similar or the same (Europe, 2002). PCFs, therefore, play an essential role in the healthcare system and have unique characteristics. First, PCFs are confronted with a variety of different diseases for every age group. GPs treat chronic illnesses and acute emergencies daily (Europe, 2002). A unique approach of GPs is that the patient-centered approach common in PCFs means that the symptoms and the patient's holistic circumstances are considered in treatment. These include, for example, the patient's social circumstances (Europe, 2002). Primary care is usually the first point of contact for individuals seeking healthcare services. These facilities are easily accessible to their community, ensuring timely and convenient healthcare access. In this context, these facilities often serve as gatekeepers, helping to manage and prioritize access to specialized care and other healthcare services based on patient needs (Europe, 2002). However, in contrast to specialized care, primary care providers are often in a favorable position to build long-term relationships with their patients, allowing them to understand better individual health needs, family dynamics, and community factors that may impact health. Therefore, GPs may care for individuals over extended periods, managing numerous acute illnesses and supervising chronic conditions. In that context, GPs often monitor and accompany long-term therapy (Europe, 2002).

2.3 eHealth Technology

Electronic health services (eHealth) use state-of-the-art information technology (IT) to support the treatment and care of patients. One aspect of eHealth is mobile health (mHealth), which includes medical practices supported by mobile devices such as smartphones, patient monitoring devices, or other wireless devices (e.g., wearables) (Medina & Isomursu, 2023). mHealth is already widely used in medicine, for example, in cancer patients (Gong et al., 2023), and its importance has been further emphasized by the COVID-19 pandemic when personal visits to doctors were restricted as part of contact restrictions. The use of technology in mHealth is also growing in importance (Aboye et al., 2023), supported by employers who promote using such devices through wellness programs (Gorm, 2017). In 2023, Germany had about 68.5 million smartphone users and 6.6 million users of wearables such as fitness trackers or smartwatches (Statista, 2020, 2024).

2.3.1 Mental Health Apps

Mental health apps are digital tools typically installed on smartphones designed to support mental health management and care by facilitating symptom tracking, cognitive exercises, stress relief, and mood monitoring. They can range from self-management aids for users monitoring their mental health to supplemental support in clinical care. They often integrate features such as behavioral interventions, reminders, and even passive data collection for mood or anxiety monitoring (American Psychiatric Association, 2024a, 2024b; National Institute of Mental Health, 2021).

Mental health apps designed for smartphones or tablets aim to improve mental health by increasing the availability and quality of mental health treatment (Chandrashekar, 2018; National Institute of Mental Health, 2021). These apps offer support throughout the care process, including immediate crisis intervention, prevention, diagnosis, primary treatment, and post-treatment management (Chandrashekar, 2018). As of 2019, over 10,000 mental health apps are available across various app stores. The most popularly downloaded mental health apps focus on brain training, meditation, mindfulness, relaxation, peer support services, mood-tracking tools, and therapy (American Psychological Association, 2019). Generally, mental health apps offer five types of services, some apps offering multiple services simultaneously (American Psychological Association, 2019; National Institute of Mental Health, 2021):

1. Information or psychoeducation: These apps aim to increase mental health literacy by promoting knowledge about mental disorders, their recognition, management, and prevention. They target individuals with mental disorders and society as a whole (Martinengo et al., 2022).

2. Therapy or treatment: These apps encourage users to learn coping skills or develop new ways of thinking. They often incorporate engaging features like educational videos and storytelling to motivate users (Lister et al., 2014; National Institute of Mental Health, 2021).

3. Symptom or mood monitoring: These apps provide features for users to track their progress, offering an overview of their current health status and helping them identify

deviations from their typical patterns. Some apps may utilize additional devices to track physiological parameters like heart rate and blood pressure (Caldeira et al., 2017; National Institute of Mental Health, 2021).

4. Self-assessment and management: These apps assist users in collecting their health data and providing feedback afterward. Standard features include medication reminders and tools for managing stress or sleep problems (National Institute of Mental Health, 2021).
5. Community or peer support: These apps facilitate connections with peers or direct users to trained healthcare providers (National Institute of Mental Health, 2021).

Mental health apps can help bridge the treatment gap in mental healthcare, as healthcare systems often struggle to adequately meet the needs of all individuals with mental disorders (World Health Organization, 2022). These apps offer cost-effective and easily scalable solutions, reaching many people. They can complement traditional therapy, reinforce newly learned skills, and provide additional support. The availability and convenience of using mental health apps anywhere make them valuable intervention tools that are always accessible. Furthermore, these apps allow individuals with mental disorders to seek treatment anonymously and serve as an introduction to mental healthcare without involving others (Chandrashekar, 2018; National Institute of Mental Health, 2021). With a wide range of mental health apps available (American Psychological Association, 2019), users can find apps that align with their specific needs and interests, ensuring sustained engagement over time (Chandrashekar, 2018; National Institute of Mental Health, 2021; Torous et al., 2018).

However, many mental health apps offer limited empirical evidence of effectiveness and may not involve healthcare professionals during their development. Some apps even provide potentially harmful or dangerous advice (National Institute of Mental Health, 2021; Schueller et al., 2018; Torous et al., 2018). The sheer number of available mental health apps poses a challenge in finding reliable options, as online app reviews often do not provide information on clinical usefulness or utility. App rating guidelines and platforms can assist users in identifying effective mental health apps more efficiently (Schueller et al., 2018; Torous et al., 2018). Moreover, user concerns regarding privacy regulation hinder the widespread adoption of mental health apps, as they may be reluctant to share sensitive health data. However, people recognize the potential benefits of these apps and are willing to use them more if developers address their privacy concerns appropriately (Kern et al., 2018; Koulouri et al., 2022).

Mental health apps targeted at depression have shown potential for reducing depressive symptoms. Standard features include cognitive-behavioral therapy (CBT), mindfulness training, mood monitoring, and cognitive skills training. However, these apps may not completely alleviate all symptoms of depression and often do not address post-treatment or residual symptoms. They are most suitable for individuals with mild to moderate depression (Chandrashekar, 2018). Table 3 shows an excerpt of current mental health apps from the DiGA directory.

Table 3: Mental Health Apps in the DiGA-Verzeichnis – Overview (Bundesinstitut für Arzneimittel und Medizinprodukte, 2024)

Name	Applicable to	Platforms
Deprexis	• Mild depressive episode • Moderate depressive episode • Severe depressive episode without psychotic symptoms	• Web application
edupression	• Mild depressive episode • Moderate depressive episode • Recurrent depressive disorder, currently mild episode • Recurrent depressive disorder, currently moderate episode	• Web application
elona therapy Depression	• Mild depressive episode • Moderate depressive episode • Severe depressive episode without psychotic symptoms	• Smartphone app • Web application
Hello Better Schlafen	• Non-organic insomnia • Difficulty falling asleep and staying asleep	• Smartphone app • Web application
Invirto- Die Therapie gegen Angst	• Agoraphobia: Without indication of a panic disorder • Agoraphobia: With panic disorder • Social phobias • Panic disorder [episodic paroxysmal anxiety]	• Smartphone app
Mindable: Panikstörung und Agoraphobie	• Agoraphobia,Panic disorder [episodic paroxysmal anxiety]	• Smartphone app
MindDoc Auf Rezept	• Mild depressive episode, Moderate depressive episode • Recurrent depressive disorder, currently mild episode • Recurrent depressive disorder, currently moderate episode	• Smartphone app
My7steps App	• Mild depressive episode • Moderate depressive episode • Recurrent depressive disorder • currently mild episode • Recurrent depressive disorder, currently moderate episode	• Smartphone app

NeuroNation MED	- Mild cognitive impairment	- Smartphone app
Novego: Ängste überwinden	- Agoraphobia,Social phobias - Specific (isolated) phobias - Panic disorder [episodic paroxysmal anxiety]	- Web application
Novego: Depressionen bewältigen	- Mild depressive episode - Moderate depressive episode - Severe depressive episode without psychotic symptoms	- Web application
Selfapys Online-Kurs bei Binge-Eating-Störung	- Binge eating with other mental disorders - Other eating disorders - Eating disorder	- Smartphone app - Web application
Selfapys Online-Kurs bei Bulimia Nervosa	- Bulimia nervosa - Atypical bulimia nervosa	- Smartphone app - Web application
Selfapys Online-Kurs bei chronischen Schmerzen	- Persistent somatoform pain disorder - Chronic pain disorder with somatic and psychological factors - Back pain	- Smartphone app - Web application
velibra	- Agoraphobia: With panic disorder - Social phobias - Panic disorder [episodic paroxysmal anxiety] - Generalized anxiety disorder	- Web application
vorvida	- Mental and behavioral disorders caused by alcohol: Harmful use - Mental and behavioral disorders caused by alcohol: dependence syndrome	- Web application
HelloBetter Panik	- Agoraphobia: With panic disorder - Panic disorder [episodic paroxysmal anxiety]	- Smartphone app - Web application

2.3.2 **Smartphone**

Smartphones are equipped with modern technologies and features such as cameras, microphones, and Bluetooth, but especially with sensors such as accelerometers, gyroscopes, and GPS, which collect large amounts of raw data that can be used by various applications (Tiglao et al., 2021). These measurements usually occur in the background, so the user does not have to provide any active input. This increases user-friendliness, as no manual software operation is required (Becker et al., 2016). This is particularly beneficial for older people. Because of these features, smartphones are among the most cost-effective and versatile medical data collection systems (Tiase et al., 2020). Continuous improvements in functionality and technology and falling prices make the smartphone an indispensable system for medical monitoring and communication (Trifan et al., 2019).

2.3.3 **mHealth Apps**

Mobile health, or more generally mHealth, has been defined as “the use of wireless communication devices to support public health and clinical practice” (Barton, 2012). mHealth apps are defined as applications (rather than web-based tools) on portable devices (including smartphones and tablets) (Patel & Thind, 2020).

Due to the large user base of smartphones, more and more apps have been developed over the years to address health issues such as mental illness (Bakker et al., 2016). With about 53,000 mHealth (mobile health) apps in the iOS Appstore (Statista, 2021a) and about the same number in the Google Play store (Statista, 2021b), many people generate large amounts of personal health data. According to an international study, almost half of all adults were already using a health app in 2018, corresponding to a tripling number of users compared to 2014 (Huckvale et al., 2019).

2.3.4 **Digital Health Applications (DiGAs)**

Since their introduction on December 19, 2019, digital health applications[1] (DiGAs) have offered a unique opportunity for patients. DiGA refers to products designed, for example, to detect or alleviate illnesses and support making a diagnosis, and they are based primarily on digital technology. These are low-risk digital medical devices that directly benefit you as a patient. DiGA includes, among other things, apps or browser-based applications. A DiGA can be used by the patient alone or by the doctor and patient together. DiGA can be combined with other devices such as heart rate monitors, DiGA, or software. If this is the case, you can see in the directory whether these additional components can also be reimbursed by your health insurance company or what other costs their use may entail. The DiGA must offer your situation a “positive care effect” through its technology. The BfArM determines whether this is the case in an evaluation procedure (Bundesamt für Arzneimittel und Medizinprodukte, 2024).

2.3.5 **Wearables**

In consumer health there are now many non-implantable wearable devices for use in consumer health and medical research. These sensors fall into three categories: mechanical (e.g., movement), physiological, and biochemical. These wearables include headbands, wristbands, chest straps, smart rings, smart watches, and even smart glasses (Dunn et al., 2018). As the use and availability of devices and their accuracy have increased, researchers are also increasingly showing great interest in wearables (Roos & Slavich, 2023).

2.3.6 **Information Overload in Clinical Settings**

Overload refers to an individual's evaluation and perception of being overwhelmed by an excessive number of objects or people beyond their capacity to manage (Saegert, 1973). In the

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[1] German: **Di**gitale **G**esundheits **A**pps

domain of information, this concept has been adopted to describe the perception of dealing with an excessive amount of stimuli stemming from being exposed to excessive amounts of data (Chen et al., 2009; O'Reilly III, 1980). Information overload manifests in various forms, the most prominent being the overwhelming introduction of communications, mainly through emails, phone calls, and constant alerts from computers, mobile devices, and other electronic gadgets. The impact of information overload on individuals and organizations is significant, resulting in direct loss of productive time, reduced mental capacity due to continuous interruptions, diminished opportunities for quality thinking and concentration, breakdown of organizational processes, and reduced quality of life for workers and their families (Zeldes & Baum, 2011).

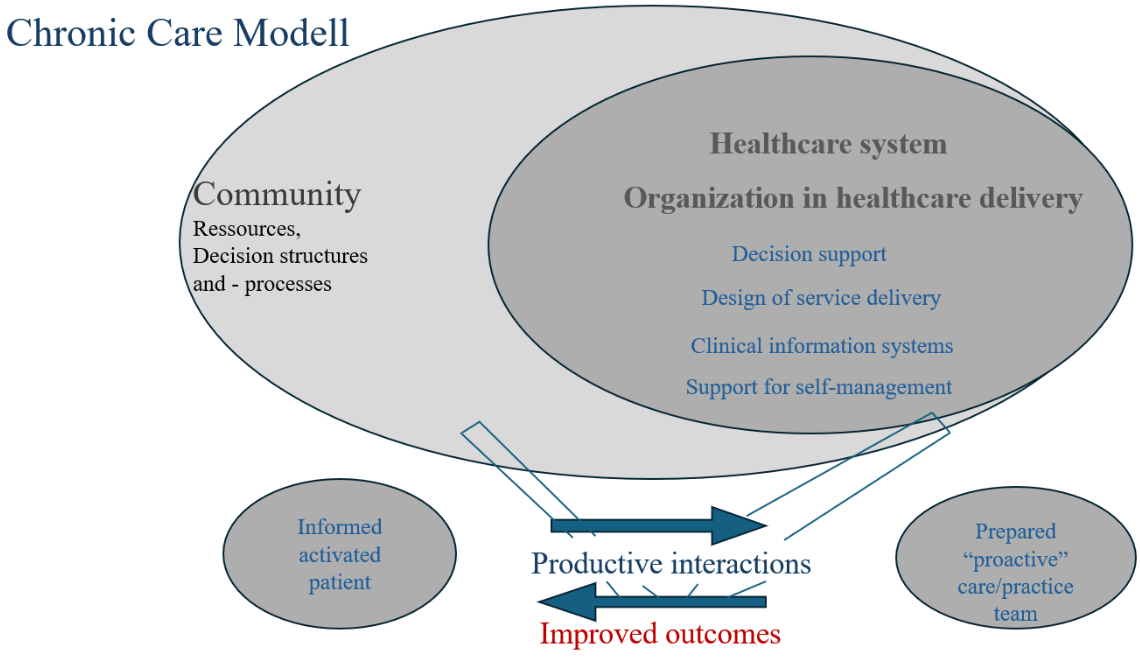
In clinical practice, information overload is characterized by excessive data, including patient charts, medical history, physical examination findings, and other sources (Beasley et al., 2011). This abundance of information hinders healthcare providers from formulating accurate diagnoses and treatment plans. Several contributing factors to this information overload are copying and pasting into patient charts, reliance on templates, excessive alerts, and including data primarily for billing purposes rather than clinical care (Beasley et al., 2011; Singh et al., 2013). Due to this abundance of data necessary for each patient, the potential to disrupt patient care and patient-clinician interaction grows. Extracting clinically relevant information efficiently from digital healthcare interfaces poses a challenge for clinicians (Ratwani et al., 2018; Wright et al., 2016). This heightened data exposure imposed on clinicians increases the likelihood of clinical errors, jeopardizing patient safety (Wright et al., 2016). Therefore, it becomes increasingly critical to deliver clinicians with the most relevant PGHD only to avoid potential information overload.

Nevertheless, various studies have established a connection between the utilization of PGHD and the issue of information overload among healthcare professionals. The information and potential alerts associated with PGHD significantly contribute to this concern (Ye, 2021). Clinicians express apprehension that integrating PGHD into patient treatment might heighten the likelihood of crucial information being overlooked due to an overwhelming display of excessive data.

2.4 **Chronic Care Modell**

There are various theoretical models for the treatment of chronic diseases. Whether these diseases are diagnosed individually or the patient's illness is accompanied by so-called multimorbidity frequently contributes to this context. Multimorbidity is the simultaneous presence of two or more chronic diseases or conditions in an individual. It is a growing health problem, especially in aging societies, and challenges the healthcare system as it often requires more complex medical treatments and intensive care (Fortin et al., 2005). Multimorbidity can significantly affect the quality of life of those affected and requires a holistic approach to treatment that considers both patients' medical and social needs. Multimorbidity varies by definition and affects around one-third of adults globally and more than half of all adults with a chronic condition. It is more strongly associated with age and varies by gender, educational level, and socioeconomic status (Skou et al., 2022). Mental illness often accompanies other diseases, so the treating clinician must usually deal with a complex clinical picture when diagnosing these disorders. The patient's psychological complaints are often accompanied by somatic illnesses, which can frequently "hide" the mental illnesses. For these reasons, we have chosen the Chronic Care Model (CCM) as the theoretical model for this dissertation. Based on collaborative care, this model is an evidence-based approach to structuring the clinical care of illnesses, thus ensuring a coordinated, patient-centered, and anticipatory course of treatment. The CCM (Wagner et al., 1996) is a theoretical framework that provides high-quality care to individuals with chronic conditions, such as diabetes and heart disease. The CCM highlights the advantage of involving patients in diagnosing and treating their diseases and thus supports patients' self-management. The CCM emphasizes a proactive, patient-centered approach to care delivered through a coordinated, integrated healthcare system. Although the model encompasses different critical elements, it underscores the significance of active patient participation in their treatment to enhance effectiveness. Educating patients to learn skills and tools to monitor their symptoms encourages self-monitoring. This prevents an excessive focus on the negative, which may contribute to the patient's anxiety (Purtzer & Hermansen-Kobulnicky, 2016). Figure 2 provides an overview of the CCM.

Figure 2: Chronic Care Modell (Gensichen et al., 2006)



3 Research Methodology

In this section, we describe the research methodology used in this thesis. First, we explain the theory of the design science approach. We then rigorously apply the design science methodology to the construction of our patient-clinician platform, as illustrated in the derived research design of this thesis. Finally, we demonstrate the design theory of the developed artifact and its potential use in IS research.

3.1 Design Science Research

IS research studies artifacts as opposed to natural phenomena. These include human-made creations such as organizations and IS (March & Smith, 1995). Researchers can observe and analyze artifacts in IS research or design and create them (March & Smith, 1995). The goal of theories in IS research is to understand and describe reality (Hevner et al., 2004; March & Smith, 1995). We, therefore, distinguish between natural science, which is concerned with explaining how and why things are (March & Smith, 1995), and design science, which, on the other hand, is concerned with how things should be, with developing artifacts to achieve goals (Hevner et al., 2004; March & Smith, 1995; Simon, 2019). While natural science seeks to understand reality, design science aims to create things that serve human purposes. It is technology-oriented (March & Smith, 1995).

Hevner et al. (2004) introduced a conceptual research framework for IS design, emphasizing the significant influence of the intended environment and a knowledge base on the design process. These factors serve as direct research constraints and shape the research environment of people, organizations, and technology. Each component has its own goals and objectives, defines problems, and influences the development of new IS.

This dissertation uses the Design Science Research Methodology (DSR) of Hevner et al. (2004). DSR is a widely used framework in design science that integrates principles and practices from the relevant literature (Peffers et al., 2007). Building on the technology-oriented research framework of March and Smith (1995), which categorizes research results into constructs, models, methods, and instantiations, Hevner et al. (2004) presented a framework and guidelines for conducting, evaluating, and presenting design science research in the field of IS. According to Hevner et al. (2004), “design science creates and evaluates information technology artifacts intended to solve identified organizational problems”. These artifacts include products, processes, constructs, design principles, models, methods, technological rules, and instantiations (Gregor & Hevner, 2013). DSR has three primary goals. First, it aims to align with previous literature and provide a nominal process model and a mental model for representing and evaluating design science research in IS. This structured approach ensures a comprehensive and rigorous method for conducting design science research in IS. In the following, we describe these guidelines and how we applied them in this project:

- **Guideline 1 - Design as an Artifact: Design-science research must produce a viable artifact such as a construct, a model, a method, or an instantiation.**

  Design science research aims to create a valuable artifact in the form of a construct, model, method, or instantiation. By using a design science methodology, an IT artifact is created. Variations of these artifacts can occur in different ways, e.g., in applications (initially referred to as “instantiation”), constructs, models, methods, or design guidelines used in the field. Innovative technological solutions address specific problems through an IT artifact, presented as a visible result in design science research. In the course, the artifact is provided by the patient-clinician platform. This prototype is a new type of data source to help clinicians treat depression, as it offers a high level of user-friendliness and addresses shortcomings identified in the literature. Patients will also have access to a prototype in the system that makes it easier to record data and improves the data quality while also focusing on user-friendliness and data protection. To ensure that the final artifact meets the specified requirements and effectively promotes the desired learning process, the artifact undergoes a development process that consists of repeating various phases, such as design, testing, and optimization.

- **Guideline 2 - Problem Relevance: Design-science research aims to develop technology-based solutions to important and relevant business problems.**

  Design Science research aims to identify solutions to fundamental problems based on technology. To demonstrate the purpose of the study and its potential impact, it is essential to ensure the essence of the problem as it confirms it. In this thesis, the problem is presented in many ways. A central point of these problems in which action is needed is the care of depressive patients, especially in general practice. Innovative technical solutions could overcome obstacles, and the work could be meaningfully supported. According to a thorough needs assessment, doctors and patients are confronted with inefficiency and challenges in equal measure. To ensure better results and efficient treatment, research aims to improve the effectiveness and efficiency of depression treatment.

- **Guideline 3 - Design Evaluation: A design artifact's utility, quality, and efficacy must be rigorously demonstrated through well-executed evaluation methods.**

  The evaluation must be used to prove the effectiveness of the artifact since the evaluation is empirical evidence and, thus, an essential part of the design research. Various evaluation methods must be used during the relevance cycles to obtain comprehensive feedback and collect performance data. In each research phase, hypotheses are tested with qualitative and quantitative research methods. Pilot studies enable us to identify and confirm areas for improvement through evaluation methods so that the platform fully meets the needs and expectations of users.

- **Guideline 4 - Research Contributions: Effective design-science research must provide transparent and verifiable contributions to design artifacts, foundations, and/or methodologies.**

Effective design research provides clear and understandable contributions essential for further developing knowledge and practice in artifacts, basic research, and research methods. In the further course, the guideline is followed up, and the result of implementing a patient-clinician platform is realizable, which can thus be deployed. The subsequent literature research summarizes the current problems and possibilities in the field of PGHD, provides a comprehensive overview of existing approaches, and identifies gaps, which are ensured by qualitative and quantitative research methods addressed by the current research to present results accurately and unaltered.

- **Guideline 5 - Research Rigor: Design-science research relies on rigorous methods to construct and evaluate design artifacts.**

  Research using the design science research methodology is robust and reproducible when conducted through proven rigorous methods, so the research has a system. The course of this thesis first includes Hevner et al. (2004) by incorporating the three different cycles: relevance, rigor, and design. In the rigor cycle, the methodology of vom Brocke et al. (2009) and Webster and Watson (2002) enable a systematic literature search and important selection and analysis of the literature to create a theoretical basis.

- **Guideline 6 - Design as a Search Process: Searching for a compelling artifact requires utilizing available means to reach desired ends while satisfying laws in the problem environment.**

  The artifact is developed closely with specific user groups, using various process phases (iterative exploration, prototyping, testing, and refinement processes). By involving users in the entire design process, they can provide feedback anytime and ensure that the artifact is developed according to their preferences and needs. This guarantees a high level of user-friendliness and makes it easier for users to operate the end product. The iterative nature of the search process ensures that unforeseen problems can be more easily identified and overcome.

- **Guideline 7 - Communication of Research: Design-science research must be presented effectively to technology and management-oriented audiences.**

  Effective communication will summarize all the results of this work, including detailed documentation of the research process, results, and implications, as stakeholders must interpret the research results correctly. Other technically oriented target groups will receive detailed descriptions of the artifact's design, implementation, and evaluation, as well as the relevant data and analysis. The other target group, which is more management-oriented, receives an overview of the problem, the solution, and the potential impact on business performance. To promote further development in the field, the needs of the various target groups must be considered to generate a broader understanding, acceptance, and application of the results and to obtain practical implementation of the developed solutions.

In addition to these guidelines, the DSR process includes three cycles that guide the implementation of this work Hevner (2007):

The Rigor Cycle ensures that the design process is based on existing literature and contributes to existing knowledge. This provides the research with its theoretical and methodological basis. The aim is not only to ensure that the developed artifact is based on existing literature but also that the results, in turn, contribute to the expansion or refinement of existing knowledge (Hevner, 2007).

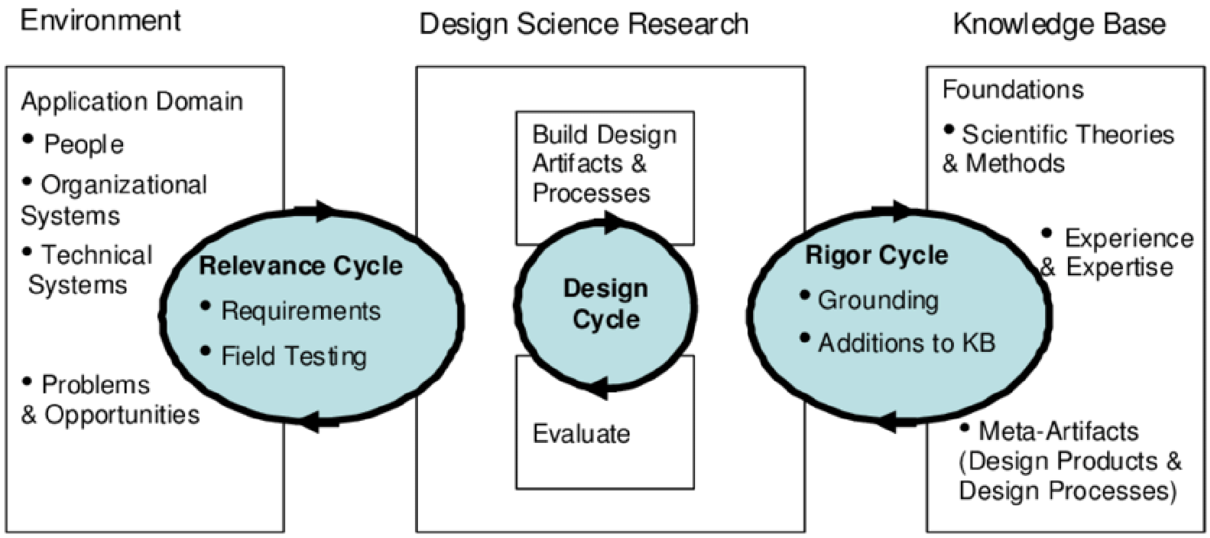
The Relevance Cycle links the research to the intended use environment, ensuring that the developed artifact also solves a real-world problem. Inputs such as requirements, constraints, and practical knowledge are incorporated into the design process, and the resulting artifact is evaluated in that environment. This evaluation step leads to insights into whether the artifact can be used in the intended environment (Hevner, 2007).

The Design Cycle is the central process for creating the artifact. The artifact (models, methods, or systems) is made, tested, and improved in this cycle. This cycle focuses on enhancing the artifact and how the artifact can meet the requirements of the identified problem. Through a feedback loop of continuous evaluation and incorporation of feedback, this cycle enables continuous improvement of the artifact. This ensures that the artifact is theoretically sound and practically applicable (Hevner, 2007).

The three cycles complement each other. The Rigor Cycle provides the necessary theoretical background, the Relevance Cycle ensures applicability to real-world problems, and the Design Cycle ensures iterative creation and improvement of the generated software artifact. The iterative step-by-step implementation ensures that knowledge contribution and practical applicability are utilized during development. In this way, new findings from the literature (theoretical) and real-world applications (practical) can be constantly incorporated into the development of the artifact (Hevner, 2007). Figure 3 illustrates the three DSR cycles and their respective tasks.

The evaluations in the design and relevance cycle have different tasks. The evaluation in the design cycle focuses primarily on the internal quality and implementation of the artifact's functionality during development. These evaluations are mainly carried out in controlled environments. The aim is to continuously improve the artifact. In contrast, the evaluation in the relevance cycle focuses on how the developed artifact works. The objective is to test the applicability of the artifact to the problem on the one hand and, on the other hand, to evaluate the usefulness, practicality, and fit with the users. In summary, the evaluations in the design cycle are primarily technical, which improves the artifact. In contrast, in the relevance cycle, the evaluation is somewhat practically motivated, which ensures applicability in the intended usage environment (Hevner, 2007).

Figure 3: Design Science Research – 3 Cycles based on Hevner et al. (2004)



3.2 **Research Design**

This work is based on the DSR Methodology (Hevner, 2007; Hevner et al., 2004). In this dissertation, we have used qualitative and quantitative methods to develop and evaluate our artifact. In this section, we first provide an overview of which method we used for which step and then give an insight into the techniques used. We describe how the methods were specifically applied and contextualized during the individual steps, together with the presentation of the individual steps in sections five and six, and go into more detail about the methods, the sample sizes, and other relevant information.

We used a systematic literature review as the basis for the creation of our artifact. This systematic literature search is based on vom Brocke et al. (2009) and Webster and Watson (2002). In this literature research, we look at the possibilities and barriers of PGHD in the healthcare sector from three dimensions. These three dimensions relate to the stages in the use of PGHD. They are, therefore, the collection of PGHD, the incorporation of PGHD into clinical workflows, and the use of PGHD in clinician-patient conversations. These findings contribute to a broader understanding of the use of PGHD in depression care and help us to address the problems of using PGHD in GP practices for the treatment of depression care through our artifact.

We developed qualitative focus groups and guidelines for qualitative interviews with healthcare professionals and patients to develop requirements for a patient-clinician platform for using PGHD in depression care. Based on the focus groups, we conducted interviews with GPs and potential users of PGHD apps and carried out a quantitative questionnaire with patients. For GPs, we assessed requirements in the dimensions of PGHD collection, which PGHD types are relevant for the treatment of depression in general practice, how the data is integrated into workflows, how the data should be presented, and what barriers there are to the use of PGHD in general practice. On the patient side, we have identified requirements in the dimensions of

PGHD collection, PGHD types for depression care, PGHD communication, PGHD concerns, PGHD app functionalities, and what concerns patients have regarding PGHD. Based on the results of these steps, we formulated design principles for implementing our artifact and requirements for a patient-clinician platform for using PGHD in GP depression care. Based on the requirements and the design guidelines, we developed a prototype for a patient-clinician platform called POKALConnect. During the implementation of this platform, we used iterative sprints with continuous feedback from test users.

Finally, we evaluated the prototype with patients and GPs in the intended field of use to verify the requirements and design elements we derived through our qualitative and quantitative assessment. It is important to emphasize that the prototype's role in this research project goes beyond a final product; instead, it serves as a dynamic tool for continuous evaluation of results and iterative improvement throughout the research process. This iterative feedback loop ensures that the prototype evolves in response to real-world use cases and stakeholder feedback, increasing its relevance and effectiveness.

In addition, the development of this prototype takes an interdisciplinary approach that integrates insights from IS, healthcare, and user-centered design. Collaboration with various stakeholders, including patients, clinicians, and IT professionals, will ensure the platform is user-friendly and technically robust. This collaboration will encourage innovation and ensure the platform meets end users' practical needs.

The methods used in the steps are presented in the following sub-chapters.

3.2.1 **Literature Review**

Literature research is crucial for science since scientific progress is cumulative (vom Brocke et al., 2009). A well-founded literature base is essential, especially in research fields such as IS or healthcare (e.g., psychology), for which IS is a vital reference discipline and is dynamic and constantly growing (King & He, 2005). Therefore, conducting scientific literature research is “essential for every research project” (Webster & Watson, 2002).

This detailed documentation of the search methodology is crucial for the credibility and methodological transparency of the literature research. vom Brocke et al. (2009) found that the search methods for literature research in ten leading IS journals are often insufficiently documented. They called for a stricter methodology through more detailed documentation of the literature research process. They developed a guideline summarizing findings from various studies on conducting literature research. The guideline presents a five-step process for conducting literature research, particularly in IS. This guideline, which consists of best practices for literature research, served as the basis for the present literature research and fulfilled various purposes. First, the guide should provide a detailed and precise presentation of the results of this literature review. The second important point is that using the guide validates it and thus confirms its effectiveness, which creates confidence in our research approach (vom Brocke et al., 2009).

In the literature research, we follow the approach of vom Brocke et al. (2009), which is based on five phases (these are illustrated in Figure 4):

(I) Definition of the scope of the literature review

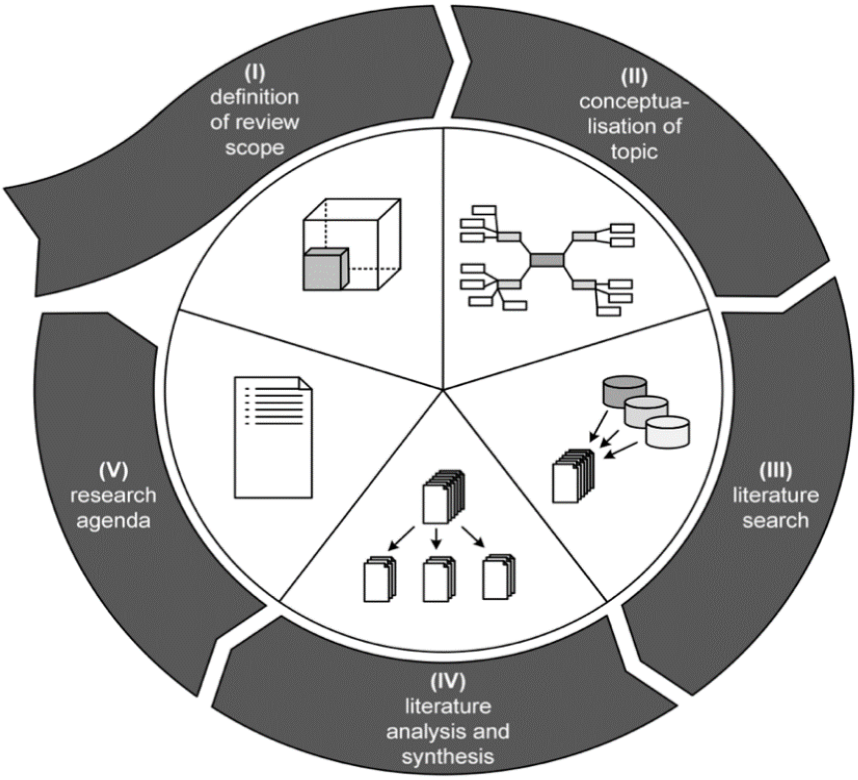
(II) Conceptualization of the literature review topic

(III) Search for literature based on the previously defined concepts and the specific scope of the work.

(IV) Determination of relevance criteria to filter the articles deemed relevant for this literature review from the search results. The relevant publications identified in this process are then analyzed qualitatively and quantitatively.

(V) Postulate a research agenda based on the results of the literature research.

Figure 4: Framework for Literature Reviews by vom Brocke et al. (2009)



3.2.2 Qualitative Methods

Qualitative research is based on methods that aim to explore the interpretation and discovery of meanings in the qualitative material collected. Qualitative methods originate from social sciences such as anthropology and focus on research results that emerge inductively from empirical data (Creswell & Creswell, 2017). These include observations or discussions with individuals or small groups of people (Denzin & Lincoln, 1996). Directly observing phenomena is suitable for measuring reality and establishing truths about the world (Given, 2008). Therefore, using qualitative research methods allows us to uncover and describe the characteristics, meanings, similarities, and differences in the actions and beliefs of people in the context of our research phenomenon. In this, we are supported by qualitative methods, requirements for patient-clinician platforms for your use of PGHD in depression care. Therefore, qualitative research usually precedes quantitative research by shedding light on the fundamental characteristics of a phenomenon, which can then be measured using quantitative research methods (Creswell & Creswell, 2017).

Through the chosen qualitative methods (described below), we try to gain insight into PCFs and the requirements of patients with depression. These qualitative assessments address the identified obstacles and opportunities and formulate design principles (Gregor et al., 2020; Gregor & Hevner, 2013). Design principles are central to developing IT-based artifacts within sociotechnical systems because they ensure they are both understandable and practical for real-world application. The importance of design principles arises from their role in formulating prescriptive knowledge that directly impacts design decisions and outcomes. Achieving these principles requires a qualitative research approach that accounts for the complexity and nuances of human interactions with technology. Through interviews, observations, and case studies, researchers can uncover the underlying mechanisms and contexts that influence the formulation of design principles. This process helps synthesize actionable and relevant design knowledge and ensures that the principles are grounded in users' experiences and needs, improving their usefulness and applicability in professional practice (Gregor et al., 2020; Gregor & Hevner, 2013).

Focus Groups

Focus groups are a research method in which data is collected through group interaction on a topic determined by the researcher (Morgan, 1996). The dynamics of groups tend to quickly reveal similarities and differences in the participants' perspectives, attitudes, preferences, and behaviors (Iacobucci & Churchill, 2010; Stewart & Shamdasani, 2014). Focus groups are exploratory and participatory, allowing us to identify unmet needs that form the basis for developing an artifact. Focus groups also allow us to explore a topic about which little is known (Krueger, 2014).

Semi-Structured Interviews

To gain in-depth insights into individuals' experiences, attitudes, and perspectives concerning PGHD, we used semi-structured interviews to collect qualitative data. This method allowed open-ended conversations and participants to freely express their thoughts and experiences. Due to the subjective nature of mental health experiences, a qualitative methodology was deemed appropriate to explore the use of PGHD in the context of depression. Semi-structured interviews gave us flexibility and allowed us to collect rich and contextualized data. We used semi-structured interviews because they offered the possibility to discover new concepts in the data: Those that would be overlooked with more rigid data collection methods (Gioia et al., 2013). We chose semi-structured interviews because they offer space for improvisation and exploring the underlying phenomenon. The interviews are based on the model by Myers and Newman (2007).

3.2.3 **Quantitative Methods**

In contrast to qualitative research methods, quantitative research methods are used to test theories and investigate relationships between variables. These variables can be measured so that numerical data can be analyzed statistically (Creswell & Creswell, 2017). Both data collection and analysis can take different forms, such as surveys or experiments, descriptive statistics, or regression analysis. These approaches allow researchers to generate and examine data to explore variables and constructs (Creswell & Creswell, 2017). This approach is strongly associated with positivism, which helps these natural science methods improve social science research (Creswell & Creswell, 2017).

Surveys

Surveys are a non-experimental method for collecting quantitative research data (Creswell & Creswell, 2017). Surveys are suitable for collecting information from a specific sample of participants to be extrapolated to a larger population (Creswell & Creswell, 2017). For this dissertation, we used surveys to validate some of our qualitative results. This method enabled us to obtain structured results and to ask a more significant number of participants questions. In this study, we use these quantitative surveys primarily to collect relevant and accepted PGHD types and identify functionalities for mental health PGHD apps. We mainly used the online survey platform LimeSurvey (LimeSurvey, 2024) to conduct these surveys. R was used to analyze the data.

3.2.4 **Design Principles**

To better communicate our results of the requirements engineering process within the design science research approach, we decided to formulate design principles (Gregor & Hevner, 2013). Design principles communicate design knowledge in an accessible format (Gregor et al., 2020). Design principles are essential to design theory because they contain prescriptive statements that distinguish design knowledge (Gregor et al., 2020).

In this dissertation, we use design principles to process the results of the requirement engineering process and prepare them for academics and designers of PGHD platforms for depression care. In addition, the 17 design principles developed provide a basis for implementing the design elements and constructs for our software artifact.

3.2.5 **Ethical Considerations**

As this dissertation is an interdisciplinary project in which the vulnerable group of depressed patients plays an important role, we were in close contact with a wide range of different experts in the field of depression care during all phases of this dissertation. This dissertation is embedded in the research training group “POKAL” (Gensichen et al., 2022), which promoted close cooperation with clinicians, psychiatrists, psychologists, and health scientists. In addition, we included the patient perspective during all steps of the qualitative and quantitative surveys

(Di Meo et al.). We presented our concepts for focus groups and discussed questionnaire design or interview guidelines for the interviews. During all interactions with depressive patients, we took advantage of the opportunity to have a psychiatrist present.

4 Exploration of Opportunities and Barriers for PGHD in Depression Care

This chapter is dedicated to exploring the opportunities and barriers of PGHD in the context of depression care, a topic of significant relevance. The following chapter is structured as follows. First, we discuss the methodology used for the literature search and then present our approach in detail. Finally, we use the collected literature to examine the existing opportunities and barriers in the context of depression care in GP practices. This section follows Reindl-Spanner et al. (2022).

4.1 Review Design

The following section describes the structure and implementation of our literature review on PGHD in healthcare.

4.1.1 Definition of Review Scope

First, it is essential to define the scope of the review. For this purpose, taxonomies have already been defined to better structure literature reviews. For this review, we use the taxonomy of Cooper (1988) as a guide to describe the characteristics of the review and categorize literature reviews based on six attributes: Focus, Aim, Scope, Organization, Audience, and Perspective. In the following, we present the details of our research scope. An overview can be found in Table 4.

This literature review aims to explore the integration of PGHD in depression care and specifically addresses the challenges and barriers encountered. It looks at the methods used in applying PGHD and the theoretical framework underpinning these practices. We also look at similar concepts to provide a holistic overview of the topic and all related aspects. Therefore, the overarching goal of this literature review is to synthesize different issues and thereby identify opportunities and barriers of PGHD in the care of depression. As literature reviews rarely have only one specific aim, as the analysis and integration of the literature requires a critical appraisal of the literature, we can define further aims. For example, this literature review also aims to identify existing solutions for integration and methods from related fields, which can be used to develop solutions for integrating PGHD into everyday practice. This results in further objectives, such as identifying solution approaches and contextualizing these approaches based on the use of PGHD in depression care. Therefore, the aim of our literature review can be seen as a critical analysis of the existing literature.

In this literature review, we focus on journal articles and conference proceedings from IS and related healthcare-related domains to ensure that the articles included are high-quality. Therefore, our review can be categorized as a fully selective literature search.

The organization of a literature search can be based on three dimensions: Historical, Conceptual, and Methodological. Since this literature review looks at different aspects of the implementation of PGHD in the care of depression and shows the opportunities and barriers, we have opted for a conceptual presentation of the literature review results.

The audience of this review is mainly scholars in the field of PGHD research. However, we do not only address scholars from the field of IS but also from related fields that may address the same topic as medical informatics. In addition, we also address practitioners for whom we use this literature research to identify opportunities to improve their applications and add further functionalities. The challenges and opportunities we have identified can also help to solve previously unknown problems.

Finally, we examine the perspective from which we view the identified literature. Although we focus primarily on barriers and new opportunities, and this perspective provides room for subjective assessments, we conduct the literature research from a neutral position.

Table 4: Taxonomy of the Literature Review (Cooper, 1988)

Characteristic	Categories
focus	**research outcomes**, research methods, theories, **applications**
goal	**integration**, criticism, **central issues**
organization	historical, **conceptual**, methodological
perspective	**neutral representation**, espousal of position
audience	**specialized scholars**, general scholars, **practitioners/politicians**, general public
coverage	exhaustive, **fully selective**, representative, central/pivotal

4.1.2 Conceptualization of the Review Topic

In this section, we describe the conceptualization of our literature search. Several important factors must be considered.

The focus of this literature search is to identify opportunities and barriers to PGHD in depression care. However, to ensure that the review coverage is comprehensive enough not to exclude any publications relevant to the topic, we need to include related terms in the search. It is also essential for this review to not exclude too many terms so that nothing relevant is left out.

Although this literature search is intended to provide insights into the use of PGHD in depression care, we do not limit ourselves in this review to analyzing only publications that deal exclusively with depression. Therefore, at the time of the literature search, our investigation does not yet exclude specific disorders, as problems or opportunities that arise in the context of another disorder may also apply to depression.

Based on these criteria, we decided to use the following search engine to find articles for our literature review:

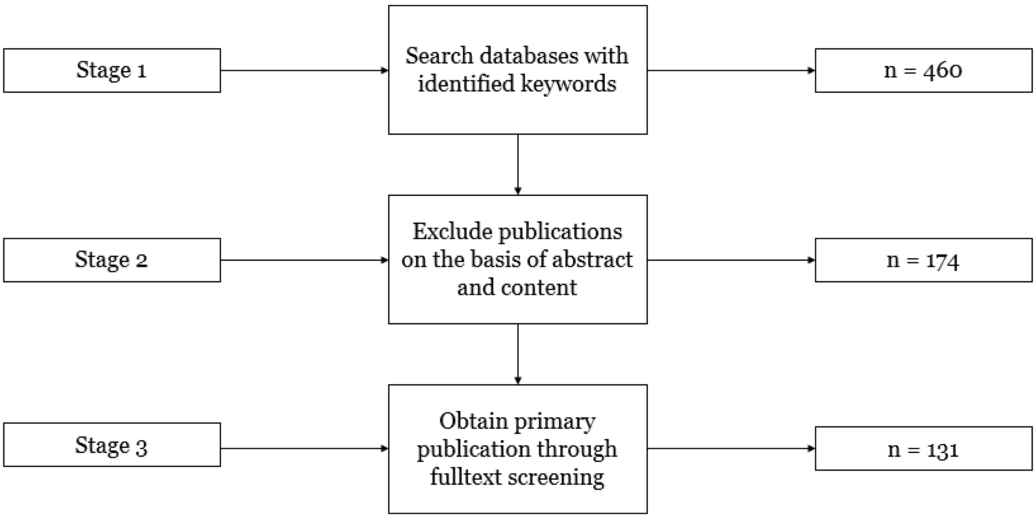
```
TITLE-ABS-KEY("patient-generated data") OR

TITLE-ABS-KEY("patient-generated health data")
```

4.1.3 **Literature Search**

In line with our research protocols, we meticulously selected pertinent articles, as Figure 5 outlines our selection process. Initially, we set criteria for including articles, requiring that they meet at least one of the following: (a) utilization of PGHD to enhance diagnostic or treatment procedures, (b) discussion on the usage or integration of PGHD into clinical workflows, or (c) description of how PGHD is collected or processed. We first screened titles and abstracts, eliminating 286 articles that did not satisfy our criteria, leaving us with 174. After reviewing the full texts, we pinpointed 131 articles aligned with our criteria.

Figure 5: Search Process (own illustration)



Subsequently, we evaluated the characteristics of these articles. Table 5 summarizes the most significant sources. Initially, we consulted the Senior Scholars' Basket of Eight (Association for Information Systems 2022) to find relevant literature on PGHD, recognizing it as a premier source for IS research. This search yielded no results. Given the interdisciplinary nature of PGHD, our primary goal became identifying the leading journals in this field. Among the pre-screening list of outlets, four out of the five with the most entries were in the medical informatics category, notably including journals from JMIR Publications, such as the Journal of Medical Internet Research and JMIR mHealth and uHealth, which focus on eHealth management and are ranked as A+ or A Tier.

We excluded "Studies in Health Technology and Informatics" from our review. Other key journals included the Journal of the American Medical Informatics Association (A+) and Surgical Infections (unranked). The only conference of note was the Conference on Human Factors in Computing Systems, ranked A*.

Adhering to our guidelines, we categorized the 131 selected articles by several dimensions pertinent to our research questions. We classified articles based on (1) thematic relevance (e.g., integration of PGHD into clinical workflows), (2) associated diseases (e.g., diabetes), and (3) collection methods (e.g., active vs. passive collection). These classifications are detailed in a concept matrix in Table 5, which we discuss further in the subsequent sections of this thesis.

Table 5: Concept Matrix - Perspectives on PGHD

Article	Thematic Association			Disease					Collection Method	
	Data Collection	Workflow Integration	Patient-Clinician Interaction	Cardiovascular Diseases	Diabetes	Cancer	Mental Health	Other Diseases	Active Collection Methods	Passive Collection Methods
Alpert et al. (2020)		X								X
E. Austin et al. (2020)	X			X	X					X
L. Austin et al. (2020)			X					X	X	
Bourke et al. (2020)		X	X							
Burgermaster et al. (2020)		X			X				X	X
Burns et al. (2019)			X							
Chung et al. (2016)		X	X						X	X
Cohen et al. (2016)	X	X			X				X	X
Cresswell et al. (2019)		X								
Dixon and Michaud (2018)			X					X		
Hartmann et al. (2019)	X						X		X	X
Holt et al. (2020)		X								
Hong et al. (2018)	X		X					X	X	
Hussein et al. (2021)		X								
Kumar et al. (2016)		X	X		X					X
Lindroth et al. (2018)			X							
Marceglia et al. (2017)		X								
Ng et al. (2019)	X	X	X				X		X	X
Nittas et al. (2019)	X	X		X	X	X	X	X	X	X
Panda et al. (2020)			X			X		X	X	X
Piras (2019)	X								X	
Plastiras and O'Sullivan (2018)		X							X	X
Raj et al. (2017)			X		X				X	X
Rodriguez et al. (2019)		X		X					X	
Saudek (1989)	X				X					
Vaughn et al. (2019)			X					X		X
West et al. (2018)	X	X		X	X	X	X		X	X
Whitney et al. (2018)		X						X	X	
Wu et al. (2020)		X					X		X	X
Ye (2021)		X						X		
Zhang et al. (2019)	X		X							
Other	44	67	31	22	48	29	21	15	49	83

4.2 Analysis of Data and Results

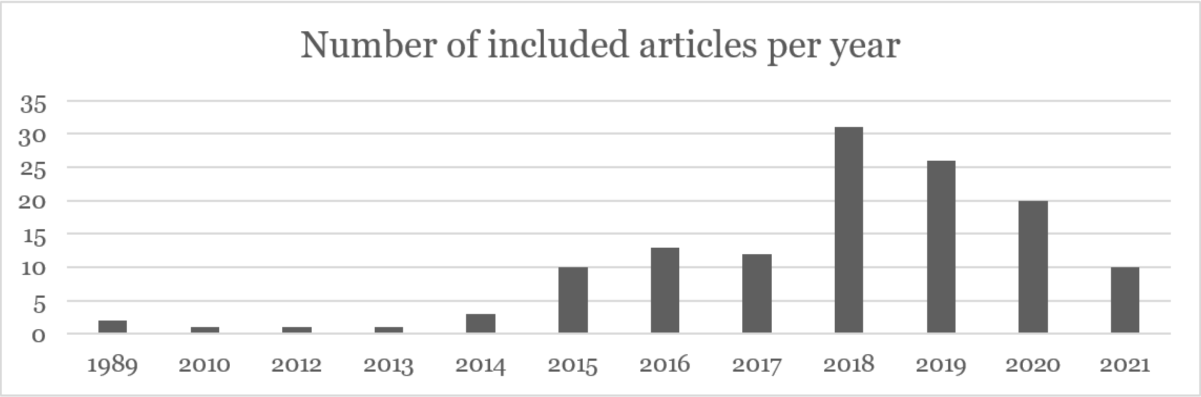
Before we turn to the qualitative content of the articles in our literature review, we first want to analyze our results from a quantitative perspective. We focus on two central metrics. First, we examine the years of publication to gain insights into when the included articles were written. This allows us to identify trends and developments and understand how research interest in our topic has changed over the years. Second, we analyze the keywords used primarily in the articles. This examination allows us to identify the thematic priorities and determine which concepts and terms are particularly prominent in the research. Combining these two quantitative approaches provides a sound basis for further qualitative literature analysis.

Our quantitative analysis of the included articles shows that research on PGHD has increased substantially since 2015 and reached its peak in 2018 (Figure 6). Our results conclude that the increase in publications on PGHD is closely related to the increasing ubiquity and growing user-friendliness of smartphones and smart devices. In addition, we have identified several essential research trends within PGHD research. These trends include studies on smartwatches, which are covered in 11 articles, smartphone and smartphone-based PGHD collection, which is covered in 54 articles, and the integration of PGHD into EHRs, which is covered in 29 articles.

The significant emphasis on smartphone-based PGHD collection highlights the central role of mobile technology in modern health data collection methods. Similarly, the integration of PGHD into EHRs underscores the critical importance of seamlessly incorporating patient data into existing health systems to improve clinical decision-making and patient outcomes. Research on smartwatches also indicates a growing interest in wearable technology and its potential for continuous, passive health monitoring.

The following sections provide detailed insights into these literature streams on our defined research questions (RQs). This analysis will explore the technological advances, challenges, and implications for future research within each trend and provide a comprehensive overview of the current state and future directions of PGHD research.

Figure 6: Number of Articles per Year (own illustration)



4.2.1 PGHD Collection Methods

In this section, we look at the literature on collecting PGHD. We found articles in our literature search that describe the process of collecting data from PGHD as early as 1982 (White 3rd et al., 1982). These early articles on PGHD mainly presented this data to diabetes patients who independently measured and documented their blood sugar levels. This documentation of their health status was then regularly discussed with their doctors (Saudek, 1989; Ziegler et al., 1989). The authors describe early methods of data collection that typically involved handwritten files collected and created by patients and then transferred by clinical staff into early clinical computer systems (Saudek, 1989). In addition to documenting blood glucose levels, these early methods of recording PGHD also include methods for recording blood pressure levels. These two diseases have, therefore, been treated with the use of PGHD for a long time, which is reflected in the large number of articles on these diseases with PGHD association (Table 5).

In addition to these long-used methods, which are based primarily on the use of dedicated hardware components to measure the values, the ubiquity of smartphones since the early 2010s has also changed how PGHD is recorded. While data collection for patients was initially rather time-consuming and resource-intensive (Piras, 2019), modern technologies enable the collection of large amounts of data without the patient necessarily having to be actively involved. To explore this aspect in more detail, we divide the methods for collecting PGHD into two main categories: (a) active collection methods and (b) passive collection methods. Implementing these methods in patient care brings advantages and challenges, which we describe in more detail in the following sections.

Active PGHD collection methods are collection methods that require patients to input data actively. As discussed above, this data collection method includes blood sugar and blood pressure measurements and questionnaires that patients complete independently at home (digitally or on paper) (Nittas et al., 2019). A key advantage of active data collection methods is the increased involvement of patients in their therapy (E. Austin et al., 2020). This advantage arises from the realization of better treatment (Nittas et al., 2019). Active types of PGHD can also include data that reflects patients' subjective well-being or, more broadly, measures therapy success (Nowell et al., 2019).

In passive PGHD collection methods, patients do not have to collect the data actively; instead, data collection is outsourced to technical devices that automatically generate PGHD without the patient actively entering data (Nittas et al., 2019). Digital devices mainly carry out passive data collection methods. These include, in particular, smartphones, smartwatches, smart rings, or other devices that can be worn on the body (Heintzman & Kleinberg, 2016). These sensors then measure different values while the users are wearing them. These include, for example, the wearer's activity. In particular, the number of steps taken in everyday life is measured, or the intensity of physical activity based on the pulse. In addition to measuring the pulse for physical activity, these devices also measure the pulse to reflect a daily pattern, particularly a night-time reduction. In addition, devices that measure the pulse can often also measure values such as heart rate variability, providing valuable insights into the medical field. Ultimately, data on sleep can also be collected using these devices. Here, combinations of measurements are used to determine values such as sleep duration, time to fall asleep, or sleep phases (Ng et al., 2019).

A common problem we faced during our literature research and that arises when PGHD are introduced into clinical workflows is the trustworthiness and quality of the collected data (Huba & Zhang, 2012; Nittas et al., 2019; Reading & Merrill, 2018; West et al., 2017). This problem is further exacerbated when patients present with surprising or unusual symptoms. In this case, introducing passively collected data from wearables such as smartwatches can positively influence the clinician's attitude because it is more difficult for the patient to falsify the collected data (Alpert et al., 2020). In addition to this advantage, passive collection methods can reduce the burden on the patient when data is collected automatically via wearables (Piras, 2019) and through continuous data collection (Ng et al., 2019). By reducing the burden of follow-up, passive PGHD collection methods enable data collection in patients who would not usually be able to collect data actively (Bove, 2019). While passive collection methods may have less patient involvement than active methods, patients who cannot actively collect data may feel more included.

4.2.2 **Integration of PGHD into Clinical Workflows**

In the previous section, we provided insights into the literature on various PGHD survey methods. Although these methods can be well implemented using digital methods for data collection, the current ecosystem of eHealth apps consists mainly of unconnected applications that lack a connection to standardized medical protocols (Akram et al., 2017). This causes problems for the integration of PGHD into clinical workflows or EHR (Cohen et al., 2016; Lewinski et al., 2019). According to recent studies, the integration of PGHD into clinical workflows is still in its infancy (Hussein et al., 2021). To provide a better understanding of the integration of PGHD into clinical workflows, this section offers insights from the literature into various ways of integrating PGHD workflows. Additionally, we describe various problems and barriers to using PGHD in (family) medical practices and suggest solutions for overcoming them.

We divide this section into several parts: First, we provide insights into the everyday challenges and barriers to integrating PGHD into clinical workflows. Then, we consider the technical integration of PGHD into clinical workflows through technologies such as EHR. Finally, we provide insights into how the integration of PGHD is changing the actual workflows of clinicians and healthcare professionals.

West et al. (2018) examined the general barriers to integrating PGHD into clinical settings. The authors divide the barriers into three areas: West et al. (2018) examined the general barriers to integrating PGHD into clinical settings. The authors divide the barriers into three areas:

1. Data collection and data use

2. Data interpretation

3. The use of PGHD in clinical practice

The main obstacles for each area include the following:

1. Incomplete data and unclear reliability of these data sets

2. Irrelevant data, insufficient or non-existent interoperability with healthcare IS and inadequate time to review the data

3. Unclear patient motivation, limited data use by practice or education, and the possibility that the collected PID cannot be considered concrete evidence for a diagnosis.

These barriers illustrate that while modern technology facilitates the collection of PGHD, the resulting large amount of data can pose a more significant challenge to clinical workflow.

Another challenge for the integration of PGHD is the time required to integrate the data into the EHR. These challenges have not only emerged in recent years but have been around for quite some time, particularly in diabetes and hypertension care (Marquard et al., 2013). To improve the integration of data into administrative systems, there are some suggestions as to what such platforms should require (Volkov et al., 2021):

- The platform should enable patients to share their data with family members or doctors securely
- The platform should provide an open API so that developers can request permissions and gain access to medical data
- The platform should be flexible regarding the types of health data available for monitoring

Holt et al. (2020) found that clinicians often do not have enough time to prepare for a patient's consultation; therefore, they also have difficulty examining the PGHD before and during the consultation and integrating it into the patient-clinician conversation meaningfully. Checking the integrated data requires “another click” in the system, which is an additional burden. This time deficit, combined with the increased effort of the patient to collect data in everyday life, leads to the doctor's fear that patients could label the doctor as “bad” (if he does not check the data). The literature results highlight the potential barriers and obstacles of PGHD by pointing to possible information overload and technical stress on the patient and the clinician. For patients, this stress arises from collecting the data or the pressure to collect continuously correct data. For clinicians, this technostress arises from the additional data that has to be considered alongside clinical data during an examination. Although this appears to be a current problem, the topic has not yet been sufficiently addressed in research. Fourteen articles dealt with information overload for clinicians (too much information) (Choe et al., 2018; Cronin et al., 2018; Reading & Merrill, 2018; West et al., 2018).

While there are many barriers to integrating PGHD into clinical workflows, research is being conducted on overcoming these barriers. Solutions for integrating PGHD into clinical workflows must provide ways to support both the clinician's and patient's goals (Chung et al., 2016). For the clinician, approaches that utilize existing clinical infrastructure, such as the EHR, are the most viable solutions (Cohen et al., 2016). Currently, the literature describes that the integration of PGHD into clinicians' offices is still done by manually entering the data from printed sheets into the clinical computer system (Wu et al., 2020). A direct, passive, and automated data transfer into the clinical workflow seems feasible, and it has been shown that the integration of PGHD enables a more efficient workflow for healthcare providers (Kumar et al., 2016). One solution for integrating PGHD into clinical workflows through EHR is the interoperability of the clinical platform with multiple unconnected sources (health apps) (Plastiras & O’Sullivan, 2018). This can be achieved through an application programming interface (API) that can integrate third-party tools into the clinical platform (Akram et al., 2017). Several authors we included in our literature review have developed solutions to support the integration of PGHD into EHR-based clinical platforms (Burgermaster et al., 2020; Karnati et al., 2021; Plastiras & O’Sullivan, 2018). For example, Marceglia et al. (2017). For example, Marceglia et al. (2017) have developed a solution that implements a web-based platform that integrates EHR functions, includes a workflow engine, and supports mobile apps and wearable devices for capturing patient data.

In contrast to medical-based solutions, other approaches, usually rooted in IS, have been introduced to solve problems by integrating PGHD into clinical workflows in recent years. One example is the approach of Burgermaster et al. (2020), which presents a system for nutrition recommendations based on qualitative modeling of clinical reasoning and decision-making, combining PGHD with an expert knowledge base.

Finally, the introduction of PGHD into clinical workflows can promote disease prevention. This shift targets the phase before patient consultations. Here, PGHD has the potential to be used as a tool for early detection of diseases or disease-related episodes (e.g., hypoglycemic episodes in diabetes) (Bhavnani et al., 2016). Continuous long-term tracking of PGHD and self-management can promote risk reduction and patient well-being (Hsueh et al., 2016). Successful and effective implementation of disease prevention benefits patient's health systems, companies, and society (Nittas et al., 2019).

Our results conclude that PGHD needs to be further integrated into clinical workflows to have an impact. A first step towards better integration is to follow the presented paths for integrating PGHD into standardized EHR. This includes standardizing data visualization (Kim et al., 2017). Data visualization is crucial for understanding the collected PGHD (Bourke et al., 2020). Studies show that users prefer simple displays with visualized PGHD (Whitney et al., 2018). In the following subchapter, we discuss the role of PGHD in the interaction between patient and clinician.

4.2.3 Patient-Clinician Interaction

During our thematic coding process, we identified a third important strand of literature: Patient-clinician interaction. Of particular importance here are the different perspectives on the impact of PGHD on patient-clinician interaction (Bourke et al., 2020; Burns et al., 2019; Kumar et al., 2016; Raj et al., 2017). To realize PGHD's full potential, it is essential to understand how its use changes the patient-clinician conversation. This section provides insights into PGHD's influence on this interaction. In the following, we show how introducing PGDH into clinical workflows leads to several changes in patient-clinician interactions. We discuss these findings based on expectancy, communication, and SDM theories.

Research on the impact of PGHD on patient-clinician interactions is rooted in technology acceptance and expectancy theory. This stems from the fact that introducing PGHD into the diagnostic and treatment process creates higher expectations for patients and clinicians. From the patient's perspective, these expectations are primarily linked to two essential aspects: expectations to support diagnosis and treatment and to support affective needs. In terms of diagnosis and treatment, patients expect providers to have a comprehensive overview of their daily lives to understand the tracking data and create a personalized, actionable plan. In terms of emotional needs, patients want motivation, accountability, recognition, and empathy (Chung et al., 2016). On the doctor's side, the expectations of PGHD differ. The most common expectation on the clinician side is to gain better insight into the patient's life to understand better the patient's goals and priorities (Chung et al., 2015) and to facilitate discussions and focused conversations with patients (Zhang et al., 2019).

Introducing PGHD into patient-clinician interactions can positively impact consultations by providing a more accurate overview of disease progression and response to treatment (L. Austin et al., 2020). As a result, patients and clinicians can use PGHD to identify problems in the ongoing treatment process and understand these problems to decide on the next step in treatment (Raj et al., 2017). Consequently, PGHD can improve patients' feelings about potential patient-clinician interactions (Hong et al., 2018). For providers, PGHD can aid diagnosis through more accurate symptom recognition (Zhang et al., 2019) and reporting (Vaughn et al., 2019), improve patient-clinician communication, and reduce unnecessary consultations (Burns et al., 2019). Further studies show that clinicians who use PGHD provided by their patients passively communicate that they trust their patients' data. Patients perceived this higher level of trust as a more respectful interaction (Burns et al., 2019).

However, introducing PGHD can also lead to unfulfilled patient and clinician expectations. First, the collaboration between patient and clinician could become cumbersome because introducing PGHD into the interaction can lead to undesirable differences in the risk perception of problems and the associated reactions. While differences in perception are usually not recognized during the patient-clinician interaction, they still determine the topics discussed. While the patient and doctor may not be aware of their altered expectations, it still immediately affects the patient's treatment decisions (Raj et al., 2017). Another possible adverse effect of patient involvement in data collection is that prejudices about a potential diagnosis may arise. These prejudices can lead to problems in the interaction between patient and doctor if the final (medical) diagnosis does not match the patient's prejudices. Nevertheless, these cases of self-diagnosis can be reduced if the data collection is initiated by a doctor and not by the patient himself (Burns et al., 2019).

In addition to generating expectations, the introduction of PGHD also substantially impacts the relationship and communication between patients and clinicians in several ways (Bourke et al., 2020). For example, insights into the patient's illness that increase over time help the patient to communicate about the disease (with clinicians and their relatives) (Dixon & Michaud, 2018). The data itself, combined with potentially more accurate symptom reporting (Vaughn et al., 2019), provides the clinician with the opportunity to ask questions about symptoms and facets of the patient's illness that they would not have asked without the data available during or before the consultation (Burns et al., 2019). The graphical summaries of collected PGHD positively impacted patient-clinician interaction during patient consultations. This tool allowed doctors to point out unique data points that patients might have forgotten (L. Austin et al., 2020).

In addition, PGHD improves communication between clinicians and patients by enabling intuitive visualization, data provision via the electronic medical record, and automated triage (Kumar et al., 2016). Ultimately, in this context, PGHD can completely change the classic question-and-answer process during the interaction between patient and doctor, as data generation is transferred to the patient's everyday life (Lindroth et al., 2018). By using PGHD, doctors and healthcare providers can support patients remotely (Burns et al., 2019).

A third strand of literature we found related to patient-clinician interaction is research on the decision-making process based on PGHD. While this process is not new for diabetes patients, insulin has always been self-administered according to the patient's readings. PGHD can improve decision-making in clinical settings by engaging patients and supporting SDM for many other diseases. Four key characteristics define SDM:

1. Two or more parties involved (clinician, patient, etc.)

2. Both parties exchange information

3. Both parties take steps to reach a consensus on the preferred treatment

4. A joint agreement on treatment is reached.

Improved communication through the integration of PGHD between clinicians and patients can support SDM (L. Austin et al., 2020; Bourke et al., 2020). Introducing PGHD into clinical workflows fulfills criteria (1) and (2) for SDM and supports criteria (3) and (4). Current research agrees that SDM is the preferred method for patients (Eliacin et al., 2015). Building on the improvement of SDM, PGHD has been used to improve patient recovery after surgery. To this end, patients are monitored before and after surgery to determine their physical activity levels. This enhanced patient monitoring helps to create a foundation for an SDM environment and benefits recovery monitoring and patient engagement (Panda et al., 2020).

4.3 **Summary**

Our comprehensive literature review on detecting PGHD in healthcare has revealed significant benefits and barriers. We identified 131 relevant articles from 460 articles and organized them according to PGHD detection, workflow integration, and patient-clinician interaction dimensions.

Table 6 illustrates the key findings of our literature review based on the key benefits and challenges in the three main literature streams presented. This thematic mapping is supported by two further dimensions (the disease under study and the data collection method).

In the area of PGHD, the benefits mainly include increasing patient engagement in their therapy (E. Austin et al., 2020) and the multitude of data collection methods for different diseases (Nittas et al., 2019). On the other hand, we found that barriers to PGHD collection included the need to motivate patients to collect data and share information about their daily living (Nittas et al., 2019; West et al., 2018), that data collection can be a burden for patients (Piras, 2019) and that the results can often be heavily patient dependent (West et al., 2018).

The integration of PGHD offers new ways to diagnose and treat PGHD (Burgermaster et al., 2020) and leads to a rethinking of consultation and treatment planning (Burns et al., 2019). On the other hand, it is still challenging to integrate PGHD into workflows because the accessibility of the platforms offered is often not good (Holt et al., 2020), and data visualization is not standardized (Kim et al., 2017). Integrating PGHD into EHRs is technically difficult (Akram et al., 2017).

Ultimately, we determined for patient-clinician interaction that therapy decisions can be made based on PGHD data (L. Austin et al., 2020), enabling personalized disease treatment (Cahn et al., 2018). In addition, PGHD empowers a shift in the distribution of roles in the patient-clinician interaction (Bourke et al., 2020) and enables SDM (L. Austin et al., 2020; Bourke et al., 2020). However, PGHD also carries the risk that patients have very high expectations of the treatment. Clinicians often have problems trusting the data (Burns et al., 2019) or are overwhelmed by a flood of PGHD (Holt et al., 2020; Ye, 2021).

Table 6: Overview of Opportunities and Challenges of PGHD in Healthcare

Literature Stream	**Benefits**	**Challenges**
PGHD collection methods	• PGHD results in patients' engagement in their therapy (E. Austin et al., 2020) • There is a multitude of PGHD and collection methods for different diseases available (Nittas et al., 2019)	• Patients must be motivated to collect data and share information about their daily living (Nittas et al., 2019; West et al., 2018) • Data collection can be a burden for different diseases (Piras, 2019) • Results are heavily patient-dependent (e.g., incomplete data) (West et al., 2018)
PGHD workflow integration	• PGHD enables new ways of diagnosis and treatment in healthcare (Burgermaster et al., 2020) • PGHD leads to a shift in consultation and treatment planning (Burns et al., 2019)	• Accessibility (Usability of the PGHD integrated platform) of PGHD for clinicians must be ensured (Holt et al., 2020) • Data visualization of PGHD for clinicians is not standardized (Kim et al., 2017) • Integration of PGHD into Electric Health Records involves technical difficulties (Akram et al., 2017)
PGHD in patient-clinician interactions	• PGHD enable therapy decisions based on objective data (L. Austin et al., 2020) • PGHD enables improved, personalized treatment of diseases (Cahn et al., 2018) • PGHD results in a shift in communication and role distribution in patient-clinician interaction (Bourke et al., 2020) • PGHD builds an improved base for a SDM process in therapy (L. Austin et al., 2020; Bourke et al., 2020)	• PGHD may result in possible expectations and preconceptions about diagnosis and treatment (Burns et al., 2019) • Clinicians must trust and use the provided PGHD (Burns et al., 2019) • Clinicians can be overwhelmed with the amount of data, which increases the risk of technostress and information overload (Holt et al., 2020; Ye, 2021)

5 Requirement Analysis for a PGHD Platform

In this chapter, we examine the requirements of platforms for patients and physicians to support GPs in diagnosing and treating depression. Based on the previous literature review, we developed a concept for a qualitative evaluation with medical professionals involved in treating depression. At the same time, we conducted qualitative and quantitative surveys with depressed patients to determine their requirements for PGHGD applications. This enabled us to identify essential functionalities for the implementation of our artifact.

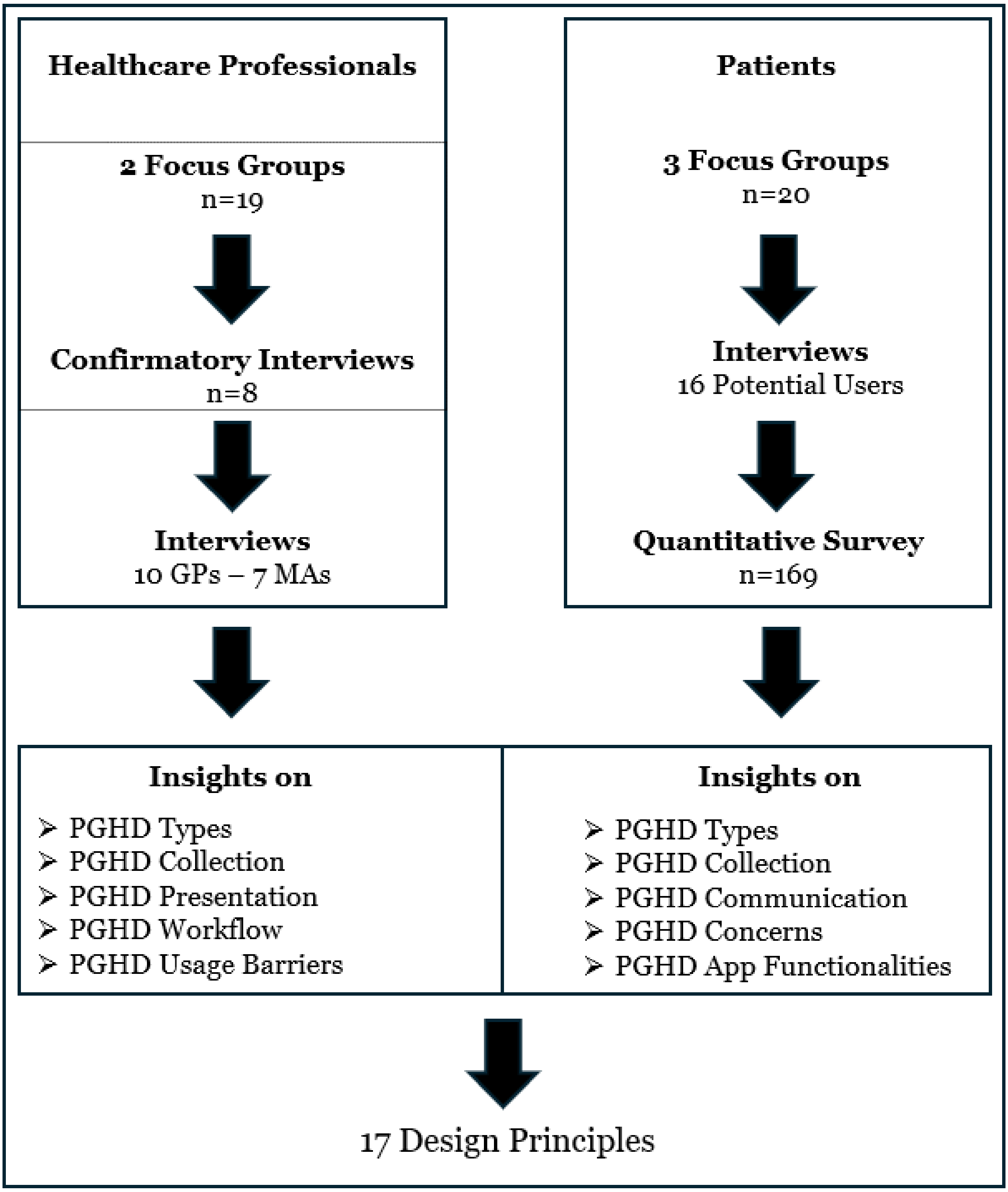
The chapter is structured as follows: First, we describe the methods for analyzing requirements in detail. We then examine the perspective of GPs and the requirements they place on a PGHD platform for treating depression in primary care. We consider five different aspects: The first aspect deals with the types of PGHD that are relevant for treating depression from the doctors' point of view. The second aspect is the collection of patient data and the requirements from the point of view of the family doctors. The third aspect deals with the presentation of the data and how it needs to be prepared for use. The fourth aspect is the integration of PGHD into clinical workflows; the fifth aspect deals with barriers to using PGHD. In the second part of the chapter, we examine the patient's perspective. Here, too, we consider five different aspects: First, we examine data collection from the patient's perspective and determine which types are relevant for patients. In the next step, we present which data types are suitable for treating depression from the patient's point of view. After that, we look at how the collected PGHD is communicated to the patient and what concerns patients have about using PGHD. Finally, we examine the patients' requirements for PGHD platforms and highlight the most important ones. Based on these findings, we formulate design principles for developing platforms for patients and doctors to treat depression in primary care at the end of this chapter. We divide these design guidelines into general principles and principles for doctors (web platform) and patients (mobile app).

5.1 **Research Approach**

The first part of this section describes our requirements engineering approach. Here, we present the steps we took to conduct our focus groups, interviews, and quantitative surveys. We also provide insights into sample sizes and the approaches we chose to gain insights into the requirements of GPs and patients with depression. We decided on a combination of focus groups and interviews for the qualitative part of our requirement analysis. We conducted two focus groups with healthcare professionals in the first step of our requirements analysis. We then confirmed the results of these focus groups by conducting interviews with selected participants. In the next step, we conducted semi-structured interviews with GPs and PCF employees to determine the requirements for integrating the PCF into the workflows of general practices. To determine requirements with patients, we conducted a total of three focus groups with depressed patients. Based on the focus groups, we then created a questionnaire for semi-structured interviews that we conducted with potential users of PGHD apps to confirm our findings and identify further requirements. For the quantitative part of the requirements engineering, we decided to survey depressed patients. Based on the results of the patient focus groups and potential user interviews, we created a survey that aimed to identify requirements for apps to collect PGHD for depression care and to determine relevant types of PGHD for depression care from a patient perspective.

Figure 7 provides a graphical overview of the requirements engineering process. In the following section, we will discuss in more detail how we applied the methods and the details of the samples.

Figure 7: Overview of the Requirements Engineering Approach (own illustration)



5.1.1 Focus Groups with Healthcare Professionals

The following describes how we applied the methods and provides details of the samples.

Focus Group Setup

In **Phase 1** - requirements specification - we conducted two focus groups with 13 and 6 participants. These focus groups aimed to collect relevant PGHD for the treatment of depression and to develop an in-depth understanding of the target group's needs in using PGHD for depression care.

In **Phase 2** - confirmation of requirements - we conducted confirmatory interviews with clinicians and psychiatrists (n=8) who had participated in the focus groups about the focus groups. These interviews were crucial to verify the participants' statements again in an individual setting at a time interval from the focus groups.

Focus Group Procedure

In the following, we describe the individual steps of the focus workshops and their results.

Phase 1: We started with the first phase of requirements specification, based on focus groups with diverse healthcare experts on depression treatment. We divided the event into the following steps to ensure a structured process:

1. Familiarization Step: To establish a shared understanding of PGHD, we started the focus groups with a brief introduction to PGHD. After the introduction, we divided the participants into four/two groups (consisting of 2 to 4 individuals), in which we asked them to identify and discuss all relevant types of PGHD for depression treatment. We encouraged the participants to use any available sources of information. This step resulted in a list of potential PGHD for treating depression without any further restriction. Subsequently, we asked the participants to cluster the identified PGHD into categories based on common themes, resulting in a list of different PGHD categories for each group. Examples include cardiac parameters, activity levels, or sleep parameters. This phase concluded with a brief presentation of the combined results from all four focus groups.

2. Focus Step: In the second phase, we aimed to reduce the number of potential PGHD in the depression context to the most relevant ones. Therefore, we instructed the participants to identify the essential types of PGHD for depression care and rank their importance without constraints, e.g., workload, effort, data security, or feasibility. Based on this ranking, participants discussed the advantages and disadvantages of the identified PGHDs.

3. Evaluation Step: We asked the participants to evaluate the types of PGHD based on effort and relevance. Participants should consider factors such as the effort required for the collection, the supply frequency, and the advantages and disadvantages associated with different data types. For this step, we provided each group with a matrix template with dimensions labeled "Effort to collect" and "Relevance for the treatment of

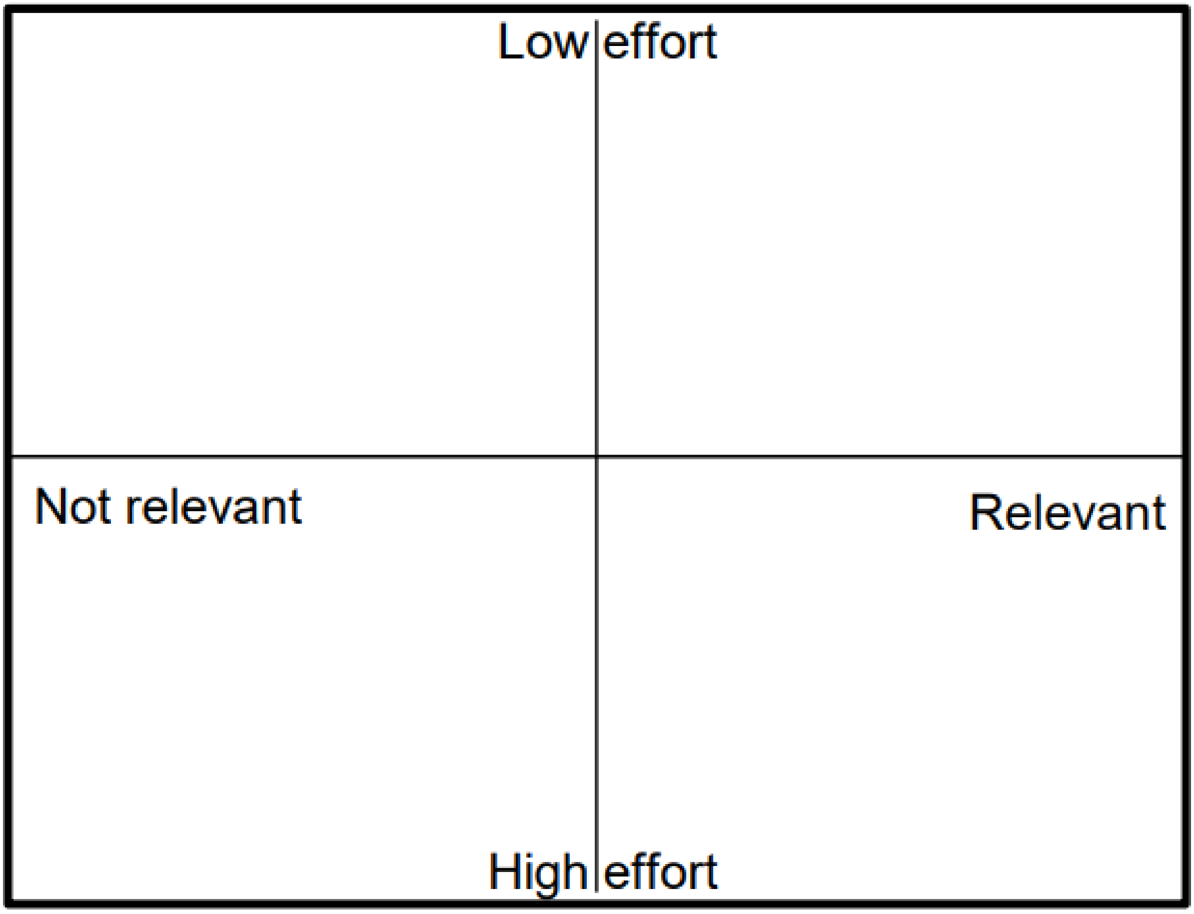
depression" (Figure 8). We requested the participants to place the identified PGHD within the matrix. This step yielded a matrix for each group, offering an overview of the rated relevance for depression care and the effort required to collect each type of PGHD. Based on these matrix results, participants were asked to identify the 3-5 most important and promising types of PGHD.

4. Exchange Step: The final step was to exchange and validate the groups' results. We asked the groups to present their matrices and highlight the most important types of PGHD for depression treatment. Together, participants engaged in discussions regarding the significance of PGHD and explored appropriate methods for collecting PGHD from the patient's perspective and integrating it into the treatment process. This phase facilitated the comparison of results among participants, leading to slight adjustments to their findings based on the plenary discussion.

Phase 2: After completing the focus groups, we started an additional interview phase to validate the findings derived from the focus groups. This phase aimed to ensure the reliability and robustness of the results by engaging selected participants (n=8). We chose the participants based on their background, age, and gender as we aimed to cover a broad range of feedback. We conducted semi-structured interviews through online meetings or face-to-face sessions, including video and audio recordings, to capture the interview interactions accurately. In the interviews, we followed four guiding questions to conduct the interviews, which we then used to develop the discussions. These four questions are as follows:

1. What is your perspective on the presented relevance-effort matrix for data collection?
2. In what manner should patients gather the data?
3. How would you integrate this data into your treatment plan?
4. What steps should be taken to prepare the data for utilization?

Figure 8: Relevance - Effort Matrix (own illustration)



Participant Details

The recruited sets of participants for the focus groups are diverse in terms of profession, gender, and age. In the first focus group, group 1 consists of four female participants, three psychologists, and one doctor, aged between 27 and 29. Most of them confirmed their interviews, with only one psychologist not doing so. Group 2 includes a mix of professions: a female psychiatrist who preferred not to disclose her age, a female psychologist and pharmacist, aged 27, and a 27-year-old male doctor. Two members of the group took part in the interviews. Group 3 consisted of two male doctors aged 33 and 43 and a 27-year-old female public health specialist, with only one participant attending the interview - group 4 consisted of two male doctors aged 31 and 36. One person from the group took part in the interviews. In the second focus group, group 1 included a 55-year-old female nurse, a 73-year-old male doctor, and a 47-year-old female doctor. Group 2 is composed of a 58-year-old male doctor and two female psychologists aged 26 and 28. The focus group participants are listed in Table 7. The participants of the interviews are listed in Table 8. This diverse cohort ensures a broad range of perspectives and experiences, enriching the study's findings and enhancing its validity and applicability to the field.

Table 7: Focus Group Participants' Demographics

Focus Group	Group	Profession	Gender	Age
Focus Group 1	Group1	Psychologist	Female	28
		Psychologist	Female	29
		Psychologist	Female	27
		Doctor	Female	27
	Group2	Psychiatrist	Female	I prefer not to say
		Psychologist	Female	27
		Pharmacist	Female	27
		Doctor	Male	27
	Group3	Doctor	Male	43
		Doctor	Male	33
		Public Health Specialist	Female	27
	Group4	Doctor	Male	36
		Doctor	Male	31
Focus Group 2	Group 1	Nurse	Female	55
		Doctor	Male	73
		Doctor	Female	47
	Group 2	Doctor	Male	58
		Psychologist	Female	26
		Psychologist	Female	28

Table 8: Participants in Confirmatory Interviews

Profession	Gender	Age
Psychologist	Female	28
Psychologist	Female	27
Doctor	Female	27
Psychiatrist	Female	Prefer not to say
Doctor	Male	27
Doctor	Male	43
Doctor	Male	36
Nurse	Female	55

5.1.2 **Interviews with Healthcare Professionals**

These interviews aimed to explore the integration of PGHD into the workflows of PCFs. Therefore, we decided to interview GPs and medical assistants (MAs) working in PCFs. 10 GPs and 7 MAs from 10 different PCFs took part in the interviews. These interviews took place in urban areas in Germany. Table 9 provides a complete overview of the participants in the interviews

Since expert interviews are an established method for analyzing problems in DSR (Österle et al., 2011), we conducted 17 semi-structured interviews (Myers & Newman, 2007). This approach allowed us to gain first-hand insights into how GPs and MAs perceive and experience the processes in their PCFs and how well-informed they are about PGHD. Before the interviews, the participants were informed about the structure and encouraged to give free and open responses. We asked participants for their consent to record the interviews for research purposes. The interviews were conducted in German and English to ensure the participants' comfort and were designed to be conversations rather than strict question-and-answer sessions. We divided the questions into four segments:

- General PCF workflows
- PGHD in general and current workflows related to PGHD
- Barriers to the integration of PGHD in PCF workflows
- Possible solutions to barriers to the integration of PGHD

These categories provided a structured approach to answering our research questions and allowed in-depth exploration of the selected topics.

Data Analysis

We analyzed the data collected during the interviews. First, we transcribed the video and audio data from the first series of interviews. We created a coding scheme to examine the interviews according to Mayring and Fenzl (2019). To do this, we created an initial coding scheme based on the scientific literature on the use and integration of PGHD. In the next step, we refined the resulting codes with the results of the interviews. We then used the coding scheme to code the transcriptions. We extracted the processes and associated obstacles from the interviews based on the results. Finally, we used the coded transcriptions to analyze our results and to expand our interview guides.

Table 9 Overview of Interview Participants

Interviewee	Gender	PCF	Age
GP	male	1	48
GP	female	1	37
GP	female	2	52
GP	male	3	63
GP	male	4	Prefer not to say
GP	male	5	Prefer not to say
GP	male	6	Prefer not to say
GP	female	7	Prefer not to say
GP	female	8	Prefer not to say
GP	female	9	59
GP	male	10	30
MA	female	2	46
MA	female	2	54
MA	female	2	62
MA	female	2	53
MA	female	3	28
MA	female	3	21

5.1.3 **Focus Groups with Patients**

For the survey with depressed patients, we also decided to conduct focus groups, as we did with the healthcare professionals. For this purpose, we conducted three focus groups with 20 patients. An overview of the age of the participants and the distribution between the focus groups can be found in Table 10. We used two different knowledge bases to prepare the focus groups. First, we relied on the results of our literature review to present the fundamental possibilities of using PGHD in the treatment of depression to the patients. We used this knowledge about the collection of PGHD to help patients understand them and enable them to evaluate the most appropriate methods. We also incorporated the results of the first part of this requirements study with healthcare professionals, focusing on the types of data sent to the PGHD and how these are used in PCFs

We structured the focus group process into several steps. In these focus groups, we oriented ourselves to the topics that were discussed:

1. Familiarization Step: During the introduction, the aim was for all those involved in the focus groups to introduce themselves and get to know each other to reduce inhibitions and fear of contact for the later group work. First, the workshop facilitators introduced themselves, followed by a round of introductions from the participants. Afterward, the participants were introduced to the project and the topic of PGHD so that all participants had the same knowledge base for the focus groups. At the end of this step, the participants were divided into groups of 2 to 4.

2. PGHD Step: In this step, we let the participants start with the topic of PGHD. In the first step, the participants were asked to think about what they knew about the concept of PGHD. They were allowed to use all the sources available to them. Furthermore, the participants were then asked to think about what types of PGHD they could record themselves with their current possibilities. The participants should then consider how laborious they would rate PGHD for the treatment of depression and how laborious they would be to collect. They should enter this assessment into a matrix. Then, the participants should rate their five favorites, which they rate as “best” suited for the treatment of depression.

3. Collection Step: In this section, the participants were asked to think about how to collect PGHD. To do this, we first introduced the participants to common technical options for collecting PGHD (e.g., smartphone, smartwatch, smart ring). We then asked the participants to consider which “tools” they would use to collect PGHD (analog and digital). The participants were then asked to rank the ideas they had gathered on a scale from “would not use” to “would use”.

4. Concerns Step: In the last step of the focus groups, the participants were asked to consider their concerns regarding health data and tools for collecting PGHD.

To ensure a consistent foundation, we analyzed the focus group results between sessions but did not incorporate them into the later sessions.

Table 10: Overview Focus Groups Participants

Focus Group	No. Participants	Male	Female	Avg. Age
1	6	4	2	30.8
2	5	2	3	26.7
3	9	6	3	40.6
Overall	20	12	8	31.4

5.1.4 Interviews with Potential Users

In addition to the focus groups, we conducted semi-structured interviews with 16 potential users of PGHD apps. These interviews were used for our qualitative data collection to gain in-depth insights into individuals' experiences, attitudes, and perspectives regarding PGHD. To this end, we developed an interview guide based on the insights gained so far, the focus groups, and the interviews with healthcare professionals.

- Common types of PGHD
- Experiences with healthcare providers
- Data sharing with healthcare professionals
- Barriers to using PGHD
- Use of PGHD for depression
- Collaboration between patient and healthcare provider for PGHD collection

We selected individuals from different age groups and educational backgrounds to capture a broad range of experiences with PGHD apps. Each participant agreed to the terms of the study. As part of our study, 16 individuals were interviewed using semi-structured interviews, with demographic details such as age and gender documented to contextualize the results, as shown in Figure 8. The cohort consisted of 11 male and 5 female participants. The age distribution was as follows: six participants aged 18 to 30, two aged 30 to 40, three aged 40 to 50, four aged 50 to 60, and one over 60. The interviews were conducted in a private setting, either in person or via Zoom, to create a comfortable and confidential environment. Participants consented to audio recording, and verbatim transcriptions were made.

5.1.5 Survey with Patients

In this chapter, we present the quantitative survey on the functionalities and types of PGHD for depression care. For this purpose, we compiled a list of PGHD that we identified as potentially relevant for depression care. These types of PGHD were initially based on our qualitative surveys with healthcare professionals and depressed patients. In addition, we identified functionalities and aspects of PGHD applications based on existing literature. We then categorized these functionalities into meta-requirements. We explain the meta-requirements below. We then created a survey using the LimeSurvey tool (LimeSurvey, 2024) and surveyed N=169 on February 14, 2024, using the online tool Prolific (Prolific, 2024).

Usability

The usability cluster focuses on the fundamental aspects of a PGHD app's design that influence user interaction and overall experience. The questions in this cluster address the importance of an engaging user interface, easy navigation, and responsive design. These features are crucial because they directly influence how easily users can access and utilize the app's features. An intuitive and aesthetically pleasing user interface promotes user engagement, while a responsive design ensures that the app remains functional and accessible on different devices and screen sizes. These questions are intended to explore the importance of user-friendly design. The insights gained from these questions should promote consistent use and enable a positive user experience (Alqahtani & Orji, 2020; Balaskas et al., 2022; Garrido et al., 2019; Oyebode et al., 2020).

Features and Options

This group of questions assesses the features for collecting selected PGHD that a PGHD app should offer to support patient depression management effectively. It includes questions on the relevance of symptom monitoring, mood logs, sleep, physical activity, and appointment and self-care task reminders. These features are critical for a PGHD app because they enable patients to approach their health comprehensively. By querying the relevance of these options, the survey seeks to identify which features are most valuable to users, ensuring that the app can serve as a practical tool in their health management routines (Alqahtani & Orji, 2020; Balaskas et al., 2022; Garrido et al., 2019; Oyebode et al., 2020; Torous et al., 2018).

Affordability and Accessibility

The affordability and accessibility cluster asks participants about economic factors and considerations related to access to a PGHD app. It includes questions about the total cost of the app, insurance coverage, subscription options, and the relationship between the quality of the app and its cost. These aspects are crucial for determining the app's accessibility to a broad user group. By examining users' perspectives on cost-related issues, this cluster aims to assess the importance of the affordability and accessibility of the app while ensuring high quality to guarantee widespread adoption and continued use (Balaskas et al., 2022; Oyebode et al., 2020).

Content and Information Confidence

This cluster of questions relates to the accuracy, reliability, and trustworthiness of the content provided by the PGHD app. It includes questions about the credibility of evidence-based content, the quality of expert material, and the frequency of updates to reflect the latest scientific research and clinical guidelines. These factors are crucial to gaining users' trust and ensuring that the app is a credible health information source. The inclusion of these questions highlights the need for high-quality, accurate content to support informed health decisions and to foster a trusting relationship between the user and the app (Alqahtani & Orji, 2020; Garrido et al., 2019; Oyebode et al., 2020; Torous et al., 2018).

Social Support

The question cluster “social support” asks participants about their assessment of the relevance of functions that facilitate interaction and support among users. In it, we ask about the relevance of sharing experiences, social support from other users, and including features such as social media. These aspects are essential for building a community within the app, providing emotional support, and enabling users to learn from each other. This cluster highlights the value of social networking and support to enhance the user experience and provide a more comprehensive approach to health management. This is how we want to answer whether users want an app like this as a social network (Garrido et al., 2019; Oyebode et al., 2020).

Emergency Support

The questions about emergency support focus on an app's ability to provide immediate assistance and information in crises. This includes the availability of crisis support, the display of support information, and the immediate notification of the user's caregiver in problem situations. The inclusion of these features is crucial to ensure the safety of users and to provide timely support when mental health reaches an alarming level. This cluster aims to understand the patient's perception of the importance of emergency support mechanisms for dealing with urgent health issues (Alqahtani & Orji, 2020; Garrido et al., 2019; Oyebode et al., 2020; Torous et al., 2018).

Security and Privacy

In this cluster of questions, participants are asked about the relevance of measures that can be used to collect and protect user data and to ensure data protection within the PGHD app. Participants rate the importance of personal data protection, informing users about the transmission of health data to their caregivers, and secure login/authentication procedures. Privacy and security are of the utmost importance in health-related apps to protect sensitive information and maintain user trust. These issues underscore the need for robust security and privacy protocols to protect user data from unauthorized access and security breaches (Alqahtani & Orji, 2020; Oyebode et al., 2020; Torous et al., 2018).

Engagement and Motivation

The “Engagement and Motivation” cluster of questions asks participants about features that promote user interaction and maintain interest in the app. Questions are asked about the relevance of not displaying negative results when monitoring mental health (optimistic app design), including missions, rewards, and goals, and providing analysis and visualization tools to track progress. These elements are designed to motivate users to interact with the app regularly, increase their engagement with health management, and facilitate monitoring of improvements over time. This cluster highlights the relevance of appealing and motivating elements to encourage regular app use and promote a proactive attitude towards health (Oyebode et al., 2020; Torous et al., 2018).

Miscellaneous

This miscellaneous cluster collects additional features that could improve the functionality and user satisfaction of the PGHD app but do not fit into the other categories. These include wearable device integration for enhanced health data tracking, regular updates to maintain feature effectiveness, minimized impact on battery and memory usage, data export options for sharing with clinicians, and customer service support. These aspects contribute to the app's overall usability, ease of use, and effectiveness as a health management tool. By evaluating these features, the survey aims to capture a comprehensive picture of what users value in a PGHD app to ensure it meets a wide range of needs and preferences (Alqahtani & Orji, 2020; Oyebode et al., 2020).

Demographics

The online survey was completed by 79 female (48.5%) and 81 male (49.7%) patients, with 2 selecting 'other' and 1 preferring not to disclose their gender. Over half of the respondents were employed full-time (52.9%). Each participant had a history of depression. We provide a full overview of the sample in Table 11. This demographic table provides a comprehensive statistical overview of a specific population sample, detailing characteristics such as age, gender identity, employment status, education level, occupation, nationality, place of residence, and household income in 2023.

The table presents age-related data for 169 people. The average age is approximately 40.86 years, with a standard deviation of 11.91 years, indicating variability in the age distribution. The age range extends from 21 to 75 years, with quartile values at 31 (25th percentile), 39 (median), and 49 (75th percentile). Of the sample, 81 are male, 79 are female, 2 identify as other, and 1 prefer not to specify. The population includes 90 full-time employees, 25 part-time employees, 23 unemployed, 17 self-employed, 6 students, 5 retired and 4 others. Education level varies, with 76 people having a high school diploma, 64 a bachelor's degree, 20 a master's degree, 5 a doctorate, and 3 a partial secondary education. The occupational data shows a wide range of occupations, with 67 classified as other, followed by services and office/administrative, with 21 and 20, respectively. Other areas mentioned include executive/management, healthcare, education/library, engineering, and agriculture/crafts. The majority (155 people) are from the US, with 15 from other countries. Place of residence closely mirrors this, with 166 living in the US and 2 elsewhere. The income distribution spans several categories, with the largest group earning between $50,000 and $74,999 annually (39 people), followed by those earning between $75,000 and $99,999 (28) and those in the $35,000 to $49,999 range (24). Other income ranges range from under $15,000 to over $150,000, showing a wide economic diversity within the sample.

Table 11: Pilot Study - Demographics

Category	Sub-Category	Value
Age	Count	169
	Mean	40.86
	Std Deviation	11.91
	Minimum	21
	25th Percentile	31
	Median	39
	75th Percentile	49
	Maximum	75
Gender Identity	Male	81
	Female	79
	Other	2
	Prefer not to say	1
Employment Status	Full-Time	90
	Part-Time	25
	Not Employed	23
	Self-Employed	17
	Student	6
	Retired	5
	Other	4
Education Level	High School	76
	Bachelor's	64
	Master's	20
	PhD	5
	Some Secondary	3
Occupation	Other	67
	Services	21
	Office/Admin	20
	Exec/Management	18
	Healthcare	18
	Education/Library	12
	Engineering	8
	Agriculture/Crafts	4
Nationality	USA	155
	Other Countries	15
Place of Living	USA	166
	Other Countries	2
Household Income - 2023	<$15k	8
	$15k-$24,999	21
	$25k-$34,999	17
	$35k-$49,999	24
	$50k-$74,999	39
	$75k-$99,999	28
	$100k-$150k	21
	>$150k	12

5.2 **Clinicians' Requirements for PGHD in Depression Care**

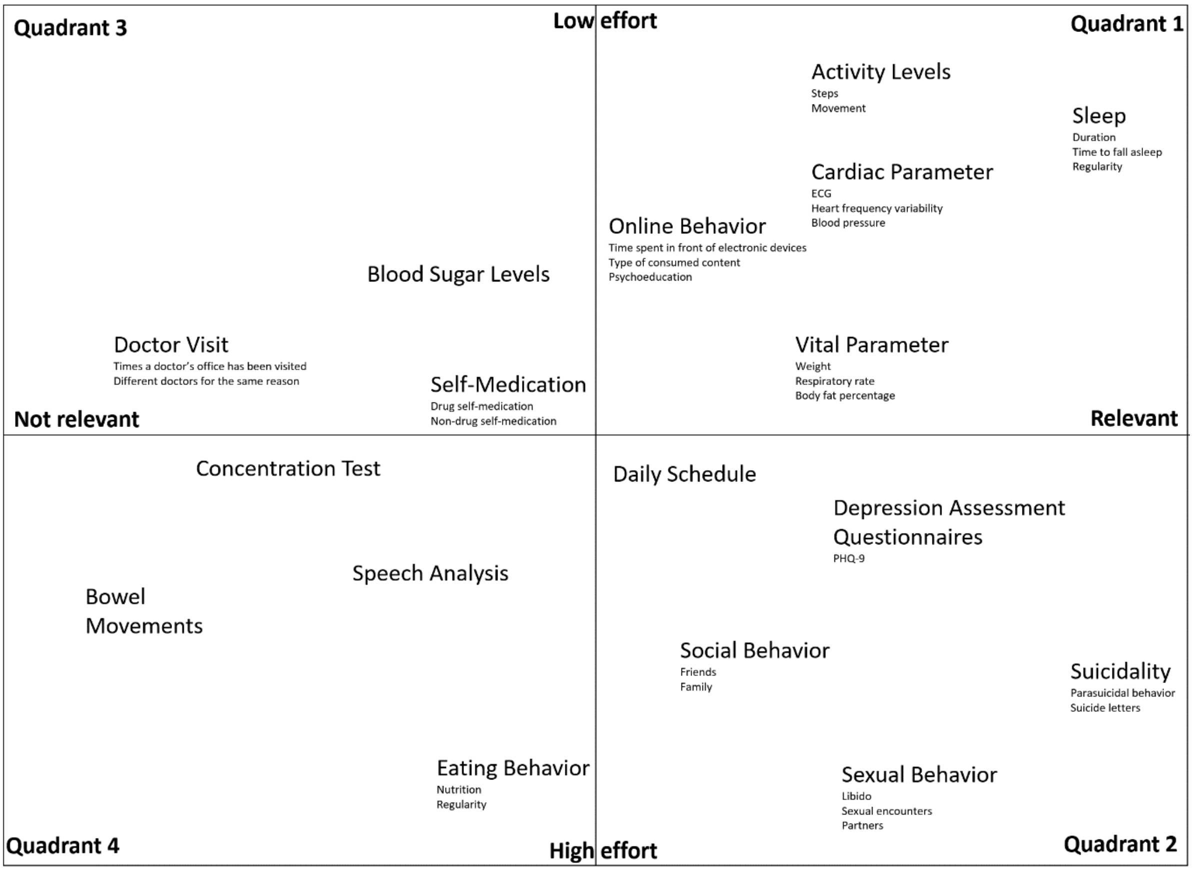
This section describes the requirements for a platform for patients and doctors to treat depression in psychiatric institutions. Our findings are based on all the methodologies described above. We will first discuss the kinds of PGHD healthcare professionals found relevant during the focus groups. We will then discuss the requirements of GPs for types of PGHD collection. We will then discuss the presentation of PGHD to GPs in depression care and the integration of PGHD into the workflows of PCFs. Lastly, we will present our results regarding the barriers to PGHD usage we identified during the interviews.

5.2.1 **PGHD Types**

In this section, we look at which types of PGHD are relevant for use in the treatment of depression in general practice and which are necessary to clinicians. This step is crucial because we can collect a large amount of data from patients, but not all this data is essential for the treatment of depression. Furthermore, the aim of this section is not only to identify relevant types of PGHD but also, of these relevant types, to highlight the data types that are most important to clinicians. The results of this section are based on Reindl-Spanner et al. (2023)

Based on the focus groups, we identified five highly relevant types of PGHD that are also easily collectible from a healthcare professional perspective (Figure 9, Quadrant 1). In the following, we explain each type of PGHD in detail.

Figure 9: Relevance - Effort-to-Collect Matrix of PGHD for the Treatment of Depression (own illustration)



Quadrant 1 (High Relevance | Low Effort to Collect): Sleep, Activity Levels, Cardiac Parameter, Vital Parameter, Online Behavior

Quadrant 1 represents the most relevant and easy-to-collect types of PGHD for the treatment of depression.

(1) **Sleep**: We identified sleep as the most essential element in depression across all demographics, becoming the most significant variable in our analysis. The focus group participants consistently emphasized the importance of sleep data as a crucial parameter in treating depression, even in the initial phase of their discussions. Currently, the medical and psychotherapeutic field relies almost exclusively on patient narratives to understand sleep in the context of treatment. Consequently, the participants stated that incorporating sleep data such as PGHD can enhance the comprehensibility of patient narratives and support the monitoring of depression. By actively utilizing PGHD, healthcare professionals can gain deeper insights into patients' sleep patterns, enabling them to make more informed decisions and potentially improve the effectiveness of depression treatment.

The correlation between sleep and depression has been well-established and is used as a diagnostic feature for depression (Tsuno et al., 2005). The sleep cluster encompasses various sleep-related data, including sleep quality, duration, interruptions, time to fall asleep, regularity, and bedtime. Collecting sleep data has become easy through smartphone apps or smart devices like smartwatches (Ng et al., 2019). This data can be collected passively, with the only requirement being wearing a smartwatch or enabling the recording app. Numerous sleep data collection apps are available in app stores, making collecting sleep data relatively simple and convenient. All participants confirmed the beneficial role of sleep data and activity tracking in enhancing depression care. However, there were variations among participants regarding the specific data points (e.g., sleep duration, time until falling asleep, etc.) considered most valuable for collection and analysis. Most participants identified sleep duration as the primary relevant PGHD in sleep data. However, one interviewee placed significant importance on time until falling asleep, citing its potential significance in assessing brooding tendencies or fear of falling asleep.

(2) **Activity Levels**: Multiple groups identified activity levels as essential PGHD clusters. These participating groups recognized the significance of identifying this type of PGHD and its associated subtypes in the treatment of depression. The participants strongly supported tracking the patient's activity levels, steps, or general movement, emphasizing that minimal movement often indicates a depressive mood and that depression can cause decreased physical activity. The participants testified that monitoring activity levels provides valuable insights into the progression of depression. Additionally, some participants frequently advise their patients to exercise daily to enhance their physical well-being. Research has shown links between physical activity and mental health, indicating that individuals with depression generally have lower activity levels than their healthy counterparts (Paluska & Schwenk, 2000). Collecting activity-level data requires users to always keep their smartphones or smartwatches with them, which imposes minimal restrictions on their daily lives. Patients can actively participate in therapy by utilizing activity data, aligning with the chronic care model (Wagner et al., 1996). The participants also mentioned the concept of gamification during the focus groups, where patients

collecting activity data could be motivated through gamification solutions to increase their daily movement and achieve activity goals. These milestones are significant in the patient's therapy and can contribute to overall mental and physical well-being (Kim et al., 2017). During evaluation, participants consistently found the number of steps and movements helpful in improving the diagnosis and monitoring of depression. It recognizes patient behavioral patterns, which can inform the effectiveness of therapy. Further, the participants also mentioned that steps are essential for cardiovascular diseases and obesity.

"The steps are quite helpful because we have many patients with cardiovascular diseases, overweight, the civilization diseases, which is an essential factor." (GP)

Additionally, participants expressed interest in an "activity level" value derived from various factors such as steps taken, duration of effort, and type of movement. Physical activity and mental well-being are associated, suggesting that individuals experiencing depression tend to engage in less physical activity compared to those who are in good health. They found this comprehensive metric intriguing and associated it with valuable insights.

"Particularly relevant, especially in the context of reduced motivation, in my opinion, is physical activity. I currently have no specific preference, but it seems important that some form of activity occurs concerning reduced motivation." (GP)

(3) **Cardiac Parameters**: All groups consistently emphasized the relevance of cardiac parameters. In our findings, we distinguish "Cardiac Parameters" from "Vital Parameters" due to the frequent comorbidity of heart diseases with depression (Carney & Freedland, 2017). This cluster includes ECG values, blood pressure measurements, and heart rate variability. Cardiac parameters can be collected both actively and passively, with some data types, such as heart rate variability and pulse, being collected passively, while others, like blood pressure, require active collection using dedicated devices (Jim et al., 2020; Nittas et al., 2019). Passive data collection often involves using smartwatches and smart sensors with smartphones.

The clinicians presented two perspectives in support of monitoring cardiac parameters and tracking their values. First, they emphasized that checking cardiac parameters is an integral part of every medical history, and they believed that tracking and displaying these values could facilitate faster analysis. Additionally, a well-documented history of accurately collected data can aid in identifying or excluding severe heart conditions. During depression treatment involving medication, it is not uncommon for antidepressants to have various side effects that can impact the heart. Continuous monitoring of these values allows for ongoing control and assessment.

On the other hand, psychotherapists expressed a different viewpoint. They suggested that when patients experience discomfort, they should note it, and based on changes in pulse or blood pressure, "bad phases" of the patients could be predicted. This information could be employed in therapy sessions to discuss strategies for better coping with such impending situations.

GPs and psychotherapists agreed that actively monitoring and analyzing cardiac parameters can yield valuable insights into optimizing treatment approaches, identifying potential complications, and providing personalized patient care.

The respondents held different perceptions regarding the implemented cardiac parameters. They suggested that these parameters could be consolidated into a single category. Clinicians emphasized the importance of such data in ruling out severe somatic illnesses. In interviews, family clinicians revealed that patients with depression often initially visit their practice for other complaints. It is only during specific questioning by the doctor that the presence of depression is revealed and subsequently diagnosed during the conversation. In such cases, the collected cardiac parameters, such as PGHD, can help facilitate the exclusion of heart disease.

(4) **Vital Parameters**: Vital parameters encompass all data collected from patients related to the body, excluding the heart. Examples discussed during the focus groups include respiratory rate, patient weight (BMI), and body fat percentage. The participating clinicians identified the vital parameters group, like cardiac parameters, as valuable for tracking and presenting through PGHD. In line with the cardiac parameters, participants emphasized the importance of routinely collecting these values during check-up examinations when patients present with depressive symptoms. Furthermore, the participants expressed that these types are also straightforward for patients to collect themselves since no special equipment is required for most values.

These parameters play a crucial role in the somatic diagnosis of depression, alongside cardiac parameters. Specific values, such as BMI, have already been linked to depression and are significant for doctors, as depression prevalence tends to be higher in individuals who are highly obese or underweight (Onyike et al., 2003; Scott et al., 2008). However, one criticism from the patient's perspective is that most of these values require active participation in data collection, making it more challenging for patients. Nonetheless, this data assists doctors in diagnosis and provides comparative values to track improvements or deteriorations during therapy.

(5) **Online Behavior**: The cluster of online behavior encompasses measurable aspects related to individuals' screen time (such as smartphones and computers). The participating psychotherapists primarily proposed tracking the online behavior of patients as a means of monitoring. During the discussion on various types of PGHD, this type was identified as a method for detecting and tracking not only depression but also social media and gaming addictions. The participants asserted that these types of (online) addictions can rapidly escalate into more severe forms of depression. By actively monitoring these types of PGHD, it becomes possible to mitigate or restrict the usage of such services.

Research has linked these data to depression and anxiety disorders, particularly among younger generations (Boers et al., 2019; Maras et al., 2015). Such data includes app usage duration, frequency of app openings, specific app preferences, and overall screen time. Collecting these values can present varying levels of difficulty. Using a single device, data collection is straightforward. However, when multiple independent devices come into play, the data must be consolidated and connected, sometimes across different platforms (Rooksby et al., 2016). Collecting online behavior data can shed light on the excessive usage of electronic devices. Previous studies have identified correlations between excessive social media use and depression (Keles et al., 2020).

Similarly, among adolescents, there are correlations between reduced sleep and excessive use of electronic devices (Boers et al., 2019; Maras et al., 2015). While these factors may not directly cause depression, they contribute to its development. Visual representations of online behavior can aid in psychoeducation, helping patients improve their electronic device usage habits. This, in turn, can create more favorable conditions for long-term depression treatment. Furthermore, participants mentioned that gathering data on patients' engagement with psychoeducation can yield valuable insights into therapy effectiveness.

Participants expressed varied assessments of the type of online behavior. The interviewed psychotherapists actively found it beneficial to include in the integration survey as part of PGHD. Specifically, they highlighted the usefulness of screen time as an item of interest. While the type of content consumed was deemed valuable in some cases, it was generally not applicable to every patient. Young people are the primary demographic to whom these types of data are relevant, as correlations between online addictive behavior and depression are particularly evident in this age group (Maras et al., 2015). In contrast, the GPs actively rejected this type of PGHD integration. They either preferred reviewing it only at the beginning of treatment to assess the presence of addictive behavior or considered its relevance when addictive behavior coexisted with depression.

Quadrant 2 (High Relevance | High Effort to Collect): Suicidality, Sexual Behavior, Depression Assessment Questionnaires, Social Behavior, Daily Schedule

Quadrant 2 represents PGHD types considered relevant for therapeutic use by healthcare professionals but are associated with a high effort to collect by the patients. For that reason, we consider these kinds of PGHD relevant for depression care but less important than the types of PGHD described in Quadrant 1.

Suicidality: Suicidality, by its very nature, is immensely important in depression. For this reason, participants saw a person's measure of suicidality as a relevant source of data. It is important to note that suicidality is extremely difficult to measure as a single data point, and current suicidality screening questionnaires only perform slightly better than random (Franklin et al., 2017). Therefore, participants suggested methods such as measuring parasuicidal behavior as a measure of suicidality. Parasuicidal behavior is understood as any intentional, acute, self-injurious behavior with or without suicidal intent, including both suicide attempts and self-mutilative behaviors (Panos et al., 2014). Some examples are driving too fast, excessive consumption of alcohol and drugs, or writing and sending suicide threats or suicide notes. Understandably, these metrics are also somewhat challenging to capture and require the patient's active involvement.

Sexual Behavior: The sexual behavior of patients may contain further indications for depression (Williams & Reynolds, 2006). The participants pointed out that the libido of the individuals may be significantly reduced. Unfortunately, collecting this data is very difficult, as these topics often cause shame among patients or are considered taboo in various cultural circles.

Depression Assessment Questionnaires: According to the current state of science, these questionnaires are mainly used to diagnose depression, determine its severity, and monitor therapeutic success (Kroenke et al., 2009). Usually, the therapists fill out these questionnaires during the treatment sessions. In a mobile setting, these questionnaires can be completed efficiently via an app and conveniently collectible under normal circumstances. However, the situation is different for patients with depression, as these patients are often lethargic and consider even the simplest activities difficult to handle (Fehnel et al., 2016). Especially patients with more severe forms of depression who have difficulties with the performance of everyday activities such as eating, showering, or keeping their home clean cannot be expected to complete a questionnaire via an app. These questionnaires include the PHQ-9 (Kroenke et al., 2001) questionnaire.

Additionally, the respondents emphasized the importance of depression questionnaires in depression care. However, differing opinions were expressed within the respondent group. Psychotherapists and clinicians were familiar with these questionnaires (particularly the PHQ-9). They incorporated them during initial patient consultations and in the ongoing treatment of depression. The participants noted that the PHQ-9 questionnaire served as a tool for identifying and diagnosing depression and suggested the potential usefulness of a specialized questionnaire for depression follow-up.

On the other hand, two participants mentioned that they do not currently utilize questionnaires in their diagnosis and treatment due to the time-consuming nature of evaluation, despite acknowledging their ability to provide valuable insights. These participants shared that they can often make a suspected diagnosis of depression through patient interviews based on their years of experience and then refer patients to a specialized practitioner. Initially, this group declined to adopt their use. However, as the interview progressed (following the presentation of the platform), they expressed openness to potentially utilizing the prepared data in the future.

Social Behavior: The participants perceived patients' social behavior as relevant information for treatment. Here, the cluster term social behavior is not specifically related to patients' behavior in social interactions but is meant to consider the larger context. Participants understood social behavior to refer primarily to whether, how often, and with whom their patients engage in social activities. Due to the very private nature of this information/data, the participants considered collecting this type of PGHD rather tricky.

Daily Schedule: A documented daily routine of the patients provides the clinicians with valuable insights into the daily lives of their patients. This renders the patients' narratives verifiable. In addition, the data allows clinicians to determine whether the values of other measurement points (e.g., activity levels) are realistic or whether the patients are falsifying the results. Furthermore, these types of data enable the treating clinicians to determine whether the patient maintains a lifestyle that is beneficial in overcoming their respective diseases. This can help the patient to make changes and establish advantageous routines in their daily lives.

Quadrant 3 (Low Relevance | Low Effort to Collect): Self-Medication, Blood Sugar Levels, Doctor Visit

Quadrant 3 represents types of PGHD that are somewhat low relevance for healthcare professionals but effortlessly collectible by patients. Low relevance in this context means this data may be relevant in some cases but not general for depression care.

Self-Medication: In many cases of incipient depression, patients try various home remedies to counteract possible symptoms. Patients also often try to help the healing process with self-medication in addition to the actual treatment (Markou et al., 1998). Exact documentation of this self-medication can help the treating clinician to detect possible interactions and to control the therapy in the best possible way.

Blood Sugar Levels: Blood sugar levels are one of the types of PGHD that have been collected for several decades. As diabetes is a common comorbidity of depression, this type of PGHD is a relevant component for participants, primarily those who have diabetes, in the treatment of depression (Holt et al., 2014; Sartorius, 2022). However, the participants mentioned that tests with non-diabetic patients with depression may be conducted to exclude diabetes as a comorbidity.

Doctor Visit: The number of visits to the doctor's office may indicate that a patient is looking for help but not getting it or that depression is not recognized. Likewise, a possible prescription drug dependency may remain undetected due to frequent visits to several different doctor's offices to obtain multiple prescriptions (El-Aneed et al., 2009). Here, insight into the number and frequency of doctor visits can help the treating clinician (Guo et al., 2017).

Quadrant 4 (Low Relevance | High Effort to Collect): Eating Behavior, Speech Analysis, Concentration Test, Bowel Movements

For completeness, we would also like to list four types of PGHD mentioned in quadrant 4 and thus may be classified as irrelevant to the treatment of PGHD.

Eating Behavior: The patients’ eating behaviors allow conclusions to be made about the body's daily routine and nutrient supply. The participants also pointed out that overeating or under-eating can be indicative of a depressive episode (Frost et al., 1982; Zung et al., 1974).

Speech Analysis: Speech analyses can give the treating clinician insight into the changes in the patient's speech behavior during treatment. So far, this analysis can only be carried out under laboratory conditions; a possible smartphone app can shift this into the realm of PGHD (Pan et al., 2018).

Concentration Test: Concentration tests can provide information about the patients’ cognitive abilities, especially during treatment. Patients must actively complete concentration tests in person or via an app.

Bowel Movements: According to the participants, bowel movements are not necessarily relevant for treating depression but were included in the matrix for completeness reasons. The patients must actively track this data.

Confirmatory Interviews

After presenting the focus group results in the first part of this chapter, we present the results of our interviews, which should confirm the findings. We present the results of the final evaluation interviews, focusing on discussing the relevant types of PGHD for depression treatment and their possible usability in the implemented platform. The presented types are the most discussed types of PGHD the participants of the prototype evaluation interviews assessed.

Sleep. All participants confirmed the beneficial role of sleep data and activity tracking in enhancing depression care. However, there were variations among participants regarding the specific data points (e.g., sleep duration, time until falling asleep, etc.) considered most valuable for collection and analysis. Most participants identified sleep duration as the primary relevant PGHD in sleep data. However, one interviewee placed significant importance on time until falling asleep, citing its potential significance in assessing brooding tendencies or fear of falling asleep.

Activity Levels. Regarding activity levels, participants consistently found the number of steps and movements helpful in improving the diagnosis and monitoring of depression. It recognizes patient behavioral patterns, which can inform the effectiveness of therapy. Further, the participants also mentioned that steps are essential for cardiovascular diseases and obesity.

> *"The steps are quite helpful because we have many patients with cardiovascular diseases, overweight, the civilization diseases, which is an essential factor." (GP)*

Additionally, participants expressed interest in an "activity level" value derived from various factors such as steps taken, duration of effort, and type of movement. Physical activity and mental well-being are associated, suggesting that individuals experiencing depression tend to engage in less physical activity compared to those who are in good health. They found this comprehensive metric intriguing and associated it with valuable insights.

> *"Particularly relevant, especially in the context of reduced motivation, in my opinion, is physical activity. I currently have no specific preference, but it seems important that some form of activity occurs concerning reduced motivation." (GP)*

PHQ-9 and Depression Questionnaires. Additionally, the respondents emphasized the importance of depression questionnaires in depression care. However, differing opinions were expressed within the respondent group. Psychotherapists and clinicians were familiar with these questionnaires (particularly the PHQ-9). They incorporated them during initial patient consultations and in the ongoing treatment of depression. The participants noted that the PHQ-9 questionnaire served as a tool for identifying and diagnosing depression and suggested the potential usefulness of a specialized questionnaire for depression follow-up.

On the other hand, two participants mentioned that they do not currently utilize questionnaires in their diagnosis and treatment due to the time-consuming nature of evaluation, despite acknowledging their ability to provide valuable insights. These participants shared that they can often make a suspected diagnosis of depression through patient interviews based on their years of experience and then refer patients to a specialized practitioner. Initially, this group declined to adopt their use. However, as the interview progressed (following the presentation of the platform), they expressed openness to potentially utilizing the prepared data in the future.

Cardiac Parameters. The respondents held different perceptions regarding the implemented cardiac parameters. First, participants expressed confusion regarding the demo version of the survey, where cardiac parameters were distinguished from blood pressure. They suggested that these parameters could be consolidated into a single category. Clinicians emphasized the importance of such data in ruling out severe somatic illnesses. In interviews, GPs revealed that patients with depression often initially visit their practice for other complaints. It is only during specific questioning by the doctor that the presence of depression is indicated and subsequently diagnosed during the conversation. In such cases, the collected cardiac parameters, such as PGHD, can help facilitate the exclusion of heart disease.

Online Behavior. Participants expressed varied assessments of the type of online behavior. The interviewed psychotherapists actively found it beneficial to include in the integration survey as part of PGHD. Specifically, they highlighted the usefulness of screen time as an item of interest. While the type of content consumed was deemed valuable in some cases, it was generally not applicable to every patient. Young people are the primary demographic to whom these types of data are relevant, as correlations between online addictive behavior and depression are particularly evident in this age group (Maras et al., 2015). In contrast, the GPs actively rejected this type of PGHD integration. They either preferred reviewing it only at the beginning of treatment to assess the presence of addictive behavior or considered its relevance when addictive behavior coexisted with depression.

Additional Types of PGHD. Participants held diverse opinions regarding further kinds of PGHD that are not necessarily implemented in the platform. The participants generally rejected the inclusion of psychoeducation control. However, one participant expressed interest in knowing the specific type of psychoeducation the patient utilizes, as it could enable the recommendation of alternative content.

Clinicians considered vital parameters useful but noted that these are typically collected as part of routine clinical examinations. Conversely, psychologists rejected using such data in their regular treatment and did not consider them as PGHD.

The participants perceived language analyses as valuable by participants. They highlighted that changes in speech patterns or characteristics, such as slowness, could be easily detected during patient interviews.

Regarding eating behaviors, participants acknowledged their usefulness in the context of comorbid eating disorders and depression. However, they indicated that integration into therapy goals would be necessary to pursue this data type actively.

Opinions varied among participants regarding the collection of data on daily routines. While some recognized their potential benefits, particularly in understanding social behavior, concerns were raised regarding the intrusive nature of monitoring and possible privacy issues. Data protection was a common concern expressed by many participants.

5.2.2 PGHD Collection

This section describes the types of PGHD collection that GPs considered during our focus groups and interviews. Exploring this issue is essential as the introduction of PGHD into clinical contexts is often associated with doubts about the trustworthiness of data collected from patients

(Huba & Zhang, 2012; Nittas et al., 2019; Reading & Merrill, 2018; West et al., 2017). This section provides an overview of how clinicians should assess the different types of PGHD and develops clinicians' assessments of which kinds of collection are most appropriate for patients.

Based on the evaluation of the types of PGHD by the healthcare professionals during the focus groups, tendencies towards various technologies can already be seen:

For quadrant 1 **(High Relevance | Low Effort to Collect)**, most healthcare professionals suggested using technical solutions based primarily on passive tracking. Thus, healthcare professionals suggested collecting activity levels via steps or time of movement quickly and efficiently via smartphones or wearables such as smartwatches. For the collection of sleep data (e.g., duration, regularity, time to fall asleep), the participants suggested using sleep-tracking apps or wearables with integrated features to track sleep and activity precisely. These technologies mentioned so far also include tracking options for cardiac parameters. Wearables such as smartwatches, smart rings, or chest straps can precisely and reliably measure the pulse or heart rate variability. Healthcare professionals have also suggested using the classic solution of measuring blood pressure and recording values. In contrast, digital and analog data collection methods could be used for the vital signs data class. For the last data cluster of online behavior, apps that primarily monitor and record patients' smartphone use will be used.

For quadrant 2 **(High Relevance | High Effort to Collect)**, the healthcare professionals also proposed technical solutions, primarily based on active tracking and patient participation. For assessing depression via questionnaires, for example, the classic type of paper questionnaires can be used, which are then completed by the patient at home. On the other hand, these questionnaires can also be completed digitally on a smartphone using apps. The suicidal tendencies or sexual behavior reported in this quadrant can also be surveyed in this analog or digital way. The healthcare professionals also considered the tracking of social behavior via journaling to be feasible.

For quadrant 3 **(Low Relevance | Low Effort to Collect)**, the participants primarily suggested using reminder apps and tracking medication and self-medication in smartphone apps for monitoring doctor visits and self-medication. For recording the blood glucose values mentioned, the participants suggested using modern digital solutions with invasive sensors, as the data is then recorded digitally directly on the patient's smartphone or dedicated device and can be easily transferred to the PCF's digital patient records.

For quadrant 4 **(Low Relevance | High Effort to Collect)**, the participants only suggested recording the data points in this sector via dedicated apps, as data recording is already complex in the clinical setting.

Active and Passive Monitoring

In addition to considering data collection methods, we also learned about GPs' views on collecting PGHD through active and passive data collection methods.

At various points during our focus groups, participants suggested passive methods for collecting PGHD. There were several reasons for this. First, the respondents felt that passive collection methods were less invasive and would place fewer restrictions on patients' daily activities. This would allow depressed patients to use the techniques without being restricted in their daily lives. In addition, patients would not have to remember to collect the data themselves, and they would only have the task of always carrying the tracking devices. Second, they argued that passive methods are less likely to lead to changes or distortions in the collected data and thus increase their reliability. Patients are less likely to fake their data over the long term since changing data collection with wearables or smartphones is difficult. As a final point, the GPs said that using passive collection methods would probably result in fewer gaps in the collection process. This would ensure a seamless, continuous collection of PGHD.

Although passive data collection methods were considered most helpful in treating depression, the participants acknowledged that active data collection is essential in some cases. For example, when the data collected is highly relevant to treatment (e.g., depression questionnaires for depression or blood pressure readings for hypertension), it can provide valuable insights and is often only meaningfully collectable through active methods. Another situation in which active data collection was deemed necessary, according to the participants, was when patients needed to be encouraged to develop routines through certain daily activities. In such cases, keeping a diary of daily activities could provide insights for the treating psychiatrist and help the patient create useful routines for managing their illness. However, GPs expressed concern that it could be difficult for patients in severe cases to provide regular active updates in an app.

> *“I could imagine that the patient provides regular updates via the application, but I don't think it would work for severe cases because they must take action themselves. It's also very individual...” (GP)*

Finally, we also found during the focus groups that the GPs considered a combination of active and passive methods instrumental. For example, this combination could track sleep and activity data passively and supplement it with subjective data, such as a mood barometer that patients must fill out.

5.2.3 **PGHD Presentation**

In the clinical setting, caregivers and clinicians understand that patient trends and behaviors outside clinical settings are just as crucial as observations made during visits. The introduction of mobile health monitoring devices such as smartphones, smartwatches, and fitness trackers has changed public perception, allowing individuals to monitor their health data from home via sophisticated device visualizations. This shift has sparked a growth in consumer-driven health technologies and applications, highlighting valuable data points such as mood, activity levels, diet, and environmental factors that interest clinical practitioners (Wood et al., 2015). Improved collaboration with healthcare professionals could significantly impact healthcare systems and improve treatments and patient outcomes while reducing costs (Gotz & Borland, 2016).

On the other hand, several barriers stand in the way of using PGHD and visual analytics effectively. Clinically, data is unstructured, voluminous, and often of low quality, presenting significant challenges in deriving insights. Clinicians and patients usually prefer direct interaction to analyzing data during brief clinical visits (Ryokai et al., 2015). Furthermore, issues extend beyond data collection to visualization challenges, such as presenting comprehensive patient stories, creating compelling user interfaces, and making data meaningful to all users. Privacy concerns and the potential for misinterpretation further complicate the sharing and use of this data, emphasizing the need for careful data handling and guidance (Huba & Zhang, 2012). Effective communication of PGHD through visual tools is complex and requires considering different stakeholder perspectives and realizing that a universally perfect solution is unattainable. Addressing these issues involves navigating and optimizing trade-offs between various aspects of healthcare data use (Belle et al., 2015).

That is why we also examined how patient data must be presented during our qualitative research with healthcare professionals. This is particularly important in the context of GPs, where there is a lot of time pressure. In this section, we focus primarily on the general presentation of the data and how critical values or deviations can be identified quickly.

Data Presentation

In the context of primary healthcare, the application of PGHD significantly depends on the effective visualization of the collected data. Data visualization refers to the crafting of graphical visualizations aimed at illustrating data. Such visual representations predominantly serve a descriptive purpose, focusing on unprocessed data and elementary summaries. These visualizations may incorporate the portrayal of altered data. Notably, one practitioner's interpreted statistics might constitute raw data for another. Analogous to other dimensions of graphical work, establishing a consensus on foundational concepts and terminology would greatly facilitate further development in this domain. The overarching objective is to render data and statistical analyses visually, thereby enabling the interpretation of these visual cues to deduce meaningful information.

Furthermore, the interviews revealed that the focus group participants had specific requirements regarding presenting the types of PGHD: They actively sought a clean view of the collected types of PGHD, aiming to see the core data at one glance. A key idea they emphasized was reducing the data to a few crucial data points. Clinicians desired an overview encompassing all the collected data, highlighting values that deviated from the norm. This presentation would enable them to identify any abnormal values quickly without difficulty. On the other hand, psychiatrists preferred visualizing the data as progress curves. Both groups expressed the need for detailed options within the overview to explore the data further.

Severity Assessment

A crucial component of the GP-specific digital platform is the systematic evaluation of PGHD. All stakeholders involved emphasize the need for this analysis to maximize the platform's utility within the limited consultation time. For each PGHD category, such as sleep, data collected over time should be synthesized to assign a severity rating. This process is designed to augment, not replace, the GP's judgment, directing their focus to pivotal areas through effective visualization. This approach to PGHD severity rating is central to much of the platform's functionality and is thus discussed independently of other features.

Before PGHD evaluation, aggregation of the raw data is essential, with a 7-day average for each PGHD type recommended as a practical basis for analysis. This approach aligns with medical insights that suggest depression symptoms and disease progression often fluctuate weekly. It is essential to mitigate the impact of daily extremes, focusing instead on weekly trends to give a contextual overview. These aggregated values are calculated over the last seven days up to the current day, not by calendar week.

For the presentation of the severity assessments, we were able to develop three options in the qualitative surveys. These methods apply to all types of PGHD that we have presented in quadrant 1 of Figure 9. Data types such as the PHQ-9 results, which have an established clinical scale, should continue to be assessed and presented according to their established scale. Three levels of severity are proposed for the remaining PGHD types: normal/mild, moderate, and severe. “Normal/mild” includes data indicating healthy ranges or minor deviations. “Moderate” indicates more significant deviations that pose a higher health risk, while “severe” represents critical deviations, indicating serious health concerns

- Severity assessment can be based on absolute thresholds or changes over time and can consider the core categories of the platform for PGHD (sleep, physical activity, and cardiac parameters). The proposed method combines absolute thresholds with relative deviations for a hybrid severity assessment that is intended to be universally applicable and adaptable to other types of PGHD

- The participants also proposed a relative severity assessment without defined absolute thresholds, focusing on intra-individual differences rather than patient comparisons. This method compares a patient's current and historical data to provide personalized insights into health trends. Supported by expert interviews, it is valuable for identifying irregularities and supporting GPs in patient care.

5.2.4 **PGHD Workflow Integration**

In this section, we describe the process of integrating PGHD into PCFs and present the identified barriers to integration. In the interviews, we identified different ways of integrating PGHD into GP practices. First, we must distinguish two general cases for using PGHD in primary care. In the first case, the patient is treated for an illness over a more extended period in a PCF and collects data about themselves to treat it. This is the case for conditions such as diabetes or chronic heart disease, where the collection of PGHD is already established. Notably, these patients are usually known to the practice and ask for their data upon admission.

In contrast, many patients collect data about themselves when symptoms occur and then bring these data to practice independently. This case differs from the one described above in that patients are newly treated for the disease, and it is also not common for patients to bring PGHD with them to their first visit to a GP practice.

In our described case, we do not distinguish between new patients (or patients newly treated for an illness), but rather, depending on the case, whether the MAs ask for the data. Furthermore, we assume that in each case of our described process, the patient brings PGHD into practice. If the patient does not receive data, he or she will be treated conventionally.

PGHD Integration

After the patient has decided to make an appointment for an examination in the PCF, the process of PGHD integration in the doctor's office begins. After the patient arrives at the PCF for their appointment, there are several ways that the PGHD can be integrated into the workflow.

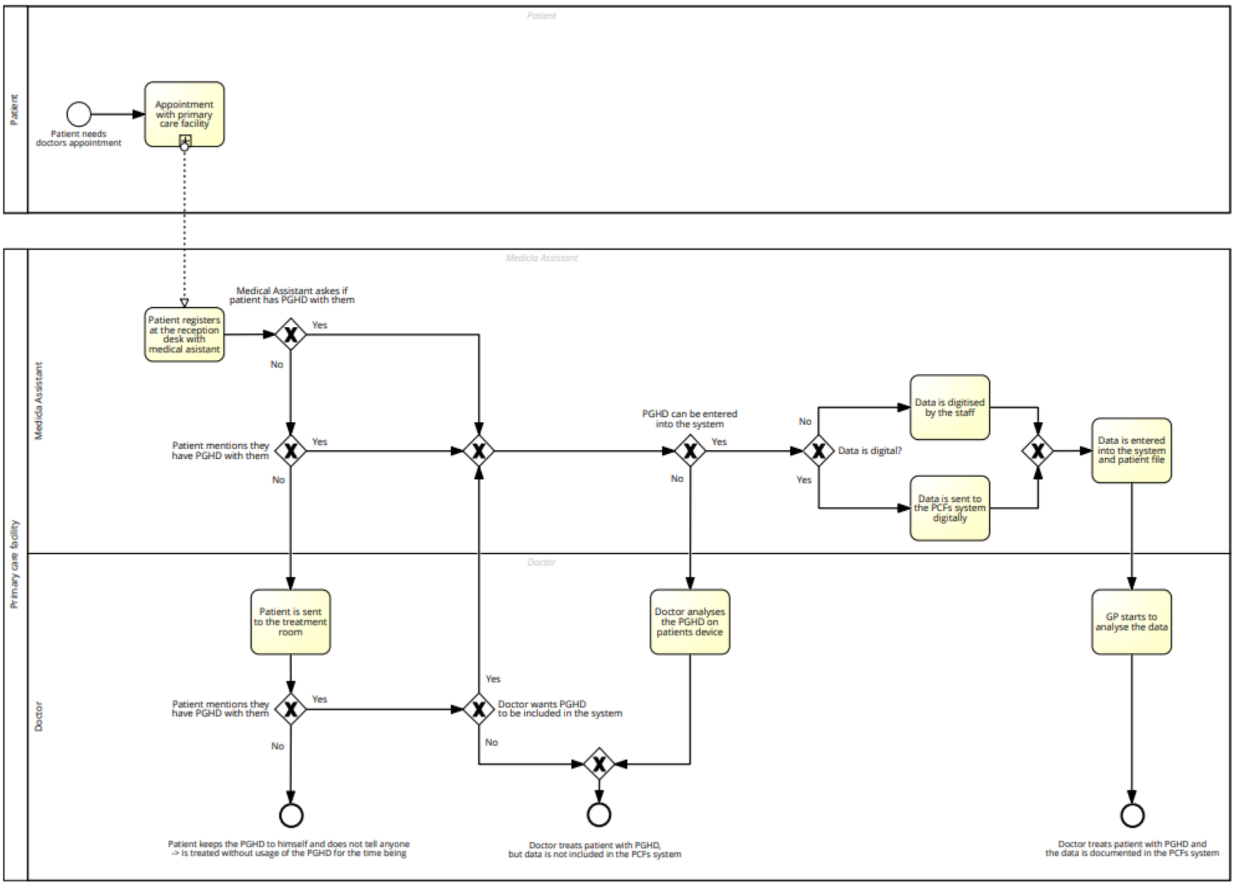
Two primary cases exist where this data can be entered into the PCFs system. In the first variant, the data the staff transfers the data at the PCF reception desk. This transfer is based on the MA asking the patient whether they have brought data for the doctor or proactively informing the MA that they have data with them. In the second option, patients do not hand in the data at reception but bring it directly to the treatment room. Here, patients either tell the GP that they have brought PGHD with them or do not tell them, which results in the doctor treating them without the data. If the patient informs the GP, they must decide whether to document or view the data in their practice system. If he chooses not to report the data, he will view the data directly in the form provided by the patient and then continue with his usual treatment. If the doctor wishes to document or view the data in his file, we have found that most patients are either sent back to reception or a doctor's assistant is brought into the treatment room and then takes the data for system transfer.

After the MA receives the PGHD (either at the reception by the patient after entering the PCF or after the patient informs the doctor during the treatment), they check the data to see if it can be added to the system. If the data cannot be added for any reason, the patient is again treated without documentation of the data by the doctor.

After checking the data, there are typically two options from which the data can be obtained. Either the patient brings analog data (usually in paper form) or digital data (in apps or PDFs) on a smartphone or similar device to the practice. With both options, we have found that analog data in the form of printouts is mainly brought into the PCF, and digital media is still hardly used to transmit PGHD. In the analog case, the data is integrated by copying or scanning the data, whereby the scans are then attached to the digital file and copied to the analog file. Digital solutions usually email this data to the PCF and attach it to the file. Depending on the PCF, the data is printed to be available to the doctor on paper or recorded in the PCF's digital system. After this step, the data is available to the attending clinician for treatment. Finally, the doctor then treats the patient using the Integrated PGHD data.

One interviewed GP mentioned that there is currently no way to submit PGHD directly to the PCF using a health application. Therefore, patients must visit the PCF to submit their data in person. Furthermore, respondents stated that it is common practice to copy only the crucial data as not all data recorded is of clinical importance. The process is illustrated in Figure 10.

Figure 10: PGHD Integration Process (own illustration)



PGHD during Treatment

GPs use PGHD in many ways during patient treatment. In this section, we investigate the use of PGHD during patient treatment. Once the data has been transferred into the clinical workflow, the next step is for the patient to consult with the doctor and engage in a classic patient-clinician interaction. The interviewed GPs mentioned different approaches during this stage. In the first case, the collection of PGHD is planned and instructed by the GP. In this case, the doctor orders (in agreement with the patient) that data will be collected, which data will be collected, and how this data will be collected. Then, during the patient-clinician interaction, the GP and the patient briefly review this data and, if necessary, address it during the consultation. However, if the data shows no anomalies or reason for action, it is only added to the patient file for documentation.

> *"Yes, we work with some PGHDs that are recorded by patients themselves to document their mood and symptoms, for example. At the moment, however, these are almost exclusively paper-based documents filled in by hand." (GP)*

In the second case, patients bring the data they have collected to the PCF without a doctor's order. The attending clinicians then include this data in the consultation and discuss it with the patients. The interviewees noted that while patients may already be recording health data through their smartphones or wearables, the systematic utilization (if not ordered) of this information is not currently integrated into the consultation process.

> *"If patients are already recording data with their smartphone or wearable, the data can briefly be discussed during the consultation, but we do not use it systematically." (GP)*

Treatment Changes through PGHD

Most of the interviewed GPs mentioned that integrating PGHD through health apps into the treatment process creates a heightened sense of responsibility for one's health. Incorporating PGHD into primary care workflows encourages active patient engagement, offering a comprehensive overview of their health status through continuous monitoring and regular logging of health conditions. This increased patient involvement motivates self-oversight, addressing the inter-appointment gap in primary care where constant monitoring is lacking. In this context, a GP stated:

> *"It leads to the patient engaging more with their illness and taking greater responsibility for their health." (GP)*

The interviewees highlight the advantages of PGHD in PCFs, underscoring the significance of accessing a patient's digital or readily available health and medical history. This documentation is valuable for ongoing treatment and can influence future treatment strategies, addressing challenges such as medication variations or treatment assessments among doctors. The efficient utilization of PGHD is emphasized for a comprehensive understanding of a patient's medical history, preventing redundant work and ensuring uniform documentation across healthcare providers, particularly for GPs who serve as the primary overseer of a patient's healthcare and facilitate referrals to specialists. The fact that not only the GPs are involved in these processes but also the MAs play a crucial role in the PCFs and the treatment of patients is shown by the MA's statement on how helpful PGHDs can be for planning doctor's visits.

> *"That you can look more quickly and across the board at what other doctors have commissioned, what has changed. Also, especially between hospitals, you look at what has changed with the medications so that you don't have to create the medication plan repeatedly [...] That would be helpful if, for example, by reading the medical insurance card, you could somehow see what has been prescribed to the patient, what the patient needs, or what the patient has already received from another doctor so that we don't have to issue it twice and three times." (MA)*

Integrating health apps into PCFs can be beneficial in treating "standard conditions" because a doctor is not always required. GP 1 urges the integration of PGHD for all "standard conditions" or "standard diseases". Under these terms, we are supposed to understand very prevalent diseases that do not always require a doctor. These diseases can vary from blood pressure issues to obesity and even certain stages of depression. In these cases, a doctor might not always be needed to treat these standardized issues; the patient needs someone to urge them to act according to what is required to tackle their health issues. This can often be achieved by a health app or other digital devices and could prove of great assistance in primary care if implemented in the right way:

> *"Whether it's high blood pressure, obesity, depression, or any other common condition...yes, those kinds of standard cases. I always talk about standards, starting from scratch. If you need to lose weight, then you must exercise." (GP)*

> "Oh well, I don't need a doctor for that." *That's obvious, but sometimes you need to hear it, and there should be some authority behind it, right? I would really, really like to have access to that." (GP)*

Improvements for the Integration of PGHD

This section presents insights into healthcare professionals' opinions on PGHD integration in PCF workflows. We identified a general process of integrating PGHD with primary care workflows. However, this process is neither optimized nor standardized for PCFs. Based on the process, we were able to identify two basic possibilities for optimization.

The first option to optimize the process is a general solution, but it can save resources and time to include the PGHD in the practice system. It should be standardized that patients are asked directly at the registration desk each time they enter the practice whether they have brought any data that should be considered during the examination. This can prevent patients from discussing their data in the treatment room (provided they do not conceal it at the entrance). Qualitatively, this can prevent the patient from forgetting that data is available, the patient only reporting the data in the treatment room, which means that the treatment does not have to be interrupted or disturbed by the documentation and that the patient himself has to point out the data to the MA proactively.

The second way to advance the data integration process in GP practices is to provide a standardized digital interface for patients. Such interfaces can enable patients to enter data directly from home into the practice's digital file under their name. Possible patient allocation problems could be resolved with little effort by the MAs. This would make it possible to skip or simplify the steps in digitizing and entering data into the system on-site. Even if the assistants still ask for the data, the reference to the data could be given directly for treatment. Providing such an interface can also simplify the integration of digital data into the practice software. Sending emails creates significant overhead for the MAs. Using a standardized interface can significantly reduce the number of emails and the associated number.

The third option is a standardized visualization for doctors. The introduction of a standardized interface also enables standardized use of PGHD, as the integration of the most common data types for PGHD can be set up directly. This enables uniform visualization of the data. This uniform visualization means the data can be better integrated into the patient-clinician consultation. In this way, it can be avoided that doctors only take a quick look at the data, even for new patients, as the amount of data is often not manageable for the doctors. By unifying and standardizing the presentation of the data, both the most important data points can be viewed in isolation, and the period of interest for the existing symptoms can be narrowed down. This ensures that essential data is not overlooked.

5.2.5 PGHD Usage Barriers

In addition to the identified processes in PCFs, the interview participants had different views on using PGHD in PCFs. In doing so, we identified barriers to using PGHD from employees' perspective in GP practices. We have identified six barriers to using PGHD in PCFs, which we will describe below.

Information about Health Apps and PGHD

Our interviews showed that many GPs still use analog forms of PGHD. GPs stated that they perceive a deficiency in knowledge about how healthcare applications are utilized, their practical application, and the effective patient prescribing methods. The GPs expressed concerns about the limited evidence supporting the long-term effectiveness of health applications. Additionally, there is a prevailing belief among GPs that there is insufficient information regarding the appropriate prescription of health applications for patients. Given that the prescriber is not necessarily the end user, and many health apps require a prescription for download, GPs note a lack of familiarity with the intricacies of these apps' functionality. They rely on expert recommendations to select the appropriate application to address specific conditions. Furthermore, GPs highlight that information gaps exist not only on the prescriber's side but also on the user's end. Overall, there is a demand for more comprehensive information on health apps, and GPs express that with enhanced details, they would feel more at ease with health apps and PGHD in general.

> *"There is a need for more information about health apps,*
> *including long-term studies to determine their effectiveness and*
> *benefits." (GP)*

Data Privacy and Data Security

Using PGHD and Health Apps in PCFs raises data protection and privacy concerns. Because these applications collect and use sensitive information about the patient and their health condition, some GPs and MAs are concerned about potential privacy risks. The active registration of sensitive information involved in collecting PGHD through health apps is highlighted as a primary concern for privacy. The concerns extend beyond active collection to passive collection through continuous measurements throughout the day or over an extended period. Providers express anxiety about potential data leaks, emphasizing the risk to patients. The interviewees further indicated concerns about unauthorized external access to the data, recognizing the sensitivity of the information and the potential serious harm to the patient's well-being in the event of unauthorized data access. Both GPs and Mas raised these concerns:

> *"Yes, for data protection reasons. [...] But if it includes*
> *additional data, especially the health insurance number or other*
> *sensitive information, I would not approve of it..." (GP)*

> *"I think my concern would be more about data security. Who could potentially access these apps and misuse the information to harm the patient." (MA)*

Data Misinterpretation by Patients

A further concern of certain interviewees is that patients may not interpret data accurately, leading to potential misjudgment. There is a concern that patients might misinterpret entirely average values, causing unnecessary panic. The extensive collection of data, some of which may lack broader contextual relevance, contributes to this issue. Although the significance of such data is limited, it still induces a sense of urgency among patients, leading to anxiety and panic. Patients lacking the expertise of healthcare professionals may react anxiously to minor irregularities in health metrics, such as a slight irregularity in heartbeat or a temporary spike in blood pressure. Continuous health monitoring can increase anxiety, particularly for patients already subject to health-related concerns.

Furthermore, the misinterpretation of data by patients results in increased visits to PCFs, where anxious patients seek reassurance despite their metrics not indicating any actual medical issues. Multiple GPs have expressed this concern during the interviews. In this context, GP 2 emphasizes that the data collected can overwhelm patients and lead to anxiety and insecurity, even though the data does not represent a problem:

> *"Some of the collected data can be overwhelming for patients, as they may not be able to interpret or evaluate it accurately. This can lead to additional anxiety and uncertainty. [...] The comprehensive monitoring provided by these apps introduces many physiological data points that patients were previously unaware of and did not have to manage." (GP)*

Patient Preoccupation and Sensitization

Collecting and analyzing PGHD by patients can lead to an excessive focus on the data for some patients. The benefits and objectives of patient use of PGHD collection and utilization may be reversed. GP 1 points out that the data collection intended to encourage patients to pay more attention to their health and be mindful of their illness can lead to excess patients being preoccupied only with the data and its (mis)interpretation.

> *"People are becoming more sensitive about their health. [...] These kinds of situations can contribute to hypochondria. Some individuals become overly preoccupied with their health..." (GP)*

There is also the problem of patients being too fixated on data collection and analysis. MA 3 states that this results in patients' dependency on monitoring and that this over-fixation on their health can lead to an increased frequency of (unnecessary) doctor visits. This problem can lead to the PCF overflowing and patients who need treatment not being able to receive it.

> *"I see the issue primarily lying with the patients, particularly those who are anxious and tend to fixate on their health. They*

> *become excessively reliant on monitoring and often reach out, expressing concerns that something is wrong." (MA)*

Patient Self-Assessment

GP 3 underscores the concern that each patient interprets and collects data differently, making it challenging to draw definitive conclusions from PGHD (in the context of actively collected data). Similarly, subjective perceptions of emotions, such as pain, further complicate the interpretation of data. Since, for example, pain is subjective and varies from person to person, relying solely on a pain diary may not yield a precise diagnosis or prognosis; it can offer an overview but is insufficient for a comprehensive assessment. While actively collected types of data provide the potential for wrong input, passively collected data can also be inconclusive and not add additional value to the interpretation of a disease.

> *"The interpretation that individuals have of their symptoms can vary. [...] Not everyone can accurately assess their own condition, which is why not everyone may benefit equally from certain digital tools. I consider this too complex for an app." (GP)*

Data Precision and Trust

Moreover, a concern that requires improvement within health apps is the accuracy of the collected data and the connected interpretation of the data through the application used. As noted by MA 5, the technology's precision is not consistently reliable. Patients have expressed dissatisfaction with primary care professionals, citing instances where the applications inaccurately labeled their current activity, such as recording "sleeping". In contrast, the patient is awake and engaged in work. Additionally, some patients report discrepancies, like the device registering "cycling" while simply showering. Such inaccuracies pose a risk of flawed data collection, potentially resulting in misinformation about the patient's actual health status.

> *"Sometimes the accuracy. With some devices, you notice that they are more accurate during the day when you've been active, while with others, you check the time and think, "I was sleeping, I was awake, I was sitting at the computer," but the device shows something completely different. On the one hand, the touch feature is great, but you often hear, "Yeah, I stopped using it because while showering, it suddenly indicated cycling." (MA)*

In summary, we found in the interviews that there are significant barriers to integrating PGHD into primary care processes. These include insufficient information about health apps, concerns about data protection, risks of data misinterpretation by patients, excessive patient focus on the data, differences in self-assessment, and inconsistencies in data precision. These challenges highlight the need for improved guidelines, data security measures, and user-centered designs to support the effective use of PGHD in primary care, promoting patient engagement while avoiding overburdening practices or risking misinterpretation.

5.3 **Patients' Requirements for PGHD in Depression Care**

This section describes the requirements for a platform for patients and GPs to treat depression in a primary care setting. Our results are based on all the methods described above. First, we will discuss the types of PGHD collection deemed acceptable. We will then discuss the types of PGHD from the patient's perspective for depression care. After that, we will present the communication of PGHD and the concerns regarding the use of PGHD from the patient's point of view. Finally, we will present our results on the functionalities of patient apps.

5.3.1 **PGHD Collection**

Traditionally, PGHD data on mental health has mainly been collected using self-report questionnaires. However, these subjective methods are subject to biases such as recall inaccuracies or subjective misreporting. Technological advances have produced various devices and sensors capable of capturing physiological and behavioral data, leading to a distinction between active and passive PGHD survey methods (Betthauser et al., 2020; Levine et al., 2020). Active data collection requires patient involvement in recording or entering data, such as filling out surveys or manually logging information, but is limited by potential subjectivity and an inability to detect and address mental health issues early (Levine et al., 2020; Opoku Asare et al., 2021). In contrast, passive data collection uses sensors in smartphones or wearable devices to collect data continuously and objectively without patient initiation, although external variables can influence them (Levine et al., 2020; Sheikh et al., 2021).

Combined methods approaches are also emerging, consisting of active and passive data collection using self-reported mood questionnaires and passive data such as location and communication patterns for improved mental health monitoring (Betthauser et al., 2020). Approximately 15% of the studies analyzed use both types of data collection, indicating the perceived feasibility of this integrated method. In addition, passive data collection research often uses active methods to establish ground truths for analytic or machine learning validation. For example, Canzian and Musolesi (2015) investigated correlations between GPS-tracked mobility and depressive states, augmented by active symptom self-reports. For example, Canzian and Musolesi (2015) investigated correlations between GPS-tracked mobility and depressive states, augmented by active symptom self-reports. This duality is reflected in the categorization of studies in the research, with the designation “active” reserved for methods that involve direct participation by the participants, even if they are used to support predominantly passive data collection strategies for monitoring mental health.

For these reasons, this thesis must determine the acceptability of possible types of PGHD to patients. In this section, we present the results of the focus groups with patients and the interviews with potential users of PGHD apps.

First, we asked the participants in the focus groups to brainstorm the types of PGHD that could be considered. The participants created lists in smaller groups in which they collected the species. Based on these lists, the participants were asked to collect the compiled PGHD species and rank them on a scale from “Would not use” to “Would use”. It did not matter what data type the collection method was used for. The task was only about evaluating the “technology” and the associated potential effort based on the given criteria (potential use), not the associated data types. We, therefore, distinguish between four categories of collection methods:

Most preferred: Under this category we categorize methods for collecting PGHD that the participants classify as most suitable for collecting PGHD. The participants mentioned that the smartphone is often used to collect PGHD passively. Smartphones are very easily accessible because they are already omnipresent in the population and can, therefore, be easily integrated into everyday life to collect PGHD. As smartphones do not collect this data independently, the participants always mentioned the smartphone in combination with an app, so the smartphone represents the technical device, and an app for collecting or collating the PGHD represents the actual interface. These methods were directly followed by wearables such as smartwatches. There were mainly positive statements about smartwatches. The participants could imagine using them daily and collecting different data with them. Wearables also include smart rings, although these were rated differently depending on gender. While women found smart rings appealing, some men found them strange and could not imagine wearing them daily.

Preferred: In the second category, data collection methods were categorized as slightly less appealing to the participants than in the first category. This category primarily includes methods or applications for collecting PGHD that can be used digitally but are not as widespread as the strongly preferred methods. These methods include smart bracelets that can be used to collect data. In contrast to smartwatches, these wristbands can collect data but do not provide any feedback to the user and can only be read out via a smartphone app. This was assessed differently by the participants. One group found this a valuable approach because they are not overloaded with information. For others, however, the information was too little. Smart glasses were also included in this category. However, these were seen more as exciting alternatives to other wearables. Other methods here include digital apps such as tracking through calendar entries or digital tools for maintaining a diary.

Moderately preferred: This group includes the methods for collecting PGHD that received balanced participant ratings. This includes both digital and analog methods for collecting PGHD. While analog questionnaires in paper were rated very negatively, the participants could imagine filling out questionnaires digitally using a smartphone app. This also includes abbreviated measurements, such as stimulation barometers, filled out in an app. In addition, smartphone functions such as location trackers, cell phone usage, or the smartphone camera were used to generate data. Methods such as collecting weight data by using a scale were also mentioned in this category. Compared to the smart rings for women, the rings for men were placed in this category.

Least Preferred: Least preferred by participants were conventional methods that are either analog or require dedicated devices. These include tools such as questionnaires, heart rate monitors (not built into smartphones or wearables), activity trackers (not built into smartphones or wearables), blood pressure monitors, notebooks, emotion diaries (analog), and diaries/daily routines (analog). These methods are mainly manual or analog and require significant user input to collect and manage data. Participants rejected these collection methods primarily due to the high level of active engagement and could not imagine using them daily.

In the interviews, we asked the participants what barriers to collecting PGHD were and what factors influenced their ability to collect PGHD. An overview can be found in Table 12. A recurring theme was the desire for simplicity and minimal effort in data collection, with 11 participants particularly highlighting the poor usability of apps. They preferred apps with user-friendly interfaces that included checkboxes or simple yes/no prompts to enable efficient data collection. Digital tools, especially smartphones, were desirable for accessible data collection, with visualizations such as charts and summaries encouraging motivation for regular use. In addition, the participants preferred digital solutions to paper-based analog tracking methods. The main advantage here was the ability to summarize the digital data. Nevertheless, selecting suitable apps was a challenge for 11 participants, as the difficulties in finding a user-friendly app for fluid recording showed:

> *"I looked for an app like this before and wanted to input something, but so far it has all been very laborious. So I didn't do it." (P9)*

These factors, including the need for recommendations for trusted apps or common technical issues, highlight the barriers to effective PGHD recording. Furthermore, there was also a preference for passive data collection methods, consistent with the general feedback from the focus group participants. The emphasis on app user-friendliness, free access, and reminders for consistent data collection are crucial considerations when developing user-centered digital health tools that simplify data collection and improve user retention.

To summarize, the spectrum of data collection methods ranges from traditional, manual tools to advanced, integrated digital solutions. This spectrum shows the transition to technologies that simplify data collection and improve the user experience through seamless integration, advanced features, and real-time feedback. Participants also indicated a preference for passive collection methods, such as wearables. The increasing acceptance of digital tools demonstrates the importance of technology in health management in providing users with convenient, efficient, and comprehensive ways to monitor and improve their health. Table 13 provides an overview of the types of data collection we addressed in the focus groups.

Table 12: Influencing Factors on PGHD Collectability

Factor	Occurrences
Digital devices for accessible data collection and analysis	26
Effort should be minimized	11
Choosing the right app as a barrier	11
User-friendly and cost-free apps	5
Low technical know-how as a barrier	5
Analog data collection due to age or preference	5
Passive data collection for more accessible data collection	4
Reminder functions	3

Table 13: Data Collection Methods by their Perceived Utility and Preference Level

Preference Level	Type of PGHD Collection	Description
Most Preferred	Smartphone (combined with app)	Smartphone integrated with apps, enabling seamless passive data collection.
	Wearables (e.g., smartwatches, smart rings)	Wearables like smartwatches and smart rings provide continuous passive data, with smart rings more popular among women.
Preferred	Smart bracelets	Digital wristbands offering data collection with no immediate feedback, viewed variably in terms of information sufficiency.
	Smart glasses	Smart glasses seen as an innovative alternative, though less mainstream.
Moderately Preferred	Digital questionnaires	Digitalized forms of questionnaires, preferred over paper forms for convenience and ease of data input.
	Smartphone functions (e.g., location tracker, camera)	Smartphone functionalities for location, camera, and other passive data sources, seen as useful but somewhat intrusive.
Least Preferred	Analog questionnaires	Paper-based forms of data collection, seen as tedious and requiring too much effort.
	Dedicated devices (e.g., blood pressure monitors, heart rate monitors)	Manual or semi-automatic devices requiring additional effort, viewed as inconvenient for frequent use.

5.3.2 PGHD Types

In this chapter, we present our qualitative and quantitative results regarding the use of PGHD for depression care from a patient perspective. We first present the results of the focus groups and then the quantitative survey results, which are based on the focus group results. The focus groups served as an interactive platform for participants to exchange views on the types of PGHD that are important for depression care. The data collected through the workshop activities and discussions yielded important types of PGHD that illuminated the participants' perspectives on PGHD related to depression care. We consider both the perspective of which types of PGHD are deemed relevant to depression care by the respondents and which of the types of PGHD are accepted. We present the types of data we identified in categories from “most relevant” to “least relevant”:

Sleep Data

Sleep data was generally considered most relevant for depression care by the focus group participants. As with the focus groups with healthcare professionals, the participants divided this group into different types of sleep-related PGHD. Of the sleep data, sleep duration was considered the most important. Regarding sleep duration, the participants explained that it is often difficult to get enough sleep because one either wakes up frequently at night or usually lies awake at night for long periods and, therefore, does not get enough sleep. This leads directly to the second type of sleep data, the data on the duration of the time to fall asleep. This refers to the time between going to bed and the person falling asleep. This is directly related to the problem of lying awake for a long time. Finally, a recording of the individual sleep phases or the control of sleep quality via secondary metrics (e.g., sleep score) was also considered. Still, these were considered the least relevant among the sleep data.

Activity Data

The PGHD on physical activity was also considered very relevant by the participants. The participants stated that they often spend a lot of time at home in bed or on the couch and, therefore, do not get enough exercise or sports in their daily lives, even if their doctors or therapists advise them to do so. The most relevant PGHD for the patients were those on steps and the duration of physical activity. Therefore, this data should be used to get an overview of how much exercise the patient receives or give the treating clinician an overview of how much exercise the patient receives. This can be used for self-monitoring or to enable joint monitoring of the exercise goals of the therapy. In addition to these main types of PGHD, the participants mentioned other data, including range of motion, calories burned, or daily energy requirements. According to the participants, these can also be tracked but do not have the same importance as steps or movement duration.

Mental Health Data

The third major group of data is mental health data. This category mainly includes tracking depression levels, mood, and suicidality. The participants suggested that tracking depression levels via digital questionnaires would be helpful for them. This data should give their treating clinician a better insight into their illness, highlighting the importance of the healthcare professional's role in interpreting the data. The patients suggested they could fill out the familiar questionnaires they often have to fill out on paper in therapy sessions, at home in peace. The second important data point in this category is the patient's mood. This includes, in particular, tracking using a mood barometer (e.g., “How are you today?”, “How was your day?”). Patients found these mood statements helpful in getting an insight into their good and bad days or talking about them with their doctor or therapist. This mood data can be extended to include data on stress levels or anxiety. However, these are not part of the disease for every patient and must therefore be collected individually. The last important point is the assessment of suicidality. This data point can be collected using depression questionnaires that also assess suicidality (PHQ-9) or by asking other direct questions. In this case, the participants preferred to ask this discreetly using a question integrated into a questionnaire. Other data points addressed in this category include measuring cognitive and behavioral aspects, such as concentration or social withdrawal.

Medication Data

Patients also considered medication data to be relevant. This was both for themselves and for their control, and also, from their perspective, it was a pertinent insight for treating clinicians or therapists. This data includes, above all, medication adherence and the documentation of side effects. This data should provide insights into whether the prescribed medication is being taken as discussed. The patient described the data as generating valuable insights because the medication is often not taken as prescribed or is forgotten. The patients expect, that documenting side effects can help find the proper medication and minimize side effects.

Health Metrics

The next category includes PGHD on the health of patients. The participants classified these data as conditionally relevant and, according to the statements, do not apply to all depression patients. These data include heart parameters such as blood pressure, pulse, or ECG and vital parameters such as weight, body fat percentage, blood sugar, or body temperature. These data can usually be meaningfully used and collected in patients with problems in these categories. In particular, the types of data used for chronic conditions such as diabetes or high blood pressure are essential for these individuals and, according to the participants, can also influence the level of depression. In addition, weight is often a good indicator of a patient's eating behavior and whether there is drastic weight loss. Based on this weight data, possible solutions to eating behavior can be discussed with the doctor or therapist. Other PGHD in this class include nutrition and diet or respiratory rate.

Social Interaction and Support

This class of PGHD includes all data related to the patient's social network. The most frequently mentioned type of PGHD in this cluster is social interaction. This includes tracking social interactions, frequency, subjective quality, and duration. Patients indicated it was not easy to track this, but they noticed they felt worse when they had fewer social interactions with friends or family. This class also includes data about the patient's social support network and family and tracking the patient's digital communication.

Lifestyle Data

The lifestyle data class includes a wide range of different data from patients' everyday lives, both digital and analog. The most discussed here was the time spent on social media or other things on the smartphone or PC. This data can be applied in individual cases if it is specifically linked to depression. Furthermore, data on GPS location were suggested if they were not related to sporting activities (e.g., movement patterns, visits to museums, restaurants, etc.). In addition, the participants also suggested data on daily activities, such as the selection of clothing or personal hygiene (e.g., shower frequency).

External Factors

The last class contained data related to external factors such as the weather. Most participants found these less relevant and significantly more challenging to track without automation, so their use should not be pursued.

Quantitative Survey Results

An overview of survey results can be found in Table 14. In the quantitative survey of depressed patients, the data on medication and its tracking were found to be most relevant to the patients. This highlights the critical role that medication adherence plays in the effective management of depression and suggests that PGHD apps should prioritize features that enable patients to track their medication schedules, dosages, and effects. Such features could significantly improve treatment outcomes by ensuring medication adherence and enabling timely adjustments to medication schedules. Suicidal ideation, the second most crucial data type with a score of 6.20, underscores the need for PGHD apps to include mechanisms for detecting and immediately responding to signs of acute distress or suicidal ideation. Features could include alert systems for healthcare providers or support networks that proactively address crisis prevention. Mood data, associated with patient medical conditions with a score of 6.09, further indicates the importance of continuous, subjective health indicators in the treatment of depression. Tracking mood fluctuations over time can provide valuable insights into the effectiveness of treatment plans, the influence of lifestyle choices, and potential triggers for depressive episodes. Behavioral and lifestyle data, including data on perceived stress (6,08) and sleep (duration, quality, 6,04), were also critical to the treatment of depression. These results suggest that managing external factors such as stress and ensuring adequate sleep are essential for effective depression treatment. Consequently, PGHD apps should facilitate monitoring of these aspects and provide personalized recommendations for improving sleep hygiene and stress management techniques. The survey also indicates a lower yet significant relevance for other data types, such as personal hygiene (5.46), and external factors, such as the weather (4.13). While these aspects are not as crucial as medication or mood data, they still contribute to a comprehensive understanding of a patient's condition and suggest that a holistic approach to treating depression that considers a variety of physical and environmental factors could be beneficial. In summary, survey results show a clear preference for PGHD apps that prioritize data types directly impacting medication adherence, mood monitoring, and managing lifestyle factors such as stress and sleep.

In summary, we can see some differences between the qualitative and quantitative surveys. While sleep data was identified as the most important data source in the focus groups, it was ranked lower in the survey. Similarly, medication data was considered less relevant in the focus groups but was ranked as the most essential data point in the survey. Nevertheless, we can see that, as in the focus groups, the groups of health-related data, sleep data, and mental health data were found to be more relevant. Only activity data performed significantly worse in the quantitative survey when the classes were compared. External factors, such as lifestyle data or social interaction PGHD, were found to be less relevant in both results

Table 14: Quantitative Survey - Ranking Types of PGHD

Rank	Type	Rating
1	Medication taken	6.294
2	Suicidal thoughts	6.20
3	Mood	6.089
4	Symptoms	6.09
5	Perceived stress	6.08
6	Sleep data (duration, quality)	6.04
7	Depression and mental health questionnaires	6.02
8	Weight, including fluctuations and eating disorders	5.97
9	Alcohol and drug consumption	5.90
10	Daily routine	5.80
11	Blood pressure	5.74
12	Nutrition	5.66
13	Pulse rate and heart rhythm	5.66
14	Oxygen saturation in the blood	5.53
15	Personal hygiene	5.46
16	Number of steps	5.18
17	Frequency and length of social interactions	5.11
18	Type, length, and frequency of sporting activities	4.91
19	Browser and app history and usage time	4.58
20	External factors	4.13
21	Communication data	4.03

5.3.3 PGHD Communication

Examining the patient perspective on collaboration between patients and GPs in using PGHD for depression care has provided insights into the collaborative aspects of integrating PGHD into healthcare practice. Here, we identified factors for communicating PGHD in patient-clinician conversations and interviews with potential users of PGHD apps. In the following sections, we will discuss the most important factors identified for introducing PGHD into patient-clinician communication:

Data Uncertainties

A key issue identified by interviewees is that bringing PGHD into the patient-clinician conversation can lead to GPs explaining uncertainties that may arise from the data. These frequent mentions show that there are uncertainties among patients when using PGHD. These uncertainties stem primarily from medical PGHD, which, in combination with Google searches, can easily lead to uncertainties among patients, which a doctor should then clarify:

> *"Reading out the wrong data or that, of course, the internet is also not, often not such a good guide, so to speak, to google certain symptoms or perhaps also measured values, right?"*
> *(P16)*

> *"But you shouldn't forget that some patients or people are overwhelmed when they can suddenly see their data themselves. Um. So now, when you suddenly see your pulse on your watch 24/7, you suddenly run to the doctor far too often or develop*

> *hypochondriac-like symptoms because you weren't aware before that, let's say, your pulse is much lower in the morning or something or higher, whatever. And then you notice it yourself in a panic. I've noticed that in my environment. Exactly. So education plays a big role here." (P14)*

Therefore, doctors must address patients' questions and minimize patients' fears during the patient-clinician consultation, which requires familiarizing themselves with the patients' data and symptoms.

Data-Dialogue Balance

The interviewees made the vital point that the patient-clinician discussion must not be based solely on the data. In addition to using PGHD, patients must be examined with all clinical diagnostic tools to make a medically sound diagnosis, based on which therapy or therapy adjustments are then decided. Therefore, PGHDs should only be used as a supporting technology in addition to treatment. The PGHD can confirm the patient's narrative in the patient-clinician consultation or as a basis for discussion if the data contradicts the subjective perception.

> *"It will be taken in any case. Of course, there must be another basis for a diagnosis, medication, etc., which must happen. But simply as a guide and to substantiate the doctor's snapshot, it is certainly helpful if he realizes that what he has measured now is consistent with the other. Then, I think there is some support for medicine. You might have to look closer if they differ, but it's also helpful." (P12)*

Patient-Clinician Partnership

Furthermore, the partnership between patient and provider with shared responsibility was seen as crucial for effective treatment, combining the expertise of both parties. Several participants emphasized the importance of trust and building a personal relationship with GPs. Patients expressed a willingness to work with GPs and take joint responsibility for their health. One person emphasized the importance of patients taking responsibility for their health:

> *"Of course, it would be ideal if the initiative came from the patients themselves. In other words, the patient comes to the doctor because of their mental health problems and tells them about their symptoms, including their medical history. And then he says: Yes, something happened again yesterday, for example, and I noticed it on my smartwatch or my habit tracker, or as far as sleep is concerned, last week, for example. It's easy to see here, so I say as proof that it was. That would be the ideal step, of course." (P15)*

Data Skepticism

In addition, participants expressed that it was important that the GPs treating them were not skeptical about the data collected and took the collected data seriously. The interviews revealed that there is sometimes a fear of being ridiculed by the doctor when bringing such data and that it will not be considered.

> *"So that you are also taken seriously when you go to the doctor with your health data and say: I have this app and can show this, can show that and so on. If, if you are then just smiled at. That is of course something - what do you mean by smiled at - or not taken seriously. I see that as somewhat problematic." (P1)*

One solution to this could be for the doctor to suggest collecting the data. Through the motivation to collect data about the doctor, this approach has several advantages. First, patients may feel encouraged to actively participate in the data collection, which ensures that the data is considered during treatment. Second, this can also resolve concerns about data handling and give patients an understanding of the purpose behind data collection.

> *"Ultimately, the doctor has to do something with the data. I don't just want to generate data so that an insurance company or the state knows something about me; I want to feel better. That's the background. I feel bad, go to the doctor and want him to help me. And the doctor has to explain plausibly why or how he can help me better if I tap data into this cell phone." (P9)*

5.3.4 **PGHD Concerns**

The integration of PGHD into the treatment of depression in GP practices has many advantages. Using such technologies promises to improve various aspects, such as therapy's precision, personalization, and efficiency. However, introducing these technologies is not without significant concerns and challenges. This chapter will present our findings from the focus groups and interviews and introduce concerns related to PGHD in depression care. The issues raised by respondents range from privacy and data security to psychological impact, accessibility, effectiveness, and communication of data with clinicians. By considering these concerns in depth, the chapter aims to provide a comprehensive understanding of the potential risks and benefits and to highlight the need for a balanced approach that prioritizes patient welfare, ethical considerations, and practical ease of use. Below, we present the issues raised by participants and elaborate on the concerns:

Data Privacy

The most critical factor in our surveys was data privacy and security concerns. These concerns include data privacy and confidentiality. The main issue here is the protection of highly sensitive personal patient information. As healthcare becomes increasingly digitized, the risk of data breaches and unauthorized access to personal healthcare data also increases, necessitating strict data management practices and robust security measures. These practices are necessary to meet legal requirements, maintain patient trust, and ensure individuals feel safe when sharing their health data. Another primary concern raised by participants was the issue of data security. While all participants cited potential negative consequences of data leaks, such as increased insurance fees, as perceived barriers, the majority expressed a willingness to use PGHD for their care.

Burden of Tracking

Another crucial point raised by participants was the burden of tracking and using PGHD for depression care. The participants expressed various concerns and reservations about this. Many issues were raised during the workshop, with some participants expressing concerns about the burden associated with data collection. An essential point in this context was that it is possible that depression could become slower due to the pressure of using PGHD and the collection methods chosen. Some participants in the focus groups noted that they could feel overwhelmed by the use of technical devices. In contrast, others felt the potential benefits outweighed the burden, mainly when using wearable devices such as smartwatches. However, participants noted that smartwatches are often unavailable, and the varying levels of user acceptance and high purchase costs are barriers to using these devices for medical applications.

Skepticism towards Passive Data

Another common theme was skepticism about the accuracy of passively collected data, such as sleep quality measurements from smartphones or smartwatches. Participants raised questions about the accuracy of these devices and whether the information collected without the active involvement of the user can be relied upon. Participants compared the reliability of passively and actively collected data and raised issues related to the latter, such as perceived stress or mood. These types of PGHD are highly subjective and can also change significantly throughout the day. Participants pointed out that such subjective PGHD types should be collected at set times or with additional contextual information. The group discussion generated the idea of an individual baseline per person and other ways to measure stress (e.g., resting heart rate, stress/heart rate variability) or to capture subjective and objective (active and passive) types of PGHD combined.

Tracking Adherence

In addition, participants identified tracking (non-)adherence as a potential problem in the collection of PGHD. In particular, the impact of depressive episodes on the ability to track adherence was identified by participants as a major challenge where even basic tracking methods are seen as a significant effort. The first solution to this problem was to design the data tracking so that it only minimally interfered with the patient's daily lives. This could alleviate both the issues of exposure and adherence. Possible solutions discussed by the group included wearable devices that allow monitoring of mood, activity, and stress levels on a scale, as well as passive data collection. This combination should enable patients to track data either actively or passively (as appropriate) when it is difficult for them to do so. Another challenge that participants mentioned when tracking PGHD, especially during more severe depressive episodes, was a lack of confidence in their self-assessment skills. Participants discussed tracking certain data types, such as medication, and completing self-assessment questionnaires as part of PGHD. Participants mentioned that it is challenging to answer questions about themselves in a way that reflects reality, as all impressions during such phases always seem more harmful than they are. Discussions about the posters created revealed that patients feel even more pressured to give a truthful answer, which can lead to an emotional downward spiral.

Patient-Clinician Relationship

Although we have already devoted a separate chapter to the patient-clinician relationship, patients rated these concerns as necessary. Patients expressed concerns about the GP's reduced appointment time and open conversations, which could be affected by the data. Possible provider bias due to the data was also mentioned as a negative effect. In addition, participants feared that the provider would focus solely on the data and not allow time for open conversations. Participants noted that the clinician might be skeptical of subjective, self-reported, or self-collected data. While concerns focused primarily on the provider's role in the patient-provider relationship, participants also noted that incorporating PGHD into their care would create expectations for utilization because they had invested time and effort in collecting it. Other concerns in this group are that the doctor does not look at the data despite collecting it or is just “put off” using it instead of a diagnosis.

Constant Monitoring

Concerns were raised that if patients felt constantly monitored, they could feel health and psychological effects, which could lead to exacerbation of depression, hypochondria, and neurotic behavior. The psychological burden of continuous data tracking and the potential for negative feedback loops, where patients become overly fixated on their health data, can lead to increased self-obsession and anxiety. In addition, there is a risk of stigmatization, where individuals feel labeled or judged based on their health data, which can lead to social isolation or discrimination. These psychological impacts emphasize the need for a balanced approach that considers patients' psychological well-being and includes measures to support and mitigate adverse effects.

Access and Cost Issues

Access and cost issues highlight the financial burden that these aids could place on patients. The cost of purchasing and maintaining health monitoring devices, as well as the cost of therapy and treatment, can be prohibitive for many people. There is also the issue of equity: these advanced health tools may not be accessible to all, especially those from lower socio-economic backgrounds. The notion that these technologies should be available to all, regardless of financial situation, is crucial to ensure that healthcare remains inclusive and equitable. The potential for these tools to create a divide between those who can afford advanced healthcare and those who cannot is a significant ethical issue. While reimbursement by health insurance companies is one solution, many patients questioned this possibility. They expressed additional fears of being treated worse if this data ends up with health insurance companies.

Usability and Effectiveness

Usability and effectiveness are vital aspects that must be considered to ensure the successful implementation of data collection tools. Concerns in this area include the practical effort required to use the methods to collect PGHD and whether the benefits justify the burden. Another issue is delays in using these tools, leading to frustration and reduced patient engagement. The reliability of technical devices is another important issue, as any malfunction or inaccuracy can lead to incorrect data and potentially harmful decisions. In addition, using these tools can sometimes lead to a loss of autonomy as patients feel that their health is determined by technology rather than their personal choice. Safety in the workplace is also an issue, especially with wearable devices that could interfere with daily life or pose physical risks.

Efficacy

There is also a general skepticism about the relevance and impact of these tools. Concerns that clinicians may ignore the data collected, subjective evaluations of medical treatment, and divided public opinion about the importance of these tools reflect a broader uncertainty about their effectiveness and necessity. This skepticism underscores the need for clear communication about the benefits and limitations of these technologies, as well as ongoing evaluation to ensure they meet the needs of patients and healthcare providers. There is also a risk of misleading data leading to false conclusions, which underlines the importance of providing accurate and meaningful insights from these tools.

Experience with PGHD

One concern expressed by the participants was that many people either do not know about PGHD or have no experience in using PGHD. Our most commonly identified theme was “Little experience with PGHD,” which indicates that most people are not familiar to the concept of PGHD. Overall, Table 15 shows that awareness and experience with the types and tracking methods of PGHD vary greatly. For example, recording sports data is still the most common, but does not include the medical use of PGHD. Furthermore, there were many mentions of individual types of PGHD, which indicates that many interview partners have already dealt with particular kinds of PGHD but still have little experience with these data. This suggests that these data are not yet widely available in the population. The concerns of the interview partners are that they fear that they will not be able to use the types of PGHD or the associated methods out of ignorance.

Table 15: Experiences with PGHD

PGHD Interaction	Occurrences
Little experience with PGHD	22
Recording sports activities/hiking	13
No medical use of PGHD or digital devices	12
Limited/no smartwatch usage	10
Positive effects and medical use of PGHD	9
Experience with weight tracking	7
Blood sugar monitoring for diabetics	6
Tracking caloric and fluid intake	5
PGHD for menstrual cycle tracking	5
Blood pressure recording	5
Awareness of the term 'Patient-Generated Health Data'	4
Experience with pulse/heart rate tracking	4
Experience with sleep tracking	3
Experience with step tracking	3
Collecting mood/sentiment data	2
Tracking of symptoms/pain	2
Active smartphone and smartwatch usage	1
Relevance of PGHD for depressive individuals in their own circle	1
Experience with paper-based data collection	1
Experience with recording daily routine	1

5.3.5 PGHD Patient App Functionalities

When developing and refining platforms for PGHD, it is essential to understand and integrate user requirements to ensure both functionality and user satisfaction. This chapter describes the process we took to assess the criteria for a PGHD platform. Building on the findings from the qualitative phase, we extended our research by conducting a quantitative survey to explore and validate the previously identified requirements. The survey was carefully designed to capture the perspectives of potential users and provide a deeper understanding of their priorities, preferences, and the features they consider essential in a PGHD platform. Analyzing function ratings in an app for PGHD provides deep insights into user preferences. We provide an overview of the results in Table 16.

Features such as the protection of personal data, secure login procedures, and transparency regarding data sharing are at the top of the list of user requirements. These results reflect users' growing concern about protecting their health data and emphasize the need for developers to take extra care in these areas.

The user interface also plays a crucial role in user acceptance. Features that allow for easy navigation and responsive design were rated highly, highlighting the importance of intuitive design to the user experience. Users attach great significance to navigating effortlessly through the app and finding the information or tools they need quickly and efficiently.

Functionality features, such as symptom tracking and appointment reminders, were also rated particularly relevant. These ratings show that users see significant added value in features that actively support them in their health management and directly impact their health monitoring and care.

In addition, the ratings for emergency and safety features, such as the availability of immediate assistance in crises, highlight the critical role that PGHD apps can play in emergency management. These features are seen as essential to provide support and guidance in critical moments and highlight the potential of health apps to be a crucial resource in urgent situations.

Interestingly, features that promote social support and engagement, such as social interaction within the app and gamification, are secondary in their importance to users. Although these features can contribute to user engagement, the ratings show they are less crucial than security, privacy, and core functional features.

The results suggest that PGHD app developers should focus on implementing robust security and privacy features, optimizing the user interface for ease of navigation, and developing valuable functionalities that directly benefit users daily. While social and engagement features can be an asset, they are not the main priority from a user perspective.

Category Analysis

In addition to evaluating the individual functionalities, we also carried out an analysis based on the categories. The results of this analysis can be found in Table 17. By examining individual features across a broad range of categories, including user interface, functionality, app cost, content and information, social support, emergency and safety, security and privacy, engagement and motivation, and other features, we gain a nuanced understanding of what makes an effective PGHD app from the user's perspective.

The "Security & Privacy" category is at the top of user priorities, with an average relevance score of 6.588. It highlights the critical importance users place on protecting their health data, secure login procedures, and transparency around data sharing. In an era where data breaches are not uncommon, the emphasis on security and privacy is a clear mandate for developers to prioritize robust security frameworks and privacy measures in PGHD apps.

This is closely followed by the "Content & Information" category, with an average score of 6.235, highlighting the value users place on the credibility and quality of health information provided by the app. Features such as evidence-based content, expertise from qualified professionals, and regular updates reflecting the latest research are highly valued. This indicates that users seek reliable and authoritative health information to support their efforts to manage their health effectively.

The "User Interface" and "Emergency & Safety" categories also ranked highly, with average ratings of 6.125 and 6.094. A user-friendly interface, characterized by appealing design, easy navigation, and responsive design, is critical in increasing user engagement and satisfaction. Additionally, features that provide support in crises, such as the availability of immediate help and the display of crisis support information, emphasize the importance of safety and emergency preparedness in health apps.

Functionality features that include symptom tracking, mood logging, and appointment reminders have an average relevance score of 6.072, reflecting a strong demand for practical and functional tools within PGHD apps that directly contribute to managing and monitoring health conditions.

Interestingly, categories such as 'Other features' and 'App cost' present a mixed picture with average ratings of 5.834, indicating moderate importance of these aspects to users. Features such as customer support, app updates, and cost considerations are considered relevant but are not the highest priority for users.

At the lower end of the spectrum, the categories "Engagement & Motivation" and "Social Support," with average ratings of 5.012 and 3.982, show that users do not consider these areas critical. Engagement features such as gamification and social support mechanisms are seen as beneficial but secondary to the core functionalities and safety features of PGHD apps.

Table 16: Quantitative Survey - Functionalities Results

Rank	Category	Feature	Mean
1	Security & Privacy	Protection of personal data	6.682
2	Security & Privacy	Secure login/authentication	6.606
3	Security & Privacy	Informing the user about health data sent to their care provider	6.476
4	User Interface	Simple navigation	6.353
5	Functionality	Symptoms tracking	6.282
6	Content & Information	Quality of content, including material from skilled experts	6.259
7	Content & Information	Regularly update the content to reflect the latest scientific research	6.241
8	Emergency & Safety	Display of crisis support information	6.212
9	Content & Information	Credibility, provided by the inclusion of evidence-based content	6.206
10	User Interface	Responsive design	6.188
11	Emergency & Safety	Availability of immediate assistance for crisis situations	6.165
12	Other Features	Customer service support	6.159
13	App Costs	Overall costs for the app	6.106
14	App Costs	Coverage of costs by the user's insurance	6.100
15	Functionality	Reminders for appointments and self-care tasks	6.100
16	Other Features	Implementation of regular updates	6.053
17	Functionality	Sleep and physical tracking	6.012
18	Emergency & Safety	Immediate notification of the user's care provider in case of concern	5.906
19	App Costs	Quality of the app is closely related to its cost	5.900
20	Functionality	Mood logging	5.894
21	Engagement & Motivation	Analytics and visualization tools for tracking progress	5.871
22	User Interface	Appealing user interface	5.835
23	Other Features	Exporting data in various formats, such as PDF	5.706
24	Other Features	Having low impact on battery and memory usage	5.629
25	Other Features	Integration of wearable devices	5.624
26	App Costs	App offers a monthly/yearly subscription	5.229
27	Engagement & Motivation	Missions, rewards, and objectives to enhance engagement and motivation	5.012
28	Social & Support	Social support from other users	4.259
29	Engagement & Motivation	Not displaying negative results in mental health tracking	4.153
30	Social & Support	Sharing experiences with other users	4.082
31	Social & Support	Social media-like features	3.606

Table 17: Quantitative Survey - Category Results

Rank	Category	Mean
1	Security & Privacy	6.588
2	Content & Information	6.235
3	User Interface	6.125
4	Emergency & Safety	6.094
5	Functionality	6.072
6	Other Features	5.834
7	App Costs	5.834
8	Engagement & Motivation	5.012
9	Social & Support	3.982

5.4 Design Principles for a PGHD Patient Clinician Platform

In this chapter, we discuss the conclusions from the requirement analyses in the previous chapters. To this end, we use the requirements analysis results from our qualitative and quantitative results to develop design principles for the conception of patient-clinician platforms for capturing and presenting PGHD in primary care depression care. We base our formulation and implementation of the design principles on Gregor and Hevner (2013) and Gregor et al. (2020). We base our formulation and implementation of the design principles on Gregor and Hevner (2013) and Gregor et al. (2020). In the following, we first present design principles that address the general use of PGHD in treating depression. We then discuss specific design principles for the user groups of GPs and depressive patients.

5.4.1 General Design Principles

We formulated four general design principles based on literature research and additional expert interviews to address the previously identified barriers. These principles guide academics and practitioners in creating, implementing, and applying digital PGHD solutions in primary care. An overview of the derived design principles is summarized in Table 18.

Table 18: Overview of General PGHD Design Principles

Design Principle	Description
To guide academics and practitioners in designing, implementing, and applying digital PGHD solutions in primary care, it is essential to ensure…	
Data Privacy	…the protection of sensitive patient data by embedding security and privacy measures throughout the app's design and implementation.
Data Precision	… that data collection methods prioritize precision by selecting reliable data sources that are easy to interpret, enabling meaningful discussions between doctors and patients.
Societal and Ethical Soundness	…ethical soundness by considering social and cultural diversity, promoting fairness, preventing bias, and maintaining transparency in data processing to protect users' rights and foster trust.
Information about PGHD	…to provide clear, accessible information to educate users about PGHD, reducing fears, building trust, and improving usability, especially for less tech-savvy individuals.

Data Privacy

One of the most essential issues with PGHD is ensuring data protection and security. These concerns were repeatedly expressed in both the interviews and the focus groups with both user groups and are, therefore, a high priority. Due to the highly sensitive data collected by PGHD, it is essential to maintain the highest data protection standards. Disclosure of such data can seriously affect users in their private or professional lives. Setting clear data storage and transfer standards ensures that only necessary data is processed and stored. Although many apps rigorously test their security measures, different standards create uncertainty for users and doctors. Therefore, developers of PGHD apps for depression treatment should follow strict data protection regulations and embed data security and privacy in every aspect of their implementation. Adopting standards such as the GDPR (European Union, 2016) or HIPAA (US

Department of Health and Human Services, 2024) can help with implementation. *In summary, we have derived the design principle of data privacy.*

Data Precision

One problem that has been raised is the precision of the data. Various problems can influence this. Different aspects are crucial here. The type of data collection method chosen and the data source are critical for the precision. It is essential that the data sources used provide an optimal balance for both aspects. Therefore, we postulate that the collection methods used for PGHD must provide data that is easy to interpret, based on which meaningful discussions can be held between doctors and patients. *This results in the design principle of data precision.*

Societal and Ethical Soundness

Taking social and ethical issues into account ensures that the app respects users' rights and promotes fairness. The ethical use of PGHD and regular checks for bias protect users from discrimination and exploitation, encourage trust, and support equitable health outcomes. It is important to consider users' cultural sensitivity and diversity to ensure the app suits different social and cultural groups. Transparency in data processing and transparent privacy policies are also essential to maintain ethical standards. *This leads to the design principle of ethical soundness.*

Information about PGHD

The prevalence and knowledge of PGHD are not yet widespread among the population. This can lead to problems with the introduction of these technologies. People who are less tech-savvy and have not yet used a PGHD or do not know what a PGHD is may, therefore, be afraid of using these technologies. Consequently, it is essential to provide users of these technologies with much information and educate them about PGHD. By providing targeted, accessible, and user-friendly information, we can reduce fears, build trust, and improve the overall usability of these technologies. *We, therefore, postulate the design principle "Information about PGHD."*

5.4.2 Design Principles for GP Platforms

This section presents the seven design principles for implementing PGHD applications for GPs that we developed based on the literature review and the qualitative and quantitative surveys. Table 19 provides an overview of the derived design principles.

Table 19: Overview of Design Principles for GP PGHD Applications

Design Principle	Description
To guide academics and practitioners in designing and implementing PGHD applications for GPs, it is essential to ensure…	
Relevant Data	…that only relevant data are collected to minimize information overload and support effective depression treatment.
Trust in Data Collection Methods	…that data collection methods are accurate and tamper-proof to build healthcare professionals' trust in the data, enabling confident use of PGHD in treatment decisions.
Data Visualization	…to integrate clear and concise visualizations that simplify complex data, using intuitive charts, color coding, and interactive elements to enhance user interpretation and support decision-making.
Severity assessment	…to implement a systematic severity assessment approach, using both absolute and relative thresholds to quickly evaluate PGHD changes and support informed adjustments to depression treatment plans.
Integration into the PCF infrastructure	…that the platform integrates seamlessly into the PCF infrastructure by embedding data directly into digital practice files or providing easy access via web platforms, enabling systematic use of PGHD in therapy.
User-friendliness for GPs	…to prioritize user-friendliness, ensuring the platforms are intuitive and easy to use, reducing frustration, and promoting safe and effective use in primary care practices.
Implement alerts for Critical Values	…to integrate critical value alerts that prominently highlight urgent data, include actionable recommendations, and support timely interventions while minimizing alarm fatigue by prioritizing the most urgent notifications.

Relevant Data

Our first guideline relates to the use of PGHD. Only PGHD relevant to depression treatment should be used. Through our qualitative research, we were able to identify several types of PGHD relevant to depression treatment. When using PGHD in depression treatment, a selection should be made from these data to reduce the number of PGHD types to be collected and thus to reduce the flood of information for the GPs and only to collect data that has added value for depression treatment. We therefore suggest various types of PGHD:

- Collect sleep-related parameters such as quality, duration, interruptions, time to fall asleep, and regularity. These data are essential for understanding and effectively treating depression.

- Track patients' physical activity, including steps taken, exertion duration, and exercise type. These data help track the progression of depression and the effects of physical activity on mental health.

- Record and analyze cardiac parameters values, blood pressure, and heart rate variability. These parameters are essential for identifying comorbidities and understanding the side effects of antidepressants on heart health.

- Record mental health data such as depression questionnaire scores (PHQ-9) or mood barometers. These parameters provide insight into the patient's state of mind.

Based on our research, this data should suggest integration into PGHD applications to support the treatment of depression. *Therefore, we postulate the design principle of relevant data.*

Trust in Data Collection Methods

An essential aspect for healthcare professionals when using PGHD is that they can trust the data collected. From our qualitative research and literature, healthcare professionals using PGHD are particularly concerned that they are inaccurate or that the data collection methods are tracking the wrong data. It is essential to choose tracking methods that are accurate and tamper-proof so that the data truly reflects reality. This design principle differs from precision in that we want to emphasize the importance of healthcare professionals being convinced of the data collection method so that they are also confident using the data during treatment. *We, therefore, formulate the design principle of trust in the data collection methods.*

Data Visualization

Integrate easy-to-understand visualizations that present complex data clearly and concisely. This should simplify and support user interpretation and decision-making. You can highlight important information and maximize usability by integrating intuitive charts, color coding, and interactive elements. Visualizing the data is beneficial because it increases the information provided and reduces the cognitive and intellectual effort required to interpret it for decision-making (Park et al., 2022). Develop clear and concise visualizations of the collected data, focusing on key metrics and trends. Visual representations should highlight deviations from typical values and allow clinicians to interpret them easily. *Therefore, we postulate the design principle of data visualization.*

Severity Assessment

To provide an accessible overview of the changes in PGHD and thus support the use of PGHD platforms for depression care, we suggest implementing a systematic approach to assessing the severity of PGHD. Different strategies can be used to determine the severity levels. It is conceivable to use both absolute thresholds for a severity assessment and relative thresholds to evaluate the threshold change. This allows both the absolute values and changes over time to be assessed quickly. Absolute values are helpful for PGHDs with low variability and for PGHDs with evaluated fixed cut-off scores (e.g., PHQ-9). Relative cut-off scores can be used for PGHDs with much variability. This helps GPs to identify critical problems and adjust treatment plans accordingly quickly. *We, therefore, formulate the design principle of severity assessment.*

Integration into the PCF Infrastructure

Another aspect that caught our eye during the interviews is that many applications for PGHD consist of separate stand-alone applications that are difficult to integrate into the infrastructure of GP practices. This problem means that although patients often collect data, it cannot be used systematically in the PCF for therapy. We therefore suggest that when implementing PGHD platforms for the treatment of depression in PCFs, an infrastructure should be chosen that can be integrated into the practice. Either solution can be implemented that incorporates the data directly into the digital files of the practice or solutions that allow access via web platforms and simple internet access at the workplace. *That is why we call it the design principle of integration into the PCF infrastructure.*

User-friendliness for GPs

Users must not be confronted with usability issues when using such platforms in PCFs. Our qualitative surveys with healthcare professionals have shown that a significant problem is the usability of PGHD due to the poor usability of current solutions in GP practices. Good usability helps to avoid frustration and unsafe use of the PGHD platform. *Therefore, we formulate the design principle of GPs' user-friendliness.*

Implement Alerts for Critical Values

The doctors stated that it is crucial to distinguish critical notifications or values from non-critical values. This is supported by integrating warnings for critical values, which are displayed prominently and thus stand out from standard values. This is intended to improve the user's awareness of a crucial situation. This promotes the timely initiation of interventions. Nonetheless, when implementing the warnings, care must be taken to minimize alarm fatigue and prioritize the most urgent notifications (Ancker et al., 2017). It is essential to ensure that alerts contain actionable recommendations and support rapid decision-making by integrating relevant patient data and evidence-based guidelines. *Therefore, we formulate the design guidelines for GPs' critical value alerts.*

5.4.3 Design Principles for Patient Applications

This section presents the six design principles for implementing PGHD applications for patients that we developed based on the literature review and the qualitative and quantitative surveys. Table 20 provides an overview of the derived design principles.

Table 20: Overview of Design Principles for Patient PGHD Applications

Design Principle	Description
To guide academics and practitioners in designing and implementing PGHD applications for patients, it is essential to ensure…	
Accepted Data Collection Methods	…that data collection methods are widely accepted by users, either through personalized or less invasive standardized approaches and by combining active and passive methods to promote continuous, high-quality data collection in depression care.
Relevant Data Types	…that the data types collected are perceived as relevant by patients, increasing their engagement, adherence, and interest in their health.
Accepted Data Types	…that the data types collected are not only relevant to depression treatment but also accepted by patients, considering factors such as effort or discomfort to promote sustained engagement and data sharing.
Cost and Access to PGHD	…cost and access considerations by offering affordable pricing models or integrating with insurance coverage schemes, such as DiGA, to provide evidence-based, high-quality applications accessible to all, including those from lower socioeconomic backgrounds.
User-Friendliness	…to prioritize user-friendliness by ensuring an intuitive interface, fast loading times, easy navigation, and personalized user experiences, along with accessible training resources and support to enhance engagement and adherence.
Positive Data Communication	…positive data communication by presenting PGHD neutrally or positively, avoiding negative or distressing feedback, and using evidence-based interventions to support patient well-being without causing unintended harm.

Accepted Data Collection Methods

We found differences in the acceptance of data collection methods among patients. When using PGHD in the context of depression care, patients/users must agree with the data collection methods to guarantee continuous, high-quality data collection. We, therefore, suggest either selecting a personalized data collection method for each patient to get the maximum benefit from the data collection methods or, in the case of a standardized data collection method, choosing a less invasive method that most users can agree to. In addition, we recommend choosing a combination of active and passive data collection methods if possible. This ensures that the data collection methods address as many patients as possible, and that high-quality continuous data collection is achieved. *We, therefore, postulate the design principle of accepted data collection methods.*

Relevant Data Types

As with GPs and accepted data collection methods, it is essential for patients that the data types they collect are relevant for treating depression. As with the accepted data collection methods, it is also essential that patients find the data used relevant. Studies on ECG have shown that collecting further relevant data increases the perceived usefulness of PGHD applications. Perceived usefulness, in turn, influences sustained engagement with ECG mHealth technology. Combined with the statements from the qualitative surveys, this suggests that collecting relevant data also increases behavioral intention and interaction with PGHD technologies. This should then increase adherence to the collection and interest of patients in their data and their health. Based on our findings, we recommend collecting the following data points from the patient's perspective:

- Medication tracking
- Sleep data
- Mental Health data
- Symptom tracking
- Activity

Therefore, we formulate the design principle of the relevant data types.

Accepted Data Types

Another critical point is the use of accepted data types. In parallel to the relevant data types, it is also essential for patients to receive the data types. We, therefore, distinguish between them. Due to the sensitivity of the PGHD (especially in depression), a data type that is relevant for the treatment of depression does not have to be accepted by the patient at the same time. There may be different reasons, such as effort or shame towards the healthcare provider. Therefore, it is essential to ensure that data points are collected and accepted by the patient. *We, thus, formulate the design principle of accepted data types.*

Cost and Access to PGHD

Cost considerations are crucial to making these applications accessible to a wider population, including people from lower socioeconomic backgrounds. Transparent pricing and affordable options ensure that financial barriers do not prevent access to necessary mental health resources.

There are two main models to consider. One option is to offer the apps at a low price so that most people in the target group can afford them. The advantage of this is that the app can be made available to many people. However, due to the lower price, the developers must expect lower sales, which can potentially reduce the quality of the development, as it has to be done at a lower cost. However, the developers can produce the app without restrictions. This can be particularly advantageous for smaller developers who want to bring new products to market quickly. For patients, however, this may mean that apps not based on evidence-based or clinical studies are brought into circulation to test their effectiveness.

A second option would be to offer insurance companies coverage of the app. The digital health record (DiGA) model is one option in Germany. Doctors can prescribe health apps here; the patient's health insurance company covers the costs. The certification of an app to be approved as a DiGA is based on the developers conducting a clinical study demonstrating the health app's evidence-based benefits. This model has various pros and cons. The pros are that patients receive a high-quality application based on evidence-based benefits at no cost. The con is that developers must undergo a complex process to receive DiGA approval. *Therefore, we formulate the design principle of cost and access to PGHD.*

User-Friendliness

User-friendliness determines how easily patients can interact with the app. An intuitive interface and extensive user testing reduce frustration and improve adherence, allowing users to benefit from the app without extensive training or support. Key factors include fast app loading time, easy navigation, and a personalized user experience based on individual preferences and behavior patterns. Training resources and help features should also be easily accessible to increase ease of use. *We, therefore, postulate the design principle of user-friendliness.*

Positive Data Communication

It is essential that when using PGHD to treat depression, the data is communicated to patients neutrally or positively. There are several aspects to consider. First, it is essential to consider the apps' health, physiological, and psychological effects. These apps can influence the well-being of users both directly and indirectly (by providing data to treating clinicians). In case of direct influence through in-app interventions, these should be evidence-based and developed with a scientific background to help patients. Interventions in this context can also be the presentation of “bad” PGHDs, which then influence users. Above all, the apps should be designed to be helpful tools and not cause stress or unintended harm. To this end, creating the apps positively and not giving negative feedback on the collected PGHD makes sense. This means no negative or disturbing feedback should be given to the users/patients. *We, therefore, formulate the design principle of positive data communication.*

5.5 **Summary**

In this chapter, we used qualitative and quantitative survey methods to identify the requirements of patients and GPs for the use of PGHD in depression care, resulting in 17 design guidelines. In the first step, we explored relevant types of PGHD, methods for collecting PGHD, the presentation of PGHD, the integration of PGHD into clinical workflows, and barriers to the use of PGHD with a total of 19 healthcare professions in two focus groups with subsequent interviews with 11 GPs and 6 MAs. We found that healthcare professionals rated sleep, activity levels, cardiac parameters, online behavior, and vital signs as the most relevant and easiest to collect. For PGHD collection methods, there was a consensus among healthcare professionals that a combination of active and passive collection methods was most helpful. The participants' ideas on data presentation were that an easy-to-understand visualization, limited to the most relevant data, is most useful and that abnormal values are visible. The integration of PGHD into clinical workflows showed no standardized processes for integrating PGHD into clinical workflows. Ultimately, the interviews enabled us to identify barriers to using PGHD, including lack of information on PGHD, data privacy, data misinterpretation, data preoccupation, patient self-assessment, and trust in the data collected.

On the patient side, through three focus groups with a total of 20 participants, 16 interviews with potential users of PGHD apps, and a quantitative survey with 169 depressed patients, we were able to determine preferred PGHD collection methods, relevant PGHD types, aspects of PGHD communication, concerns about using PGHD and functionalities for PGHD apps based on our assessment. Smartphones and associated wearables were the most preferred among patients. In the quantitative survey with depressed patients, we found that patients rated data on medication, suicidality, mood symptoms, stress, and sleep as most relevant for depression care. This contrasts with our focus groups, in which sleep, activity, and mental health data were rated most relevant. During the interviews, we identified essential factors for PGHD communication: data uncertainty, data-dialogue balance, patient-clinician partnership, and skepticism toward the data. Accordingly, the most substantial concerns among patients also include data privacy, the burden of tracking, skepticism towards passive data, and tracking adherence. Ultimately, our quantitative survey allowed us to identify essential functionalities for PGHD applications, with patients rating security features, a simple user interface, and the quality of the content being included as the most important.

Based on these results, we then postulated 17 design principles in three categories: general design principles (4), design principles for GP platforms (7), and design principles for patient applications (6). These principles aim to guide academics and practitioners in designing and implementing PGHD applications.

6 Design, Development, and Deployment of the PGHD Application

After elaborating on the requirements for a patient-clinician platform developed explicitly for GP care for depression, this chapter focuses on the design, development, and implementation of the PGHD application “POKALConnect”. First, we present the architecture of the patient-clinician application. Here, we explain the implementation of the individual functionalities based on the PERN stack and how these relate to the platform's architecture. We then present the functional and technical aspects of the backend, the web-based frontend for GPs, the smartphone-based frontend for patients, and the integration of wearable technologies. This chapter highlights the continuous improvement process that has shaped the platform into a functional and scalable solution for managing PGHD in depression treatment in PCFs. Finally, we present our evaluation steps of the GP-directed and patient-directed applications and the resulting feedback.

6.1 Patient-Clinician Application Architecture

The developed platform, tailored to the needs of doctors and patients, is based on various technologies that, in the overall context, form a data ecosystem through which the PGHD collected from patients can be meaningfully made available to the treating. To this end, we have developed a multi-level concept that ensures patient-friendly data collection and processing for doctors at work. The architecture of our developed patient-clinician platform can, therefore, be divided into three underlying components: the platform's backend, the web-based frontend for GPs, and the smartphone-based frontend for patients. A wearable component also takes over passive data collection from patients. In our POKALConnect concept, we have used a smart ring from Oura as a wearable (Oura, 2024a). The data collected by the smart ring is then sent to the patient app. The tasks of the individual components are briefly described below. A schematic illustration of the architecture can be found in Figure 11.

Platform Backend

The platform backend is the central connection point for all components. This component is based on Node.js, Express, and a PostgreSQL database and represents the front-end and database API. This is where all data is processed and available to doctors and patients. The backend handles user authentication and ensures secure communication of the PGHD collected. The backend is also responsible for creating and sending weekly reports on the patients and the associated PGHD.

GP Front End Web Platform

We developed a web application for GPs to access in their treatment rooms. This part of the platform is designed purely for GPs and contains everything they need for treating depression with PGHD. The front end allows the GPs to use the platform to access their patients and view the data provided to them in prepared form. The GPs can also call up the weekly reports in this front end. The web front end is primarily designed to visualize the collected PGHD.

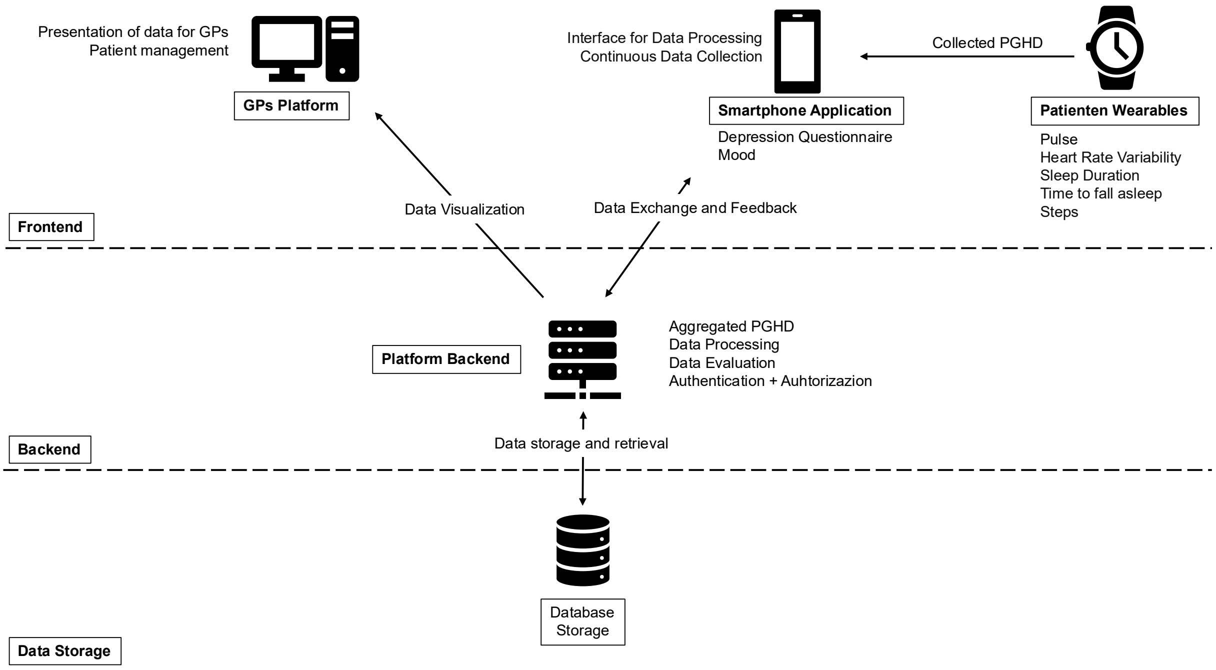
In detail, the integrated views have the following core functionalities:

- **Patient Overview:** In this view, all patients in the system are listed for the doctor. In addition to the names of the patients, this overview also contains the most critical patient data, such as date of birth, and small symbols that show the status of the most recent patient data in color (green - all okay, yellow - slightly below threshold, red – significantly below threshold).
- **Patient view:** After selecting a patient, the doctor sees all the essential information on the selected patient with various tiles (activity, heart data, sleep, and PHQ-9 (mood currently in programming)). If predefined threshold values are exceeded or fall short, the doctor is informed of this in color.
- **Detailed View:** If the doctor decides to examine a data point more closely, they will be redirected to another view that provides a detailed view of the selected data point. This view shows a severity assessment based on a trend evaluation of the data point.

Patient Front End Smartphone Application

We have developed a smartphone app for patients. This smartphone app has several key functions. First, patients can complete the PHQ-9 questionnaire in the app and record their mood on a Likert scale. The second function of the patient app is to collect data collected by smart sensors (in our case, as already described, a smart ring from Oura). This collected data is then bundled, transferred to the backend, and made available to the treating GP. The app also retrieves the data processed by the backend and presents it clearly to the patient.

Figure 11: Architecture Overview POKALConnect (own illustration)



In detail, the integrated views have the following core functionalities:

- **Active Data Collection:** We have integrated functionalities for collecting PHQ-8 data and patients' daily moods into the patient app. These questionnaires, which can be actively completed, contribute to a holistic picture of the patient's mental health.
- **Passive Data Aggregation:** The data collected by the wearable, including sleep duration, sleep onset time, steps, resting heart rate, and heart rate variability, are collected by the patient app and sent to the platform's backend for further processing.
- **PGHD Insights:** The processed data is made available to patients in a bundled overview.

Technical Stack Overview

We use the **PERN-Stack** to implement the patient-clinician platform. In addition to MERN, LAMP, MEAN, and MEVN, the PERN stack is another helpful technology stack for creating web or mobile applications. As the acronym suggests, it consists of four main components: **P**ostgreSQL, **E**xpress, **R**eact, and **N**ode.js. In combination, these technologies enable the development of full-stack applications with CRUD[2] functionality. Figure 12 provides an overview of the PERN-Stack.

PostgreSQL

An advanced, open-source relational database management system that supports SQL and JSON queries. It stores and manages the application's data, providing reliability, integrity, and powerful querying capabilities.

- **Express**

  A flexible Node.js web application framework provides robust features for building web and mobile applications. It simplifies creating server-side logic, routing, and processing HTTP requests and responses, making it an essential part of full-stack development with Node.js.

- **React**

  A framework used for building server-rendered applications, it provides features like static site generation, server-side rendering, and automatic code splitting, making it ideal for creating fast and scalable web applications.

- **Node.js**

  A JavaScript runtime built on Chrome's V8 engine allows the execution of JavaScript code server-side. It is used to build scalable network applications and serves as the

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[2] CRUD is a term used in data management and is the abbreviation for the 4 most important operations in persistent databases: Create, Read/Retrieve, Update, Delete/Destroy Truica, C.-O., Radulescu, F., Boicea, A., & Bucur, I. (2015). Performance evaluation for CRUD operations in asynchronously replicated document oriented database. 2015 20th International Conference on Control Systems and Computer Science,

backend for the web application, handling server requests and managing the application’s logic.

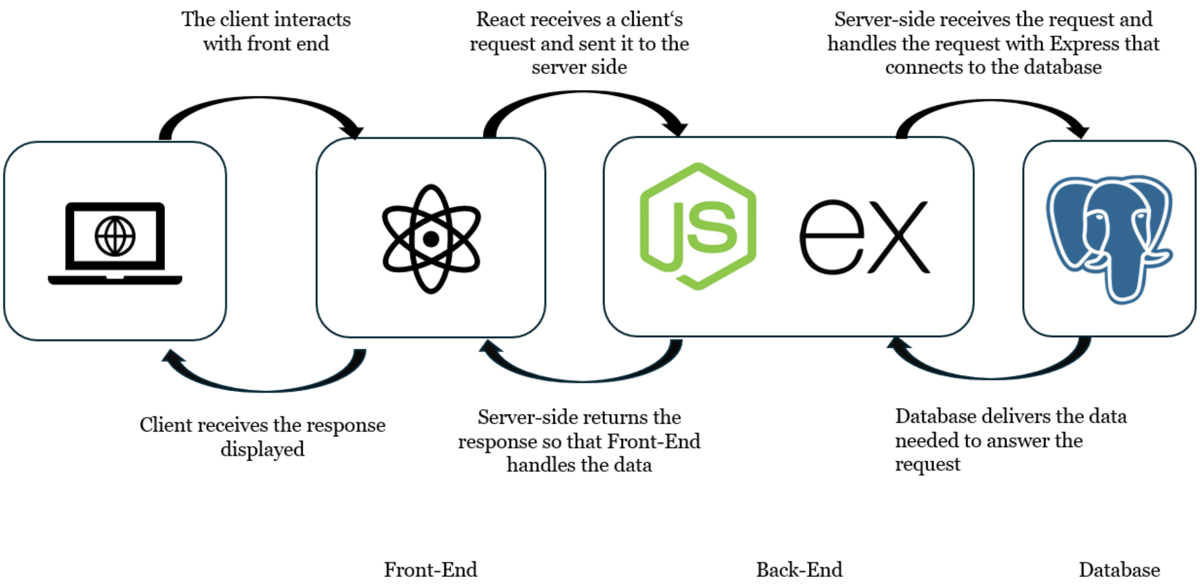
For the development of the smartphone application, we added the React Native framework to the stack.

- **React Native**

  A popular framework for building native mobile applications using JavaScript and React. It allows the development of cross-platform apps (iOS and Android) from a single codebase, providing a rich user experience and access to native functionalities.

The architecture and selected technologies provide a solid foundation for meeting the predefined non-functional requirements. The web-based architecture ensures comprehensive platform support on various devices, mainly through the GP-side application. Integrating modern frameworks and established protocols such as REST, JSON, HTTP, and JWT guarantees the platform's maintainability, reliability, and scalability. Security and privacy considerations were integral to the architectural decisions, although this project did not focus on developing specialized security or privacy frameworks for the DP platform.

Figure 12: PERN-Stack Overview (Rita Alves, 2023)



6.2 Design Elements and Constructs of the Patient-Clinician Application’s Backend and API

This section describes all aspects of the patient-clinician platform's backend. First, we discuss its functions, and then we present the technical details of the implementation.

6.2.1 Functional Aspects

In this section, we describe the functional aspects of the backend. We begin by discussing the secure authentication workflow. We then describe the routes that the backend provides in the API. Finally, we describe special backend functionalities such as adding a patient, shared access to patient data, severity assessment, and internationalization.

6.2.1.1. Secure Authentication Workflow

The POKALConnect Platform provides a secure authentication workflow for all of its services. At the deployment level, security is achieved by using SSL encryption for all services communicating over HTTP. At the service level, this is mainly achieved by requesting JSON Web Tokens (JWTs) on the backend. These tokens encrypt the sender's user ID so that we always know who is logged in and whether they are a professional or patient user. In addition, the routes used by professionals to access patient data are specially secured. A mandatory check prevents professionals from accessing data on patients with whom they are not associated. This way, we ensure that unauthenticated and unauthorized users cannot access the data. The reporting service requires service-to-service communication, secured by one-time passwords.

6.2.1.2. Routes

To use the POKALConnect app efficiently and securely, we developed an API that securely supports healthcare providers and patients in managing and sharing the generated PGHD data. The developed API thus ensures the platform's scalability and opens up possibilities for connecting POKALConnect to EHRs or other healthcare applications in the future. Table 21 provides a structured list of POKALConnect API routes, organized by target user (patient, professional, or other), request type (HTTP method), route, and a brief endpoint description. Patient routes include endpoints for patient registration, login, profile management, and data submission (e.g., questionnaires, mood and health data). Professional routes enable healthcare professionals to register, log in, access linked patient data, retrieve reports, and manage patient notes. Various routes manage office-related information for professionals. Each entry is aligned with the CRUD operations for users and their data, ensuring comprehensive functionality within the healthcare platform.

Table 21: Routes for POKALConnect

Target	Request Type	Route	Description
Patient	POST	/api/patient	Registers a new patient
	POST	/api/patient/login	Authenticates and logs in the patient
	GET	/api/patient	Retrieves patient info
	PUT	/api/patient	Updates patient details
	DELETE	/api/patient	Deletes the patient account
	DELETE	/api/patient/data	Deletes patient data
	POST	/api/patient/data/questionnaire	Submits a questionnaire response
	POST	/api/patient/data/mood	Submits mood tracking data
	POST	/api/patient/data/value	Submits generic health data
	GET	/api/patient/professionals	Retrieves professionals associated with the patient
	GET	/api/patient/data/value	Retrieves patient data over a specified period
	POST	/api/patient/token	Issues an authentication token for a patient
Professionals	POST	/api/professional	Registers a new professional
	POST	/api/professional/login	Authenticates and logs in the professional
	GET	/api/professional	Retrieves professional details
	GET	/api/professional/reports	Retrieves all reports associated with a professional
	GET	/api/professional/report	Retrieves a specific report
	GET	/api/professional/patients	Retrieves patients connected to the professional
	GET	/api/professional/patients/questionnaire/single	Retrieves single questionnaire responses of patients
	POST	/api/professional/patients/notes	Posts notes for a specific patient
	GET	/api/professional/patients/notes	Retrieves notes for a specific patient
	GET	/api/patient/data/value	Retrieves aggregated patient data based on a professional’s request
Misc	POST	/api/office	Posts information about a professional’s office

6.2.1.3. Add Patient

The fourth essential function within the platform concerns registering new patients. In the GP interface, this process involves linking a patient to the relevant doctor. The patient should first set up their account on the patient page of the platform by entering personal details such as name, date of birth, gender, body weight, and height. Once a patient profile has been created in the system, it should be linkable to the doctor's account during the patient's visit to the clinic. With the patient's consent to improve their care through the platform's monitoring features, the doctor can assist them with this linking process within the patient application. This setup process must be simple and intuitive in both applications to avoid overwhelming the doctor or the patient, as highlighted by experts during the relevance cycle. In the context of this work, the implementation focuses exclusively on the GP interface, particularly linking an existing patient account with the profile of the relevant doctor.

6.2.1.4. Shared Access to Patient Data

In addition to basic authentication requirements, such as creating accounts for healthcare professionals and standard logins and logouts, the experts emphasized the need for a robust access control system for patient data. In a typical medical practice, it is common for additional healthcare staff to assist with daily activities. Therefore, it is crucial to effectively integrate the DP platform so that support staff can access patient data with their consent. This allows the primary care team to use the platform to monitor and assess the data of patients with depression, reducing the burden on the GP. The support staff could alert the GP and coordinate the necessary follow-up for patients with serious irregularities or critical values.

In addition, it is vital that patient data can be shared within the platform between GPs from the same practice to improve collaboration and optimize workflows. This concept of shared access is not only a requirement of the experts involved but is also supported by the findings of Rodriguez et al. (2019) in their research on GP-specific digital platforms. This underlines the requirement that GPs and all healthcare professionals specify the associated GP practice when creating an account. If the practice is not yet registered on the platform, it should be possible to create a new one that can subsequently be used by other colleagues in the registration process.

6.2.1.5. Severity Assessment

One requirement for a PGHD platform is to assess the severity of the data collected. This is because PGHDs have rarely been included in determining diseases in GP practices. We decided to implement two different principles of severity assessment: an absolute evaluation of the severity of the data and a relative evaluation of the seriousness of the collected data.

Absolute Assessment

The basic principle of absolute rating is based on absolute benchmarks, according to which an assessment of the severity of a PGHD data point is determined. These benchmarks are based on evaluated questionnaire thresholds in implementing POKALConnect and are only used for PHQ-8 and mood. For the PHQ-8 questionnaires, there is an established rating scheme based on the assessment of the total scores (Kroenke et al., 2001; Kroenke et al., 2009). The evaluation scheme is shown in Table 22. The mood results are displayed on a 5-point Likert scale ranging from bad to very good, with smileys representing the values.

Table 22: PHQ-9 Evaluation Scheme

Calculated Total Score	Severity of Depression
0–4	Minimal depressive symptoms
5–9	Mild depressive symptoms
10–14	Mild to moderate depressive symptoms
15–19	Moderate depression
20–27	Severe depressive symptoms

Relative Assessment

Unlike absolute assessment, which relies on predefined numerical thresholds, the relative approach evaluates data fluctuation over time, specifically comparing a PGHD metric against the patient's historical data, identifying intra-individual changes. Both methods utilize the 7-day average for evaluation. The period of historical data considered is critical to the relative assessment's accuracy. Analyzing all historical data for a PGHD metric is impractical. Instead, this method compares the current 14-day average against a stabilized baseline established over time using a moving average to mitigate data variability. This baseline does not incorporate the current 7-day period to avoid skewed analysis. Although the literature lacks guidance on the optimal duration for this baseline, expert consensus led to selecting a 90-day window, excluding the recent 7-day span.

Calculating a meaningful relative score requires a baseline with enough data points. While 90 days of data are not mandatory, a minimum dataset is essential. Absent specific academic recommendations, a 14-day calibration period, as used by certain health tracking manufacturers, has been adopted for baseline establishment.

The quality of relative assessment heavily depends on the mathematical formula used. A straightforward percentage deviation between the 7-day average and the baseline can be simplistic, omitting data variability. Incorporating the baseline's standard deviation into the evaluation, as done with the z-score, offers a more nuanced analysis. The z-score measures how much a specific value deviates from the mean, providing insight into its extremity within the dataset.

The z-score is calculated using the following formula (Base, 2018):

$$z = \frac{x - \mu}{\sigma}$$

Where:

- x is the raw value to be put into relation
- μ is the mean value of the population
- σ is the standard deviation of the population

The s-scores' simplicity and interpretability make them advantageous, though their implications depend on the PGHD type. For instance, increasing steps (positive z-score) is favorable, whereas decreasing sleep latency (negative z-score) is preferred. The method adapts by adjusting z-scores to always interpret a negative value as deterioration and a positive one as improvement, regardless of PGHD type.

The literature lacks methods for correlating z-scores with severity levels; hence, this study introduces experimental values for such classification, pending further validation. The significance of the baseline window's size is underscored, as very stable PGHD values could lead to misleadingly severe z-scores for minor deviations. The chosen calibration and baseline periods of 14 and 90 days aim to balance sensitivity, but adjustments may be necessary to refine the methodology.

6.2.1.6. Internationalization

Another feature is developing an internationalization concept to support multiple languages. English should be the default language to serve the international research community. As this application is initially being developed for German GPs, there should be an option for users to change the language of the application to German. This customization aims to encourage broader adoption in the German-speaking research community by making the application more accessible. The language change should include all text in the user interface, units, and formats for numbers and dates.

The platform implements the internationalization requirement identified in the Relevance Cycle. The platform automatically detects the language based on the preferred language set in the browser. Accordingly, the application navigates to the URL without a route suffix for the English version or adds "/de" before any other route components in the URL for the German version.

Technically, a library was integrated that expects (at least) one JSON file for each language to be supported. Each file defines the same translation keys, assigning the text in the respective language as a value. Use these translation keys instead of static text for all locations in the UI code that should display text. At runtime, the library selects the appropriate JSON file based on the recognized language and dynamically inserts the respective translation of the key. This allows high maintainability and extensibility with new languages by changing translation in the JSON files without changing the code.

6.2.2 Technical Realization

In the following section, we describe the technical realization of the backend.

Next.js

In recent years, the Next.js framework has become a popular choice for developing frontend and backend web applications in JavaScript or TypeScript (Next.js, 2024). It extends React, a library for building user interfaces, by introducing features like server-side rendering (SSR), static page generation (SSG), automatic code splitting, and built-in routing, enhancing scalability, flexibility, and performance beyond traditional single-page applications (SPAs) like React alone. Consequently, the DP platform utilizes Next.js for its foundation. Internally, Next.js operates on Node.js for server-side execution, which is crucial for SSR. This process enables the server to pre-render UI components requiring secure data or methods, delivering them to the client as fully formed HTML. Additionally, Next.js supports direct API route integration within the application, simplifying the concurrent development of backend and frontend services without a separate server. Hence, Next.js is the core technology for the GP-facing application (presentation tier) and the application layer.

Prisma

The data layer utilizes PostgreSQL, positioning it alongside MySQL as a premier open-source database management system. Opting against commercial alternatives like Microsoft SQL Server or Oracle Database, the platform favors PostgreSQL for its enhanced capabilities. These include superior flexibility in data types, scalability, concurrency, and data integrity, making it particularly suitable for handling large and complex workloads, thus aligning with the architecture's long-term objectives (Amazon, 2024). Furthermore, PostgreSQL is tightly integrated with Prisma, an object-relational mapper optimized for TypeScript, facilitating a smooth blend with the TypeScript-centric architecture (Prisma, 2024). Prisma introduces a systematic approach to database schema migration, capturing each alteration to the data model in dedicated migration files. This schema evolution strategy ensures a manageable, version-controlled progression of the data model, significantly aiding in maintainability.

REST

For backend endpoints designated for the patient-facing application or forthcoming systems. The framework's design, optimized for remote procedure calls, does not align with these use cases, rendering it unsuitable. Consequently, the DP backend employs an alternative approach by offering a set of endpoints adhering to the REST architectural style (Fielding, 2000), a prevalent web architecture facilitating straightforward communication across various systems. Communication through these endpoints occurs over the Hypertext Transfer Protocol (HTTP), with data exchanged in the JSON format.

JSON Web Token

Authentication across both the GP-facing frontend and the backend, as well as the REST-based endpoints, is managed using JWTs. JWTs offer a compact, self-contained mechanism for securely transmitting information between two parties in a web application (JWT, 2024). These tokens, structured as JSON objects, are easily interpretable and processable across different programming languages. JWTs are delivered via cookies marked with the HttpOnly attribute to enhance the platform's security. This attribute blocks all client-side scripts, including those within the platform itself, from accessing the cookie data (Mozilla, 2024), safeguarding against client-side attacks and minimizing the risk of sensitive patient data theft. The cookie is automatically dispatched to the server with each request, where only the server can access and authenticate the data contained within.

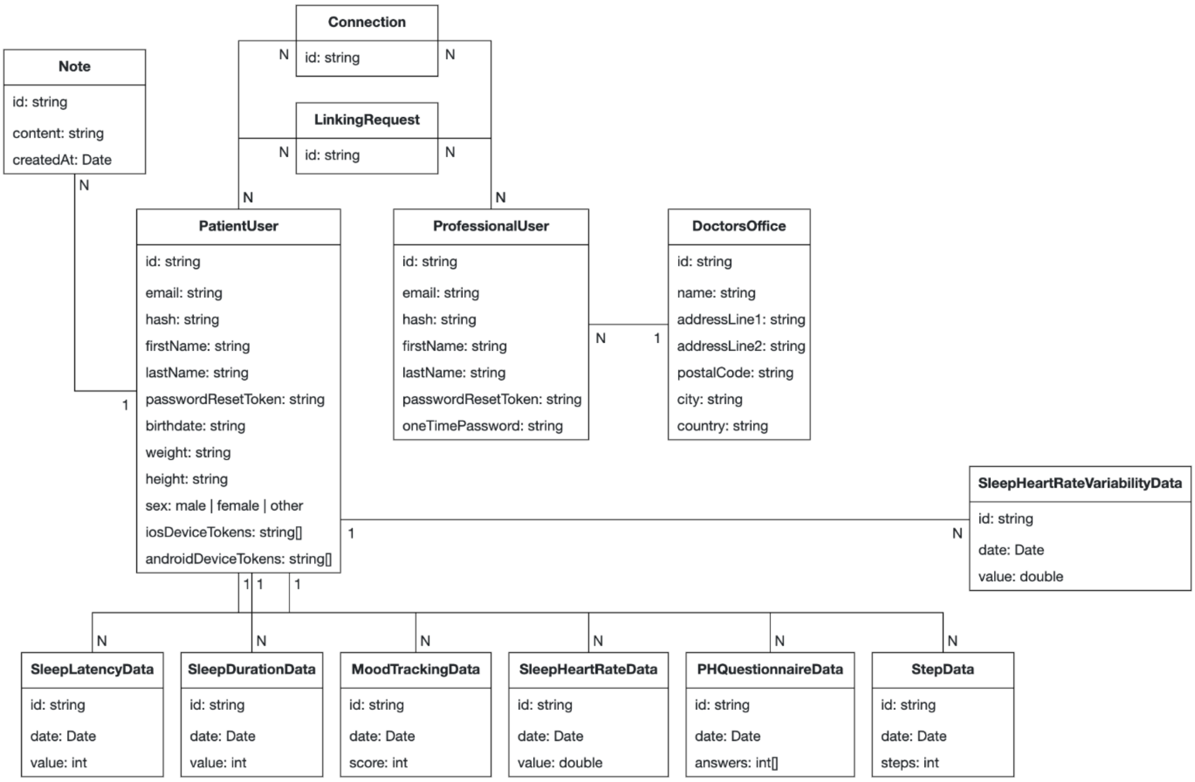
PokalAPI

The PokalAPI acts as an intermediary between customers and the REST implementation. On one side, it defines the routing details implemented by the backend, including routing location and authentication specifications, which is why it implements a specific PokalAPI version. On the other side, it provides request handlers for the clients. The PokalAPI is written in TypeScript and designed to run in a NodeJS environment. By installing this NPM package, clients (such as the web front end and application front end) can use the request handlers to interact directly with the REST implementation. It also defines socket channel keys clients can subscribe to for updates on objects in the local store. The PokalAPI also documents the route specifications exported by the REST implementation, which are displayed

6.2.3 Data Structure

This chapter provides a detailed insight into the POKALConnect data model and the key entities that form the basis of the system's database structure. Each entity plays a critical role in the management and exchange of PGHD and facilitates interactions between patients and GPs. Understanding these entities and their relationships clarifies how the system supports secure data capture, access, and management while ensuring that personal data is handled with appropriate controls and integrity. An overview of the data model can be found in Figure 13.

Figure 13: POKALConnect Data Model (own illustration)



PatientUser Entity

The PatientUser entity represents a person who uses the system to track their health data. It stores personal information such as email, first name, last name, date of birth, weight, height, and gender. Authentication features include a hashed password and a token to reset the password. Additionally, the entity holds device tokens for iOS and Android devices to enable notifications. The PatientUser entity has several significant relationships, including a 1-to-1 relationship with the Connection entity via the LinkingRequest entity, which allows professional users (such as doctors) to access their data. It also has a 1-to-many relationship with various health data entities where information such as sleep metrics, mood tracking, and questionnaire responses are stored.

ProfessionalUser Entity

The ProfessionalUser entity represents healthcare providers who access patient data. Like the PatientUser entity, it contains basic identifying information such as email, first and last name, a hashed password, and a one-time password for secure access. This entity is directly linked to a DoctorsOffice entity representing the office or practice to which the professional user is assigned. Through Connection and LinkingRequest, a ProfessionalUser can interact with the PatientUser 's data, providing a secure and structured way for healthcare providers to manage and monitor patient information.

DoctorsOffice Entity

The DoctorsOffice entity represents the office or healthcare facility where a ProfessionalUser works. It contains the name, address, zip code, city, and country. This entity establishes a link between ProfessionalUsers and their place of work and helps contextualize the relationship between patients and caregivers in the healthcare system. Multiple ProfessionalUsers can be linked to a single DoctorsOffice entity, creating a hierarchical structure that connects healthcare providers to their workplaces.

Connection Entity

The Connection entity serves as a link between the PatientUser and ProfessionalUser entities and facilitates data exchange. This entity likely manages permissions or access to patient data. It ensures that a healthcare provider is only granted access when a connection request has been validated via the LinkingRequest entity. The Connection entity helps to maintain the integrity of access to patient data and ensures that relationships between patients and professionals are clearly defined and secure.

LinkingRequest Entity

The LinkingRequest entity facilitates data-sharing relationships between the PatientUser and ProfessionalUser entities. It processes requests to link a patient to a healthcare provider and provides a secure way for patients to control who accesses their healthcare data. Once a LinkingRequest is approved, it creates a Connection entity that governs ongoing access between the patient and the professional user.

Note Entity

The Note entity stores additional qualitative data related to patients or interactions in the system. It contains fields for the note's content and the timestamp (createdAt). The Note entity will likely capture unstructured information or observations that do not fit into the structured health metrics, such as healthcare provider observations or patient personal reflections.

Health Data Entities

There are multiple health data entities, each tracking a different aspect of patient health and all linked to the PatientUser entity through 1-to-many relationships. These entities include:

- **SleepLatencyData:** Tracks how long it takes the patient to fall asleep and records the latency in minutes.
- **SleepDurationData:** Records the total duration of the patient's sleep for a given night.
- **MoodTrackingData:** Records the patient's mood, likely quantified by a score that provides insight into mental health status.
- **SleepHeartRateData:** Records the patient's heart rate during sleep, often collected via wearable devices.
- **PHQuestionnaireData:** Stores responses to the PHQ-8, which is used to assess mental health, particularly depression.
- **StepData:** Logs the number of steps a patient takes daily, a measure of physical activity often collected by fitness trackers.
- **SleepHeartRateVariabilityData:** Tracks heart rate variability during sleep, indicating autonomic nervous system activity and overall stress levels.

Together, these data entities provide a comprehensive overview of the patient's physical and mental well-being and form the core of patient-generated health data used for monitoring and intervention.

6.3 Design Elements and Constructs of the Patient-Clinician Application’s Web-Frontend

In this section, we describe all aspects of the front end of the patient-clinician platform for GPs. We first discuss the platform's functionalities and then present the technical details of the implementation.

6.3.1 Functional Aspects

The functional aspects of the clinician application of POKALConnect are based on the design principles we developed in Chapter 5 and are supplemented by additional functionalities to maximize the platform's functionality and user-friendliness.

We implement the Design Principle of **Relevant Data** in such a way that we combine the most relevant types of PGHD that we could identify during the qualitative and quantitative findings in the patient-clinician platform. For our solution, we focus on five different categories of PGHD:

- Sleep data
    - Sleep duration
    - Sleep latency
- Activity
    - Daily steps
    - Depression questionnaires
- PHQ-8[3]
- Mood Scale
- Cardiac Parameters
    - Resting heart rate
    - Heart rate variability

We implemented the design principle of **Trust in Data Collection Methods** by choosing a combination of active and passive data collection methods. For the collection of passive data, we use a smart ring from Oura, which provides the best results for tracking sleep data compared to other smart rings. For the active data, we use data from digital questionnaires. This ensures a combination of easy-to-collect and relevant data.

We implement the design principle of **Data Visualization** by preparing the aggregated PGHD of the patients in an easily understandable way. When visualizing the data, we primarily use progression graphs and a traffic light system to identify changes. The progression graphs are intended to show the progression of values over the last few weeks in an easily understandable way. These progression graphs are supported by information on the PGHD to provide precise insight into the data. By clicking on the PHQ8 values, the GPs are shown in detail the answers to the individual questions. The traffic light system is intended to give the GPs a quick insight into the changes in the progression data.

We have implemented the **Severity Assessment** Design Principle in several ways. First, the traffic light system described for the Design Principle visualizes a severity assessment in a simple and quickly recognizable way. The severity assessment is based on two methods: absolute and relative evaluation. Absolute evaluation is used for PHQ8 scores and mood, i.e., fixed or evaluated scales. Relative evaluation is used to assess sleep, activity, and heart data.

We have implemented the design principle of **Alerts for Critical Values** in two ways. Red markings in the traffic light system indicate profound changes, which stand out and are easily

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[3] Since the PHQ-9 questionnaire contains a critical question regarding the patient's suicidal tendencies, we decided to implement and evaluate a variant of the PHQ-9 questionnaire without this critical question. This version is the PHQ-8 questionnaire.

recognizable. In addition, the system sends a weekly report to the GP treating the patient over the last 14 days, which regularly alerts the GP to inferior values.

The following sub-chapters describe the implemented views and functionalities in detail.

6.3.1.1. Patient Overview

A fundamental requirement of the platform is to provide the user with an overview of all the patients they are caring for. Specifically, a list should display the most critical data for all patients treated with the platform.

Implementation in POKALConnect

After logging into the platform, the treating GP receives an overview of the patients he is treating with POKALConnect. This first page thus offers a direct patient overview. An essential requirement of the platform is to provide the user with an overview of all patients under his care. Specifically, a list should contain the most crucial data for each patient. This includes the primary data first name, last name, and date of birth. In addition, the GP should be able to see the results of the five central PGHD categories in a condensed form. To this end, the severity ratings of each category have been integrated. This allows the GP to quickly assess the overall condition of several patients as high or low risk. In this way, the data-driven platform helps to decide which patients need special attention and may require a thorough examination of their medical history. Each entry in the patient overview should display further details.

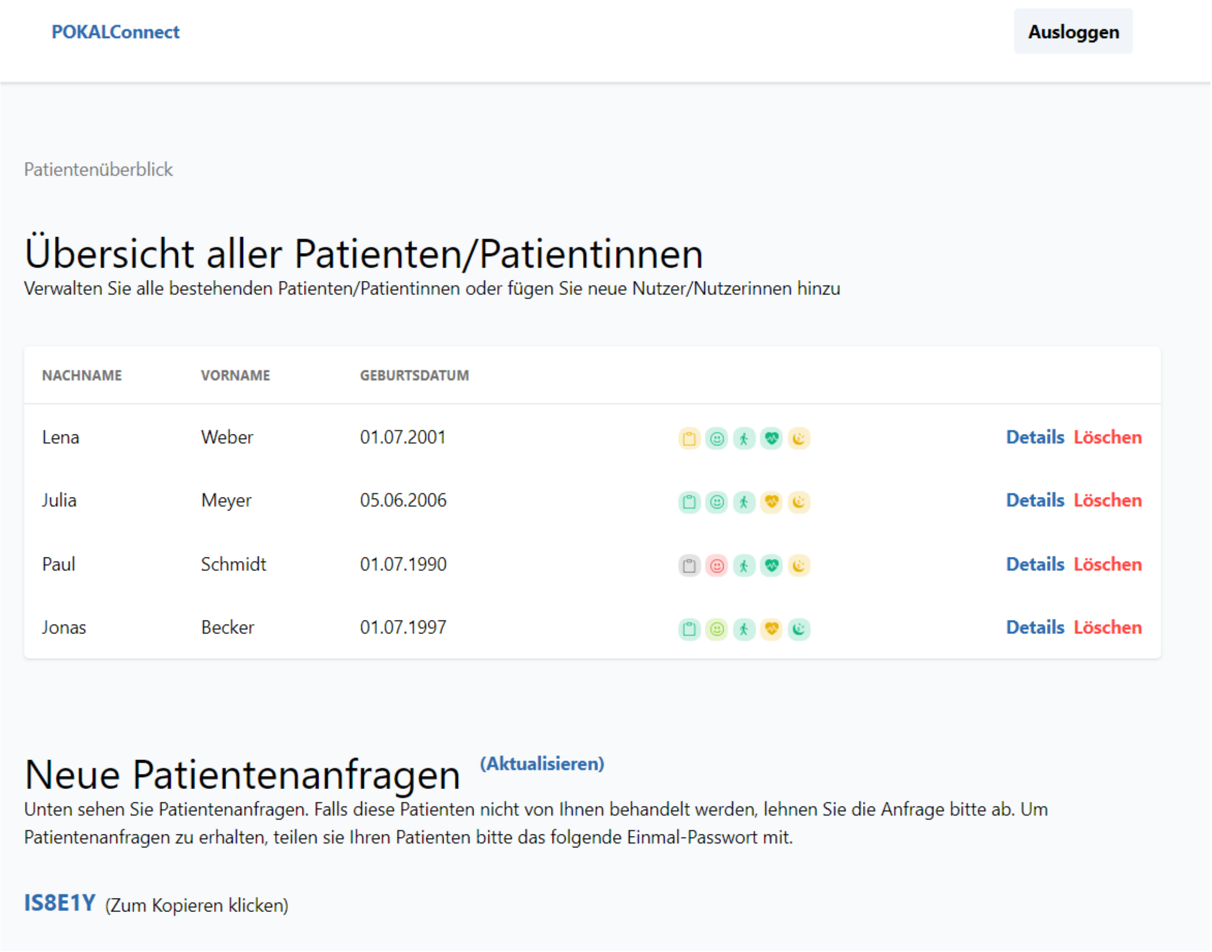
This design decision aligns with the access to patient data called for in the relevance cycle and facilitates care collaboration. As shown in Figure 14, the platform uses a table format to summarize essential information from workshops and interviews, including aggregate severities across the five monitored PGHD categories. This information is conveyed through the consistent application of icons and color-coding established in previous sections, supplemented by a legend to enhance comprehension in line with the user-centered design.

Interacting with the table - for example, highlighting a row with the mouse - signals the user that they can click the “View Details” button for more information. This consistent interactive design across all table views makes it easier for users to navigate the platform and guides them to the patient overview for more information.

6.3.1.2. Add Patient

Another requirement for the patient platform is the secure addition of patients to the patient list. We have already described the exact implementation in the backend in Chapter 4. When implementing the process, it was important to carry out it in a few steps and to be secure and user-friendly. We have schematically depicted the process in Figure 4. In the following, we describe the typical method of adding a patient to the patient list of a GP during a patient-clinician session:

Figure 14: Patient Overview (own illustration)



Übersicht aller Patienten/Patientinnen

Verwalten Sie alle bestehenden Patienten/Patientinnen oder fügen Sie neue Nutzer/Nutzerinnen hinzu

NACHNAME	VORNAME	GEBURTSDATUM	
Lena	Weber	01.07.2001	Details Löschen
Julia	Meyer	05.06.2006	Details Löschen
Paul	Schmidt	01.07.1990	Details Löschen
Jonas	Becker	01.07.1997	Details Löschen

Neue Patientenanfragen (Aktualisieren)

Unten sehen Sie Patientenanfragen. Falls diese Patienten nicht von Ihnen behandelt werden, lehnen Sie die Anfrage bitte ab. Um Patientenanfragen zu erhalten, teilen sie Ihren Patienten bitte das folgende Einmal-Passwort mit.

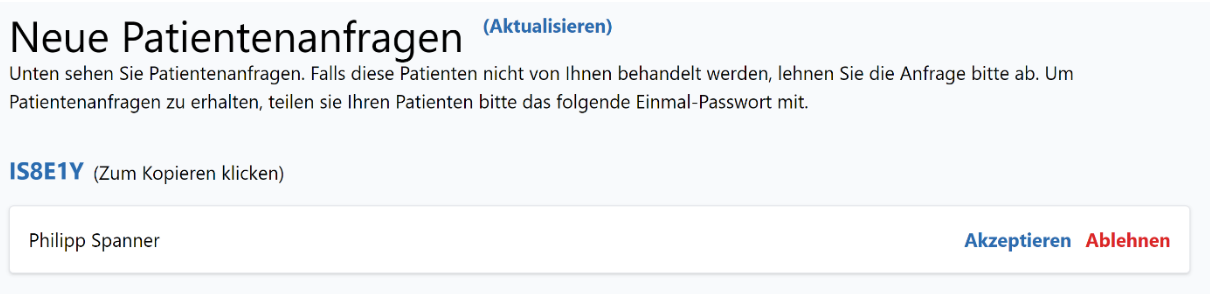
IS8E1Y (Zum Kopieren klicken)

1. The treating GP must enter the displayed one-time password (Figure 15) during the patient-clinician session.

2. After the patient receives the one-time password and enters it in the patient app, the GP must update the list with the current patient requests. This is done by clicking the “Update” button. The new patient will be displayed in the list (Figure 14).

3. After confirming by clicking the “Accept” button, the patient is added to the patient list and can now be viewed by the GP.

Figure 15: Active Patient Request (own illustration)



Neue Patientenanfragen (Aktualisieren)

Unten sehen Sie Patientenanfragen. Falls diese Patienten nicht von Ihnen behandelt werden, lehnen Sie die Anfrage bitte ab. Um Patientenanfragen zu erhalten, teilen sie Ihren Patienten bitte das folgende Einmal-Passwort mit.

IS8E1Y (Zum Kopieren klicken)

Philipp Spanner

6.3.1.3. Patient Summary

The second essential function in patient management is presenting all relevant patient data directly accessible from the patient overview. The literature research and the expert interviews clarified that this is one of the crucial views before and during a medical consultation. Therefore, we designed a dashboard that summarizes and presents the most important aspects of the PGHD. These metrics refer to specific indicators of the respective PGHD category. Furthermore, some GPs requested that the PGHD change trend be displayed over time. Although this information is related to severity, it gives the user additional value to assess whether the values are continuously improving or deteriorating. This combination of aggregated values, severity, and trend per visualized PGHD category gives the user a data-driven, holistic overview of the patient.

Implementation in POKALConnect

The patient overview provides a comprehensive snapshot of a patient's health data, as shown in Figure 16, through a dashboard layout that integrates key performance indicator (KPI) cards for each tracked PGHD category, such as sleep. These cards display 14-day averages for specific metrics within each category (e.g., average sleep duration and sleep onset delay), providing a streamlined perspective that allows for quick understanding and evaluation of key data while minimizing cognitive load. Should a GP wish to explore a specific PGHD category during a consultation, they can access more detailed information by selecting the relevant card, following user-centered design principles, and providing detailed data as needed.

Each PGHD category is identified by a unique icon used consistently across the platform for easy recognition. The dashboard also employs a color-coding system to indicate the severity of each category, using a traffic light scheme to communicate risk levels intuitively. This visual strategy helps to identify high- and low-risk categories quickly. Additional shades of color are introduced for the PHQ-9 category, reflecting the five varying levels of severity, and these visual cues are incorporated into the platform's conceptual framework to improve user familiarity over time.

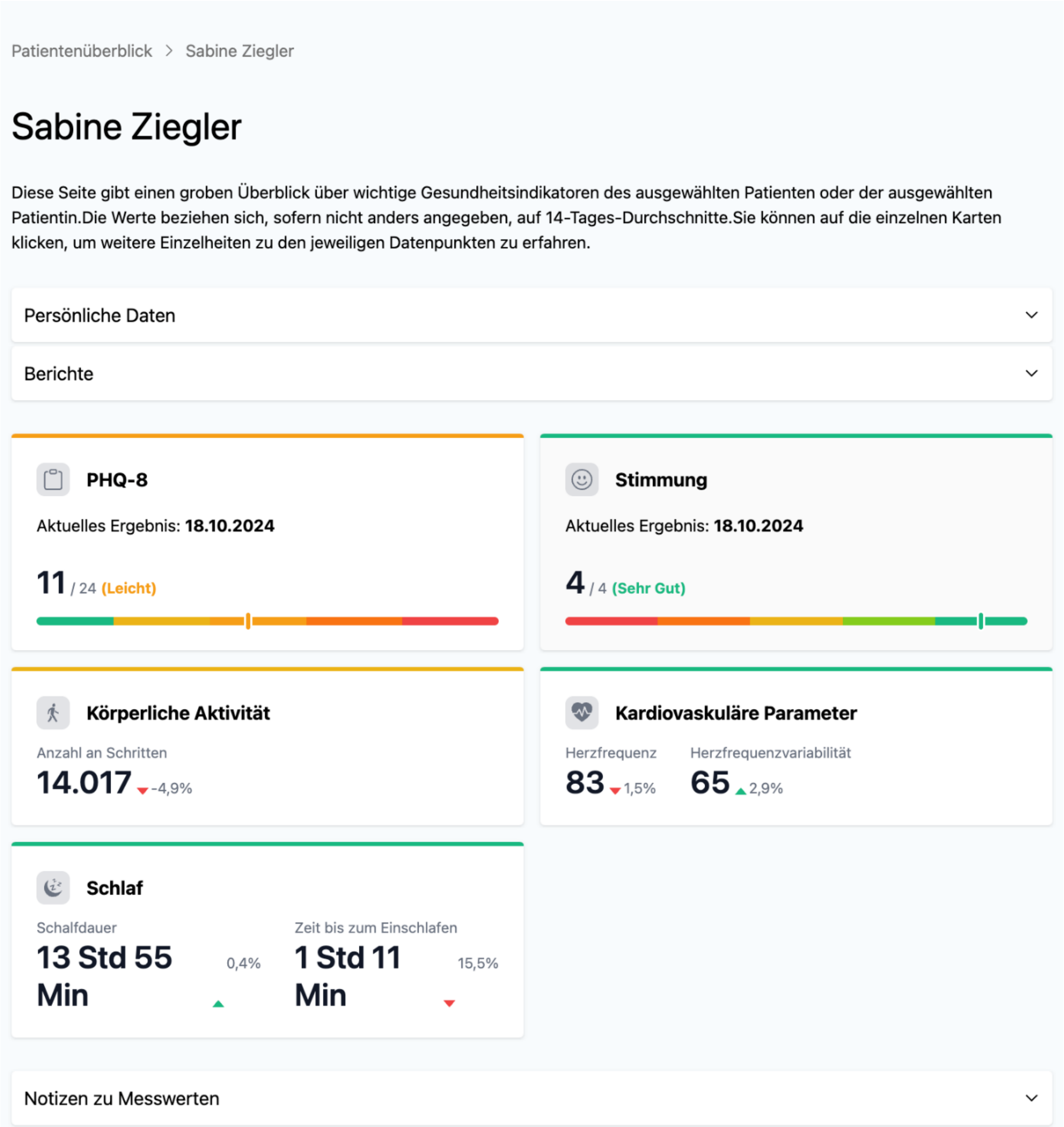
In addition, the platform generates trends for each PGHD metric, displayed as either a red or green arrow next to the 14-day averages, signaling whether the patient's condition is improving or worsening. These trends are calculated based on the percentage change from a 90-day baseline.

In addition to the five core categories of PGHD that form the dashboard's core, the patient overview provides personal information such as name, date of birth, age, and gender. The BMI is calculated for the GP to give the GP a complete picture of the patient. Since body weight and height are required for the calculation but are not constantly monitored and historicized, calculating the severity and trends for these details is omitted. In addition, the last and next appointment at the respective doctor's office should be displayed. The GP can also document findings or other data in free text notes.

6.3.1.4. Patient Details

While the patient overview briefly provides a comprehensive picture of the patient's health, the healthcare professionals also requested a detailed view of each PGHD category. This view should include the data history and all available details for each selected indicator in that category. For example, the detailed view for sleep should show the history of all data on sleep duration and time of falling asleep. For this purpose, the 14-day average history should be displayed since this aggregation is also used in other parts of the platform. Experts and researchers recommend various types of charts to visualize this data. The severity level should be displayed on the respective PGHD detail page as in the patient overview. Ideally, the detailed, historicized data view would clarify the reasons for the severity level to the GP.

Figure 16: Patient Summary Example (own illustration)



Patientenüberblick > Sabine Ziegler

Sabine Ziegler

Diese Seite gibt einen groben Überblick über wichtige Gesundheitsindikatoren des ausgewählten Patienten oder der ausgewählten Patientin.Die Werte beziehen sich, sofern nicht anders angegeben, auf 14-Tages-Durchschnitte.Sie können auf die einzelnen Karten klicken, um weitere Einzelheiten zu den jeweiligen Datenpunkten zu erfahren.

Persönliche Daten

Berichte

PHQ-8

Aktuelles Ergebnis: **18.10.2024**

11 / 24 (Leicht)

Stimmung

Aktuelles Ergebnis: **18.10.2024**

4 / 4 (Sehr Gut)

Körperliche Aktivität

Anzahl an Schritten

14.017 ▼ -4,9%

Kardiovaskuläre Parameter

Herzfrequenz

83 ▼ 1,5%

Herzfrequenzvariabilität

65 ▲ 2,9%

Schlaf

Schalfdauer

13 Std 55 Min ▲ 0,4%

Zeit bis zum Einschlafen

1 Std 11 Min ▼ 15,5%

Notizen zu Messwerten

Implementation in POKALConnect

We have implemented five types of PGHD in POKALConnect. The details of the types of PGHD are listed in Table 23. In the following sections, we explain the detailed views for all five types of PGHD implemented.

Table 23: Overview of PGHD in the POKALConnect Application

Symptoms of depression	Patient-generated health data	Source
Physical Activity	Steps	Wearable
Sleep	Total sleep time Time to fall asleep	Wearable
Cardiac Parameters	Resting heart rate Heart Rate Variability	Wearable
Depression Level	PHQ-9 (depression questionnaire)	Smartphone
Mood	Mood Tracking	Smartphone

Detail View for Physical Activity

Selecting the physical activity card in the patient overview takes the GP to the physical activity detail screen. There are two different visualizations for this view. On the one hand, the daily steps of the last 14 days are displayed in detail in a progress chart. If the GP moves the mouse over the history diagram, a tooltip with the exact number of steps for this time is displayed. A second visualization is located at the bottom of the window. This is a bar chart for the trend assessment of the progression. Each bar corresponds to a 14-day average. If the GP moves the mouse over a bar, a tooltip with the average number of steps for this period is displayed. These diagrams are shown in Figure 17.

On the right-hand side, the criteria for assessing severity are explained. This detail, consistent across the physical activity, heart parameters, and sleep data pages, gives users insight into the scoring methodology, improving their understanding and promoting confidence in the platform. The information box, which shows the 14-day average at the top, adjusts its content depending on the assessment type and data context. The severity for this type of PGHD is always calculated and displayed based on the relative severity.

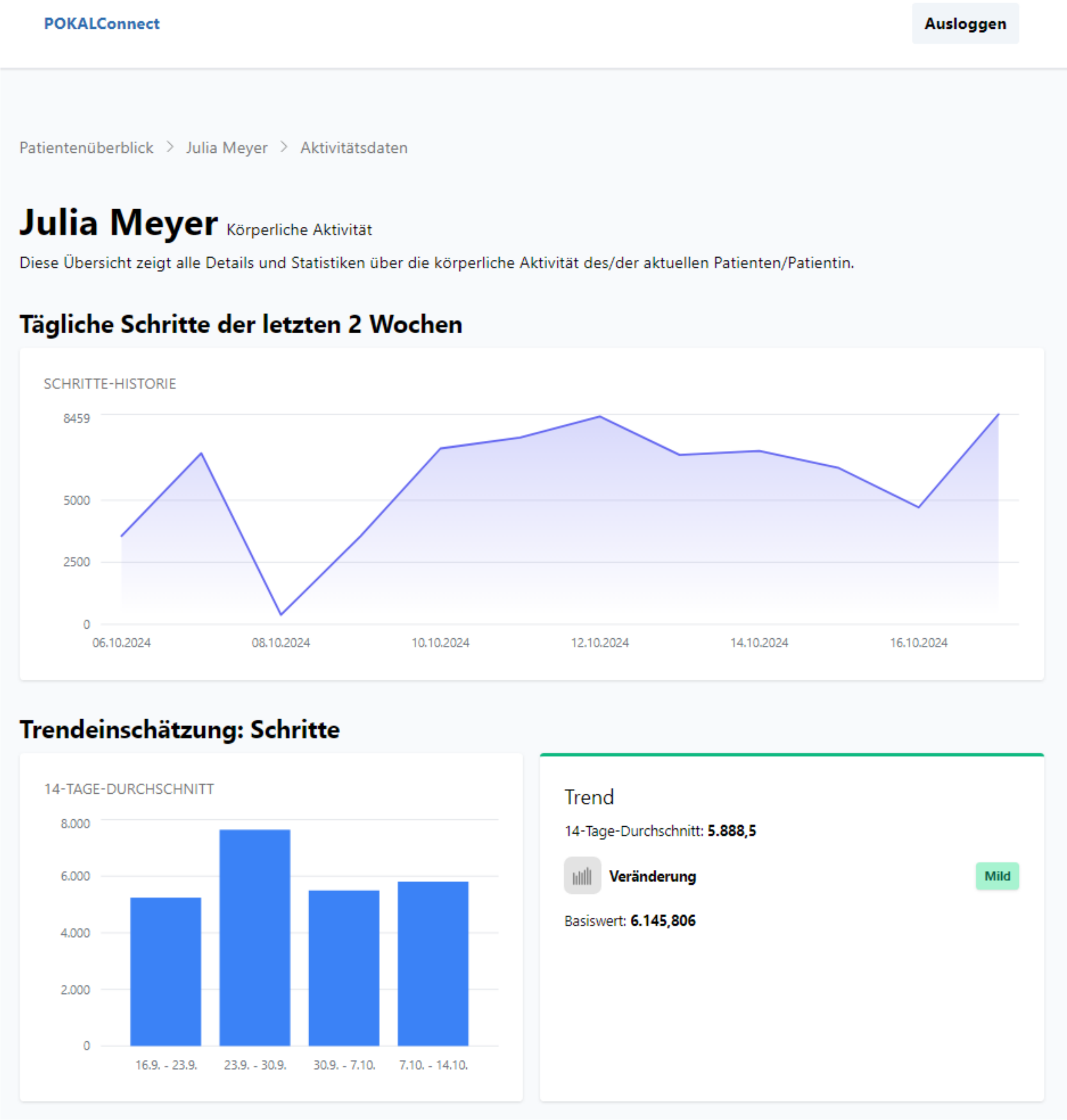
Detail View for Cardiac Parameters

The detailed view of the heart parameters, as shown in Figure 18, corresponds to the format that can be seen in other specific data views of the platform and enables monitoring both heart rate at rest and heart rate variability. This section contains two different diagrams and corresponding severity assessments for each parameter.

The overview provides two diagrams for both parameters (heart rate at rest and heart rate variability). The first diagram shows the course of the last 14 days. Here, the GP can move the mouse over the progress diagram to display the values for the individual days. The second diagram shows a progression of the changes in the 14-day averages. This results in a flatter progression that provides a better insight into the long-term value changes.

This trend is also used to calculate the severity assessment. Here, the z-value for the 14-day average is calculated compared to a 90-day baseline, resulting in the severity level.

Figure 17: Details for Physical Activity (own illustration)



Julia Meyer Körperliche Aktivität

Diese Übersicht zeigt alle Details und Statistiken über die körperliche Aktivität des/der aktuellen Patienten/Patientin.

Tägliche Schritte der letzten 2 Wochen

Trendeinschätzung: Schritte

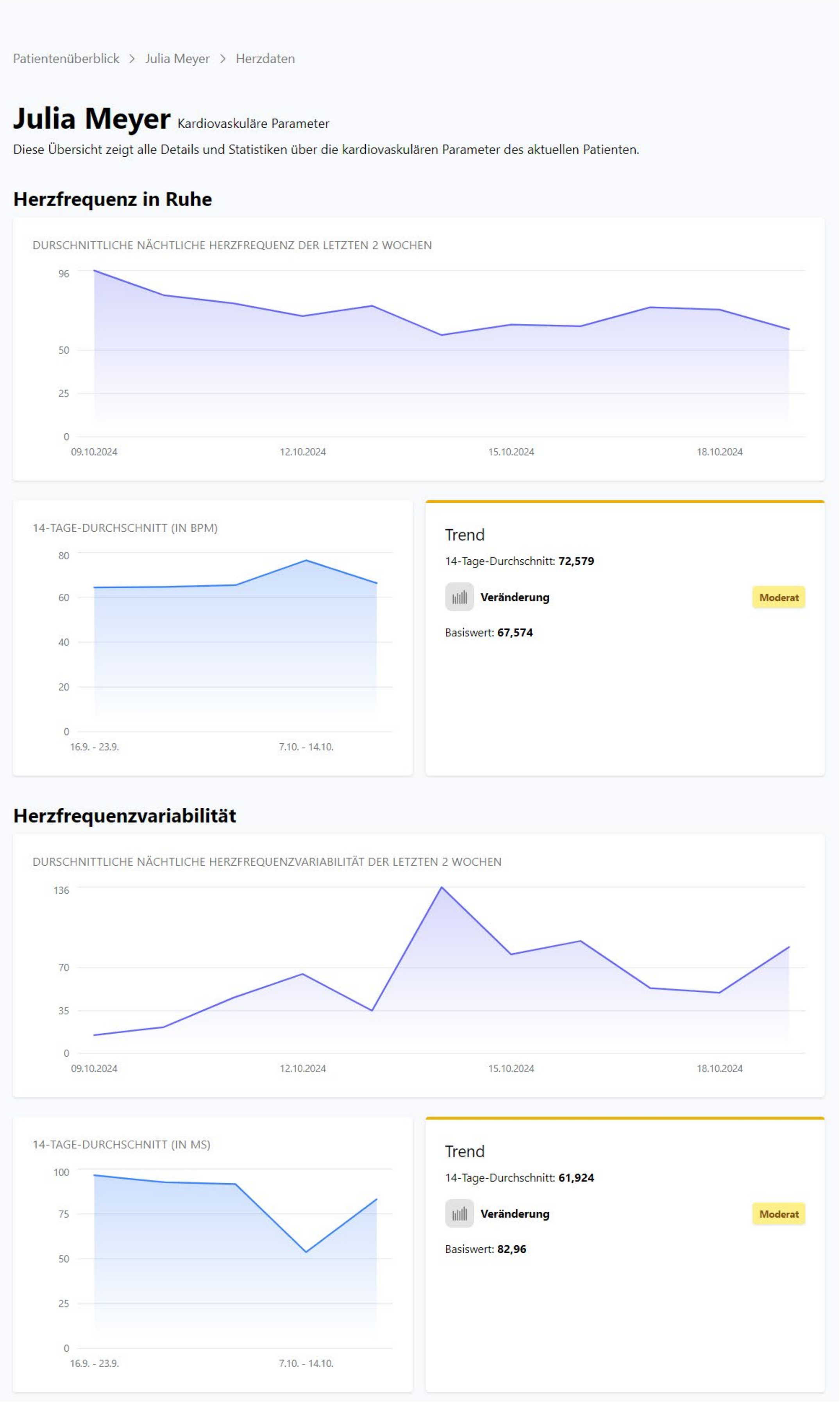
Trend

14-Tage-Durchschnitt: **5.888,5**

Veränderung Mild

Basiswert: **6.145,806**

Figure 18: Details for Cardiac Parameters (own illustration)



Patientenüberblick > Julia Meyer > Herzdaten

Julia Meyer Kardiovaskuläre Parameter

Diese Übersicht zeigt alle Details und Statistiken über die kardiovaskulären Parameter des aktuellen Patienten.

Herzfrequenz in Ruhe

DURCHSCHNITTLICHE NÄCHTLICHE HERZFREQUENZ DER LETZTEN 2 WOCHEN

14-TAGE-DURCHSCHNITT (IN BPM)

Trend

14-Tage-Durchschnitt: **72,579**

Veränderung **Moderat**

Basiswert: **67,574**

Herzfrequenzvariabilität

DURCHSCHNITTLICHE NÄCHTLICHE HERZFREQUENZVARIABILITÄT DER LETZTEN 2 WOCHEN

14-TAGE-DURCHSCHNITT (IN MS)

Trend

14-Tage-Durchschnitt: **61,924**

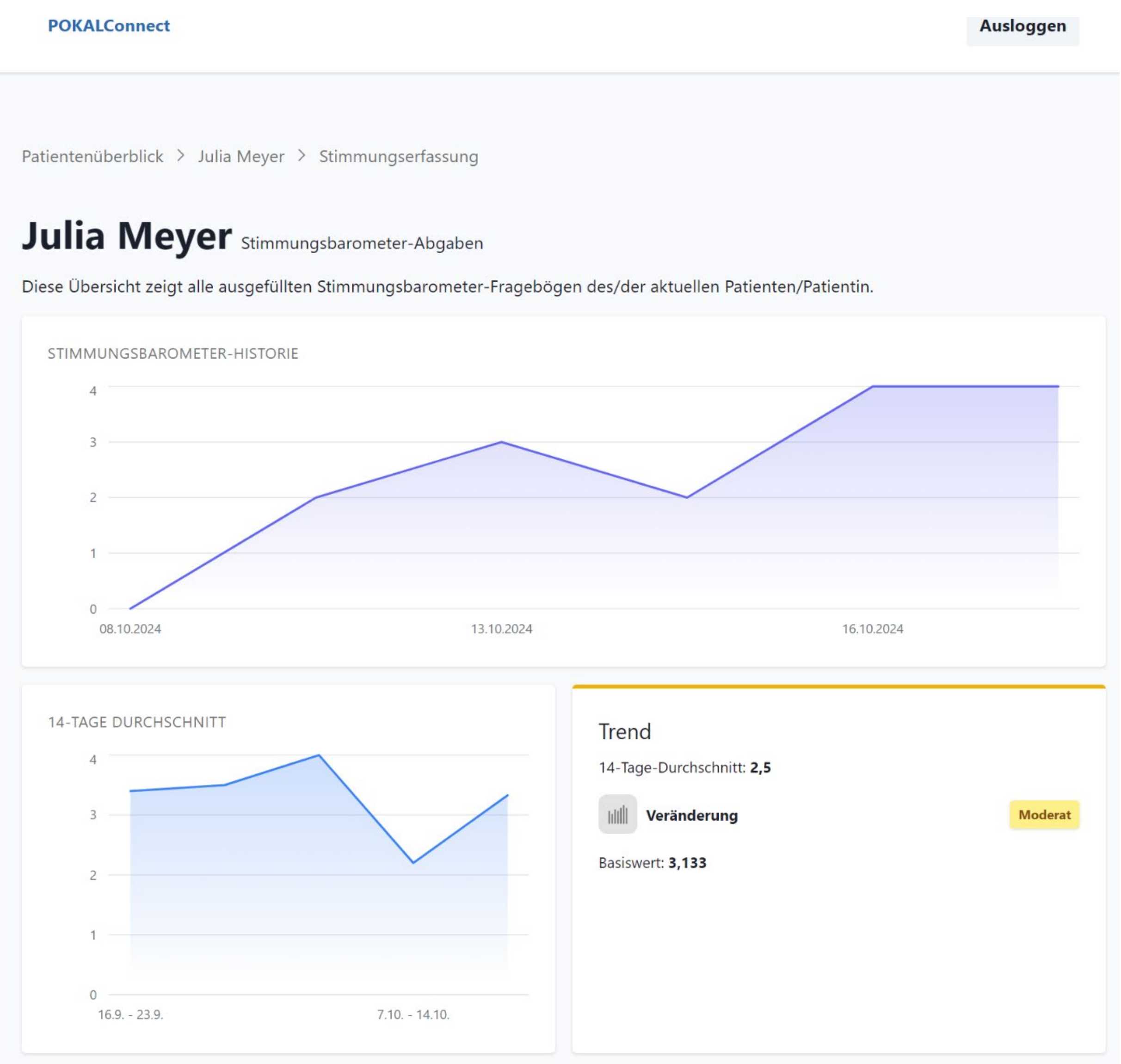
Veränderung **Moderat**

Basiswert: **82,96**

Detail View for Mood

The detailed view of the mood assessment is structured so that the GP using it can see the patient's mood over time. This section contains two graphs and a security assessment for the collected mood values. The first graph shows a history of the values over the last 14 days. Here, the progression over the previous 14 days can be viewed, and the individual values can be highlighted and displayed by moving the mouse over the line. As with other values, the second graph shows the average values over the last 14 days. This trend is also used to calculate the severity assessment. Here, the z-score for the 14-day average is calculated compared to a 90-day baseline, resulting in the severity score. The detailed view for Mood can be seen in Figure 20.

Figure 19: Details for Mood Data (own illustration)



Julia Meyer Stimmungsbarometer-Abgaben

Diese Übersicht zeigt alle ausgefüllten Stimmungsbarometer-Fragebögen des/der aktuellen Patienten/Patientin.

Trend

14-Tage-Durchschnitt: **2,5**

Veränderung **Moderat**

Basiswert: **3,133**

Detail View for Sleep Data

The detailed view of sleep data, shown in Figure 19, corresponds to the format seen in other specific data views on the platform and allows monitoring of both sleep duration and sleep latency (the time between going to bed and falling asleep). This section contains two different graphs and corresponding severity assessments for each parameter.

The overview provides two charts for both parameters (resting heart rate and heart rate variability). The first chart shows the progression over the last 14 days. Here, the GP can hover over the progression chart to display the values for each day. The second chart shows a bar chart with 14-day averages. This allows the averages for the values of the 14-day periods to be compared with each other, revealing long-term trends.

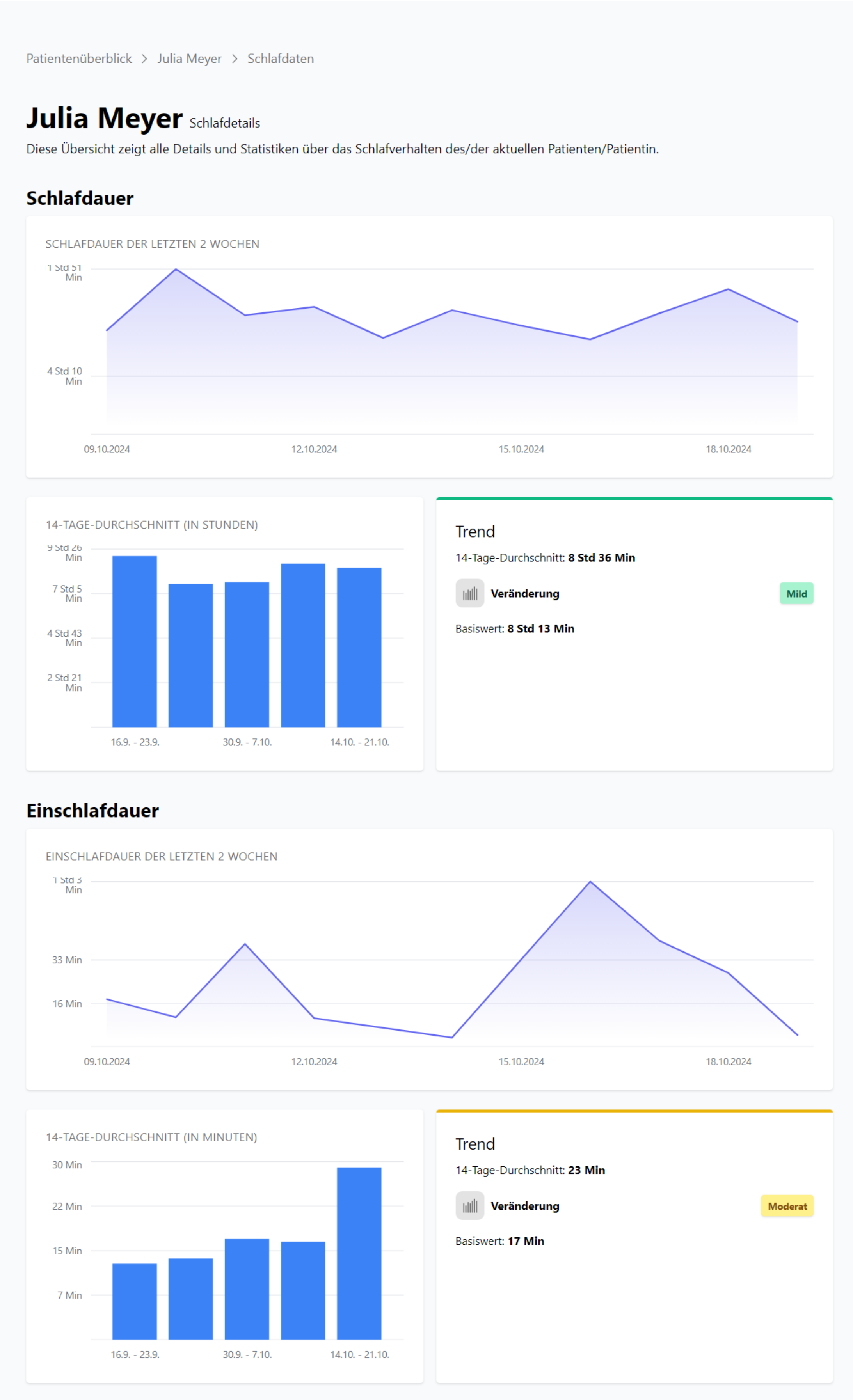
This trend is also used to calculate the severity assessment. Here, the z-score for the 14-day average is calculated compared to a 90-day baseline, resulting in the severity score.

Detail View for PHQ-8

When the user selects the PHQ-8 card in the patient overview, they are taken to a detailed view dedicated to the PHQ-8 submissions, which is different from the physical activity, cardiac parameters, and sleep opinions because it is divided into two separate sections. Initially, a comprehensive overview of all PHQ-8 submissions for the patient under examination is displayed, as shown in Figure 21. At the top of this view is a chart that represents the progression of the most recent PHQ-8 scores, quickly conveying the patient's health history in line with user-centered design principles. Below the chart, a table lists the submissions in reverse chronological order, with the most recent entry highlighted first to improve the platform's usability. This table focuses on crucial details such as submission date, overall score, and severity based on the official rating scale. When the cursor hovers over a table row, it is illuminated, signaling the user that they can click on the row or select the “View Details” button for more information.

The subsequent questionnaire detail view displays the details of a selected PHQ-8 submission, as shown in Figure 22. This view summarizes basic information such as the score, classification, and submission date and presents the eight questions and their answers. These comprehensive details enable the GP to thoroughly review and discuss the submission with the patient to ensure an informed consultation.

Figure 20: Details for Sleep Data (own illustration)



Patientenüberblick > Julia Meyer > Schlafdaten

Julia Meyer Schlafdetails

Diese Übersicht zeigt alle Details und Statistiken über das Schlafverhalten des/der aktuellen Patienten/Patientin.

Schlafdauer

SCHLAFDAUER DER LETZTEN 2 WOCHEN

14-TAGE-DURCHSCHNITT (IN STUNDEN)

Trend

14-Tage-Durchschnitt: **8 Std 36 Min**

Veränderung Mild

Basiswert: **8 Std 13 Min**

Einschlafdauer

EINSCHLAFDAUER DER LETZTEN 2 WOCHEN

14-TAGE-DURCHSCHNITT (IN MINUTEN)

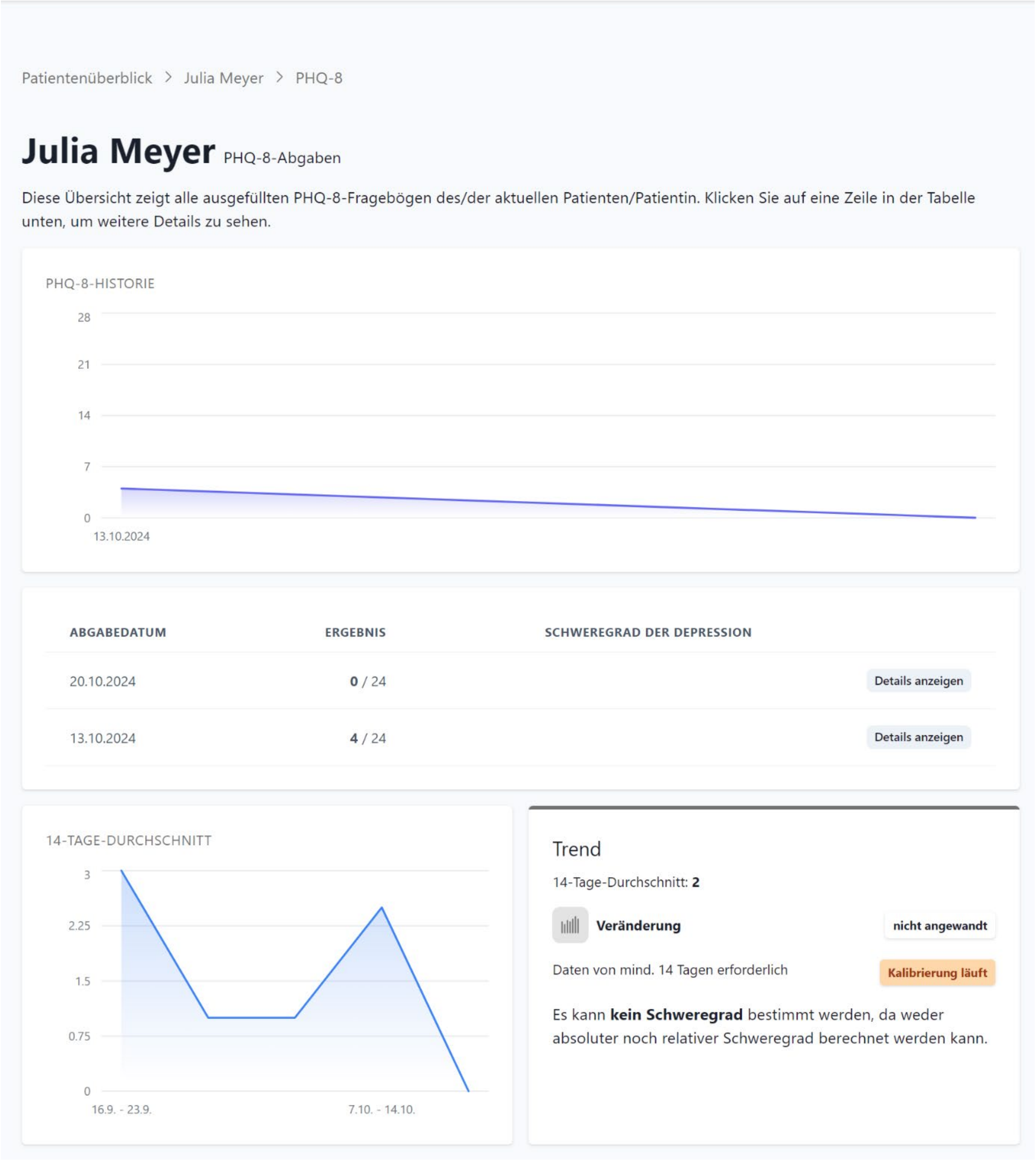
Trend

14-Tage-Durchschnitt: **23 Min**

Veränderung Moderat

Basiswert: **17 Min**

Figure 21: Details for PHQ-8 Data (own illustration)



Patientenüberblick > Julia Meyer > PHQ-8

Julia Meyer PHQ-8-Abgaben

Diese Übersicht zeigt alle ausgefüllten PHQ-8-Fragebögen des/der aktuellen Patienten/Patientin. Klicken Sie auf eine Zeile in der Tabelle unten, um weitere Details zu sehen.

ABGABEDATUM	ERGEBNIS	SCHWEREGRAD DER DEPRESSION	
20.10.2024	**0** / 24		Details anzeigen
13.10.2024	**4** / 24		Details anzeigen

Trend

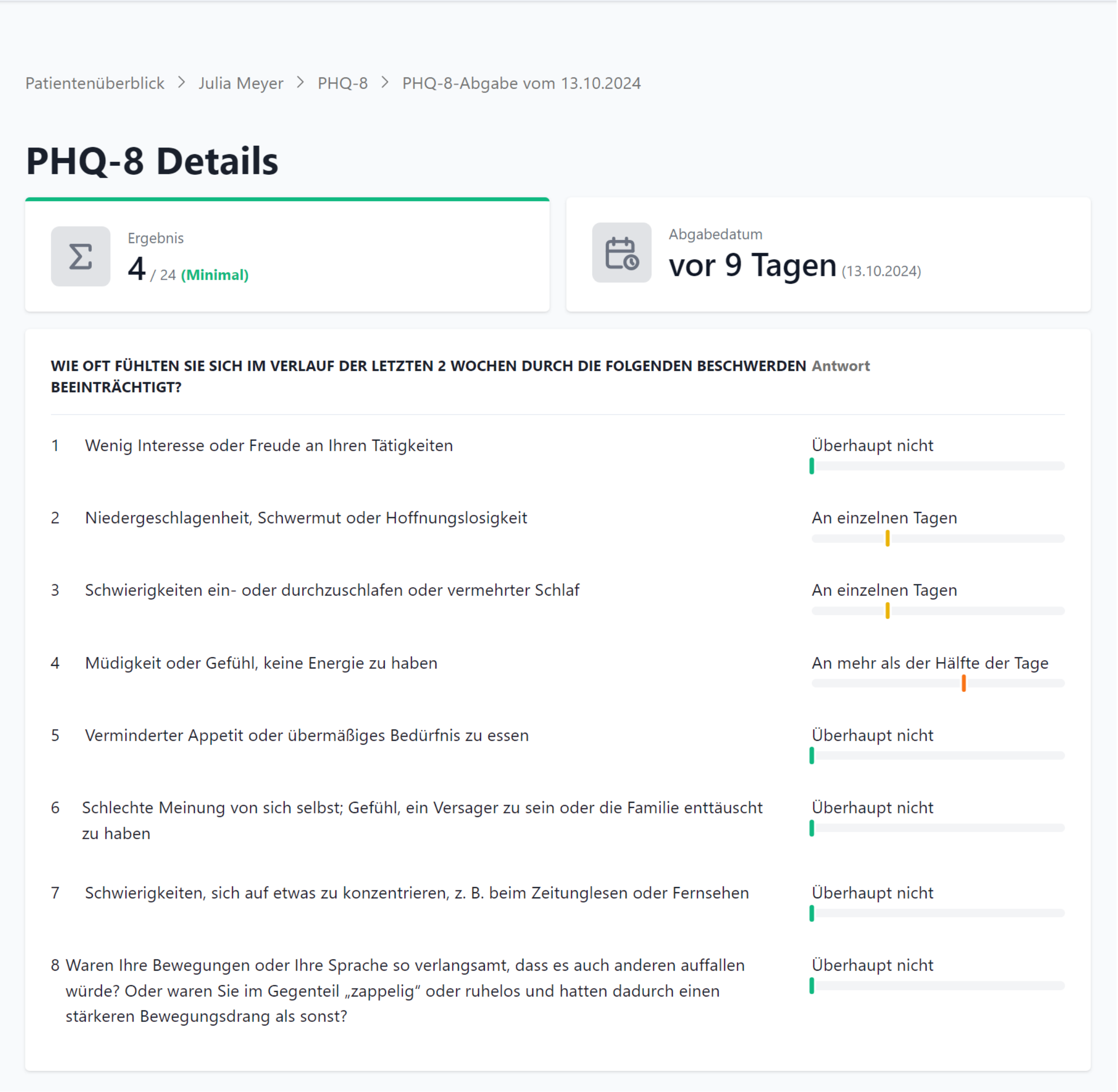
14-Tage-Durchschnitt: **2**

Veränderung nicht angewandt

Daten von mind. 14 Tagen erforderlich Kalibrierung läuft

Es kann **kein Schweregrad** bestimmt werden, da weder absoluter noch relativer Schweregrad berechnet werden kann.

Figure 22: Detailed Questionnaire Results PHQ-8 (own illustration)



PHQ-8 Details

Ergebnis
4 / 24 **(Minimal)**

Abgabedatum
vor 9 Tagen (13.10.2024)

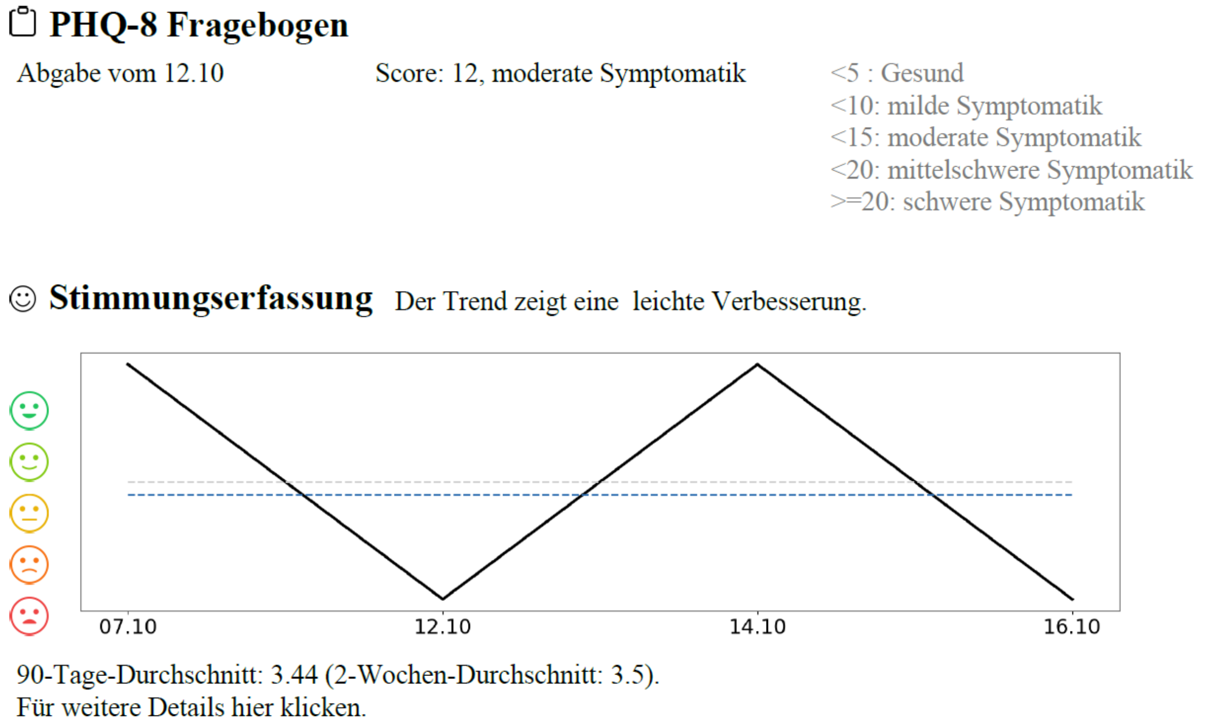
	WIE OFT FÜHLTEN SIE SICH IM VERLAUF DER LETZTEN 2 WOCHEN DURCH DIE FOLGENDEN BESCHWERDEN BEEINTRÄCHTIGT?	Antwort
1	Wenig Interesse oder Freude an Ihren Tätigkeiten	Überhaupt nicht
2	Niedergeschlagenheit, Schwermut oder Hoffnungslosigkeit	An einzelnen Tagen
3	Schwierigkeiten ein- oder durchzuschlafen oder vermehrter Schlaf	An einzelnen Tagen
4	Müdigkeit oder Gefühl, keine Energie zu haben	An mehr als der Hälfte der Tage
5	Verminderter Appetit oder übermäßiges Bedürfnis zu essen	Überhaupt nicht
6	Schlechte Meinung von sich selbst; Gefühl, ein Versager zu sein oder die Familie enttäuscht zu haben	Überhaupt nicht
7	Schwierigkeiten, sich auf etwas zu konzentrieren, z. B. beim Zeitunglesen oder Fernsehen	Überhaupt nicht
8	Waren Ihre Bewegungen oder Ihre Sprache so verlangsamt, dass es auch anderen auffallen würde? Oder waren Sie im Gegenteil „zappelig“ oder ruhelos und hatten dadurch einen stärkeren Bewegungsdrang als sonst?	Überhaupt nicht

6.3.1.5. Weekly Report

In addition to the overviews and detailed overviews in the POKALConnect platform, we have decided to provide the treating GPs with a weekly report. This weekly report is sent every Sunday to Monday night from POKALConnect to the registered email address of the practice. It contains a PDF file with an overview of the collected data from the last two weeks and the associated trends. This report can then be printed and attached to the patient file so that the attending clinician can also have it available in the paper or digital patient file for later consultations, for example. In addition to being sent by email, the generated reports can be displayed and downloaded in the patient summary under the “Report” tab. The weekly reports are structured as follows.

The report begins with the most important personal information about the patient, including name, gender, date of birth, and age. It is followed by a display of the period for which the report was issued. This is followed by the section for displaying the PGHD collected. This section begins with a presentation of the last two PHQ-8 questionnaires. This is followed by a presentation of the patient's average mood scores Figure 23. The following are then displayed: the charts for steps, sleep duration, sleep latency, resting heart rate, and heart rate variability. These graphs provide insight into the last two weeks of values and include two dashed lines for the 90-day and 2-week averages. In addition to the graphs, the absolute values for the 90-day and 2-week averages are displayed below the graph. Next to the data type is an assessment of the trend and how it has recently changed. If the GP wants more information about this data point, they can click "Click here for more details" to go directly to the details page. An example of the data point "Steps" can be found in Figure (Figure 24). The remaining data points are displayed analogously. A complete report can be found in Appendix D.

Figure 23: Weekly Report for PHQ-8 and Mood (own illustration)



PHQ-8 Fragebogen

Abgabe vom 12.10

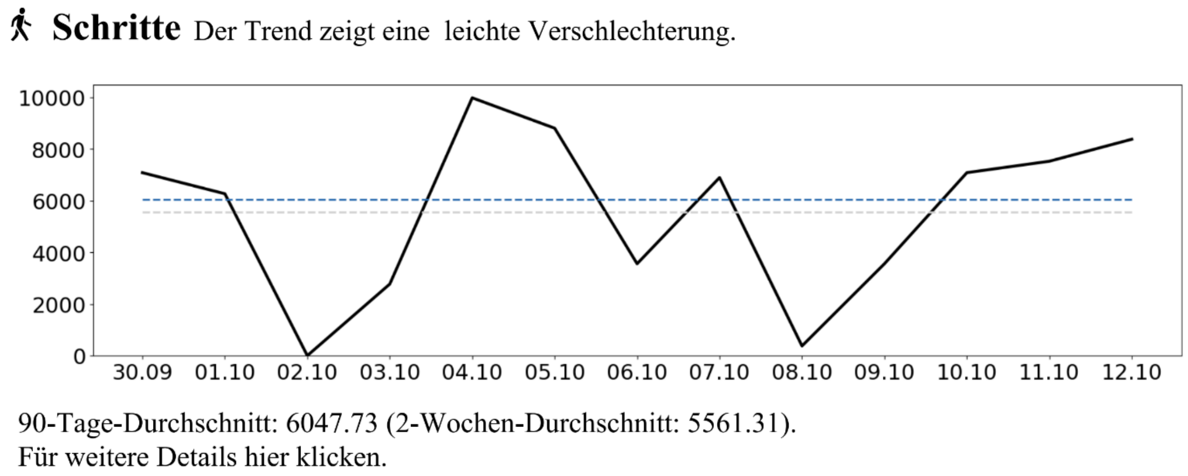
Score: 12, moderate Symptomatik

<5 : Gesund
<10: milde Symptomatik
<15: moderate Symptomatik
<20: mittelschwere Symptomatik
>=20: schwere Symptomatik

Stimmungserfassung Der Trend zeigt eine leichte Verbesserung.

90-Tage-Durchschnitt: 3.44 (2-Wochen-Durchschnitt: 3.5).
Für weitere Details hier klicken.

Figure 24: Weekly Report for Steps (own illustration)



Schritte Der Trend zeigt eine leichte Verschlechterung.

90-Tage-Durchschnitt: 6047.73 (2-Wochen-Durchschnitt: 5561.31).
Für weitere Details hier klicken.

6.3.2 Technical Realization

The technical realization of the web front-end is based on React, a JavaScript-based library for web and native user interfaces (React, 2024). With React, user interfaces can be created from individual parts, known as components. The components are structured hierarchically and can be defined as individual, user-defined tags using the JSX syntax. With unidirectional data flow and the Virtual DOM, React allows the development of complex yet high-performance applications. React is often used for single-page web apps but can also be rendered on the server side with Node.js (React, 2024).

6.4 Design Elements and Constructs of the Patient-Clinician Application's App-Frontend

In this section, we describe all aspects of the front end of the patient-clinician platform for patients. We first discuss the functionalities implemented in the platform and then present the technical details of the implementation.

6.4.1 Functional Aspects

The functional aspects of the patient application of POKALConnect are based on the design principles we developed in Chapter 5 and are supplemented by additional functionalities to maximize the platform's functionality and user-friendliness.

We have implemented the design principle of the **accepted collection methods** in our patient app, so we have chosen a combination of two methods for collecting PGHD. First, we have decided to actively have two digital questionnaires completed by patients to assess PHQ-8 and mood. The digital questionnaire method scored positively during our qualitative surveys. We used an smart ring from Oura for passive data collection (Oura, 2024a). There are several reasons for this. The female participants in our qualitative surveys received the ring well. In our qualitative assessment, the ring was less accepted among men, but several studies show that men also accepted its use. In addition, we found from studies that the Oura Ring provides the best sleep-tracking values (Mason et al., 2024; Robbins et al., 2024). Since sleep data was considered extremely relevant, we prioritized it when choosing the collection method. By using only digital tools, we are also helping to shift PGHD data collection into the digital space.

We have implemented the design principles of the **relevant and accepted data types** in our patient app by selecting the data to be collected. All data collected by patients using the patient app was classified as both highly relevant and relatively easy to collect by patients in the qualitative and quantitative surveys. Based on this assessment of the ease of collecting the data, we conclude that this data was also accepted for collection.

We implemented the design principle of **user-friendliness** in the patient app by paying close attention to usability. To ensure the application's usability, we evaluated the app with potential users during the programming process. This involvement in the development process was intended to provide the consistency and usability of the implemented functionalities. The feedback from potential users was then evaluated and incorporated into the ongoing development.

We implemented the design principle of **positive data communication** by not offering patients a full visualization of their progress but only insights into the data collected over the past day. This is intended to promote communication about the data during the patient-clinician session and avoid unsettling or frightening patients with below-average values.

The following sub-chapters describe the implemented views and functionalities in detail.

6.4.1.1. Authentication and registration

A user account must also be created on the patient side to use the patient app. To do this, the login screen appears first when opening the app. Existing users enter their email address and password to log in. However, new users must click the “Register” button to access the registration screen. In this step, patients must fill out the registration form and provide important information such as email address, password, first name, last name, gender, height, and weight. This information is processed on the back end and stored in the database.

After creating the user account, the patient can use the app but is not yet connected to the GP. To do this, the “Add Patient” process must be carried out. After logging in, the patient must enter the OTP that he receives from his GP in the field provided. The GP can then see the patient on the web platform and view the data.

6.4.1.2. Oura Authentication

After registering in the POKALConnect app, the patient must connect with the Oura server to collect patient data. An Oura account and an Oura smart ring are required for full use of the POKALConnect app. The Oura ring enables passive data collection on steps, sleep, and cardiac parameters.

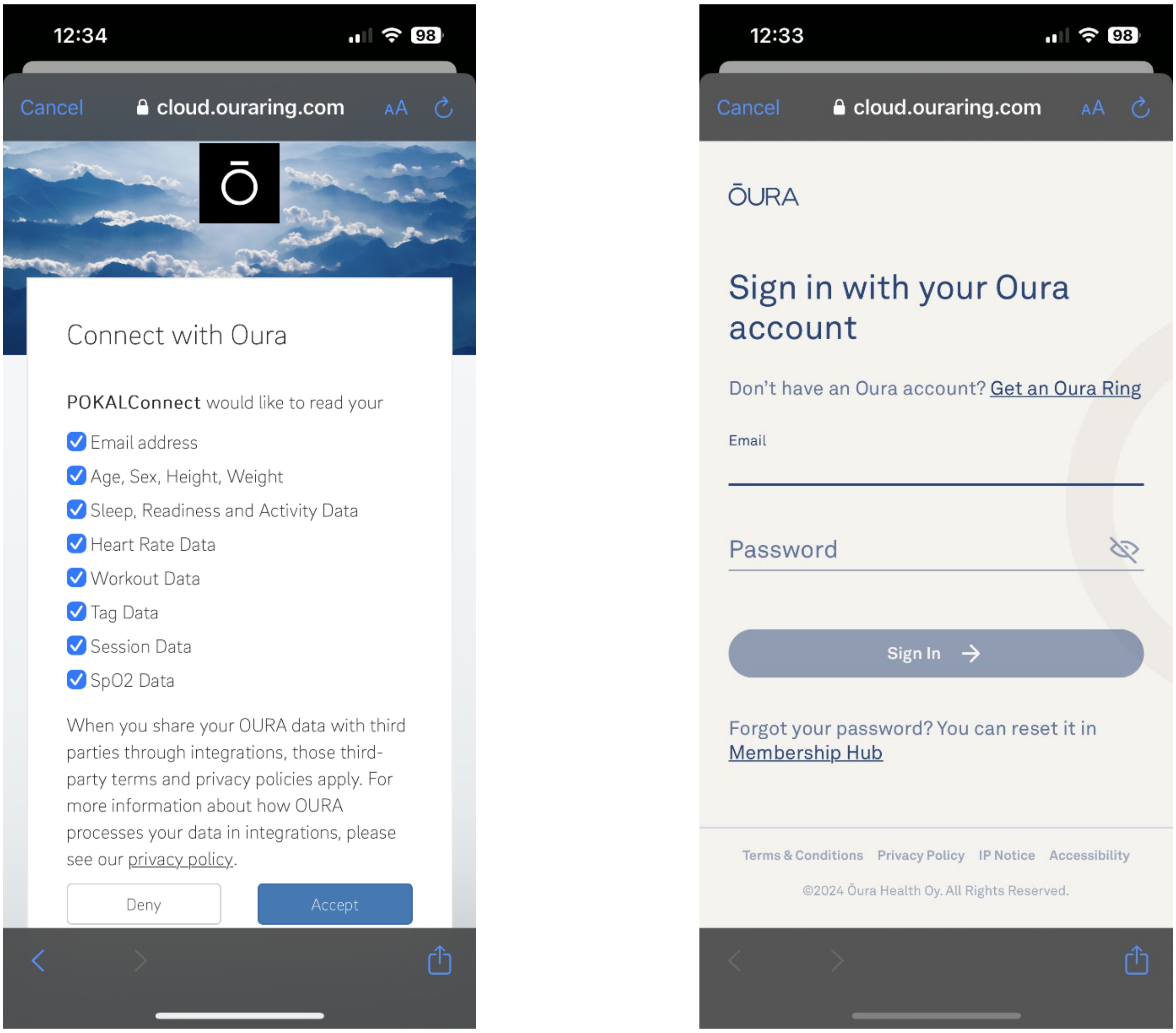
To do this, the user must start the authentication process with the Oura backend. After clicking on “Connect to Oura,” the user must enter their Oura user data (email and password). The patient then only has to accept the user's conditions. Once Oura has authorized the data collection and transmission, only the patients can use the passive data, which will be visible to the GPs. Figure 25 provides an overview of the screens during the Oura connection.

6.4.1.3. Home Screen

On the home screen of the patient app, we have to distinguish between various components.

If the patient has not connected to their Oura account, they will see a message that the POKALConnect account is not yet connected to Oura. Similarly, the patient will see an analogous message if the account is not connected to a doctor's account. The message for the doctor connection also includes the input field for the doctor's OTP. Both information fields are shown in Figure 26.

Figure 25: Oura Connection (own illustration)



Connect with Oura

POKALConnect would like to read your

- ☑ Email address
- ☑ Age, Sex, Height, Weight
- ☑ Sleep, Readiness and Activity Data
- ☑ Heart Rate Data
- ☑ Workout Data
- ☑ Tag Data
- ☑ Session Data
- ☑ SpO2 Data

When you share your OURA data with third parties through integrations, those third-party terms and privacy policies apply. For more information about how OURA processes your data in integrations, please see our privacy policy.

Sign in with your Oura account

Don’t have an Oura account? Get an Oura Ring

Forgot your password? You can reset it in Membership Hub

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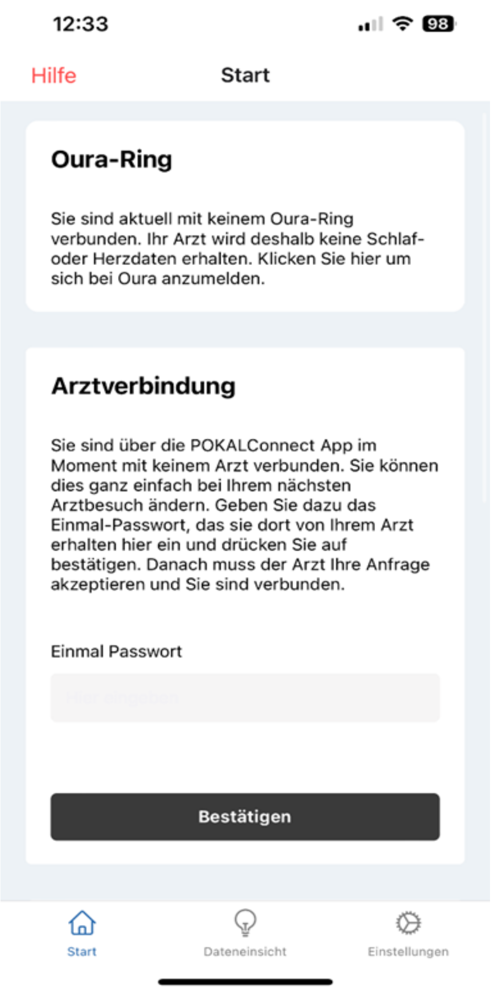
Figure 27: Patient App Home Screen before Oura and GP Connection (own illustration)



Oura-Ring

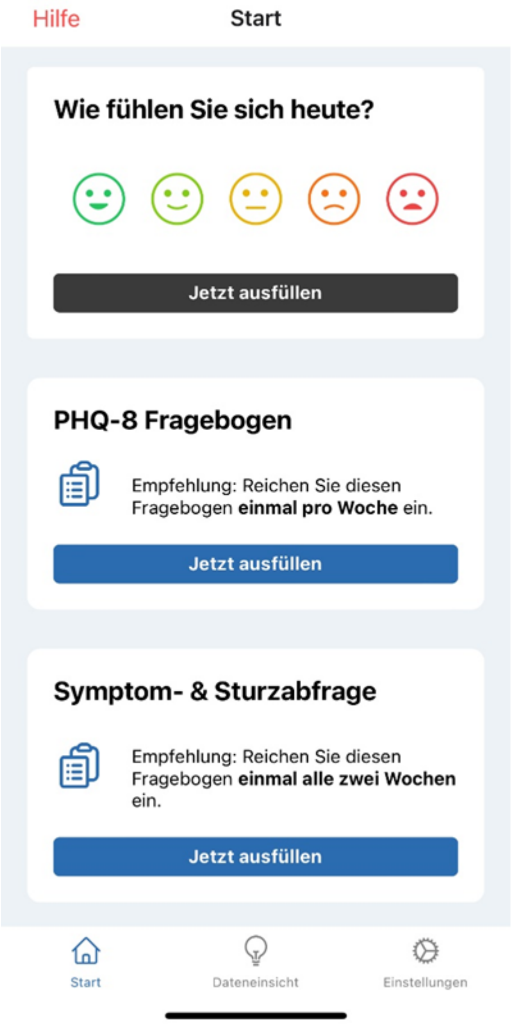
Sie sind aktuell mit keinem Oura-Ring verbunden. Ihr Arzt wird deshalb keine Schlaf- oder Herzdaten erhalten. Klicken Sie hier um sich bei Oura anzumelden.

Arztverbindung

Sie sind über die POKALConnect App im Moment mit keinem Arzt verbunden. Sie können dies ganz einfach bei Ihrem nächsten Arztbesuch ändern. Geben Sie dazu das Einmal-Passwort, das sie dort von Ihrem Arzt erhalten hier ein und drücken Sie auf bestätigen. Danach muss der Arzt Ihre Anfrage akzeptieren und Sie sind verbunden.

Einmal Passwort

Figure 26: Patient App Home Screen (own illustration)



Wie fühlen Sie sich heute?

PHQ-8 Fragebogen

Empfehlung: Reichen Sie diesen Fragebogen **einmal pro Woche** ein.

Symptom- & Sturzabfrage

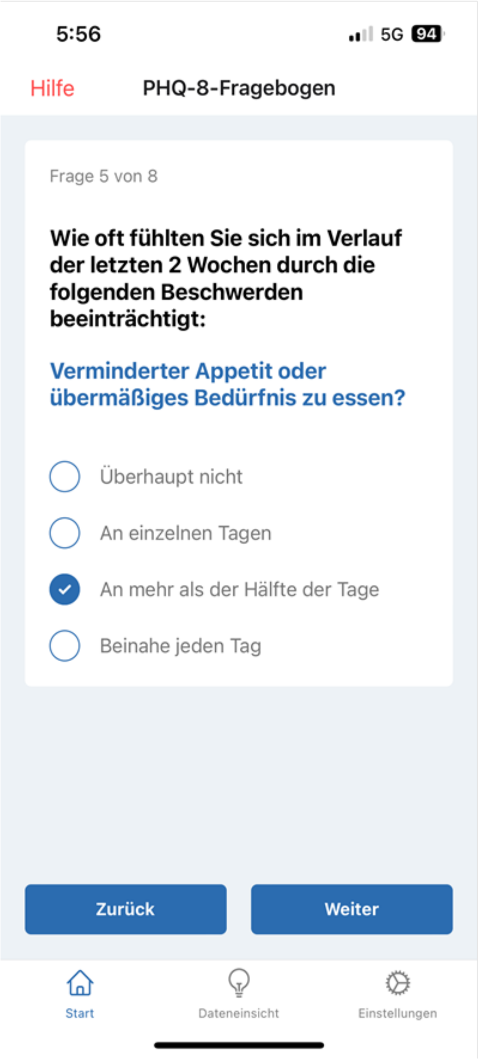
Empfehlung: Reichen Sie diesen Fragebogen **einmal alle zwei Wochen** ein.

The patient app's home screen is depicted in Figure 27. The menu consists of two main components that are always visible: the PHQ-8 questionnaire and mood. For the mood, patients only have to fill in one of the displayed smileys to complete the mood assessment for the day. For the PHQ-8 questionnaire, patients have to complete a questionnaire. These components are shown in Figure 28 and Figure 29. After completing the respective questionnaires, these are marked in a different color and indicate when the questionnaire needs to be completed again. This is shown in Figure 30 and Figure 31.

6.4.1.4. PHQ-8 Questionnaire

Due to its extensive data basis, the PHQ-8 questionnaire is a central component of the POKALConnect platform, which is crucial for assessing the patient's mental and emotional health. This form consists of nine questions. In the prototype, the answers are “Not at all” (with a score of 0), “On some days” (1), “On more than half the days” (2), and “Almost every day” (3). Each answer contributes to an evaluated rating system calculated via the backend (Figure 28).

Figure 29: PHQ-8 Questionnaire Question (own illustration)



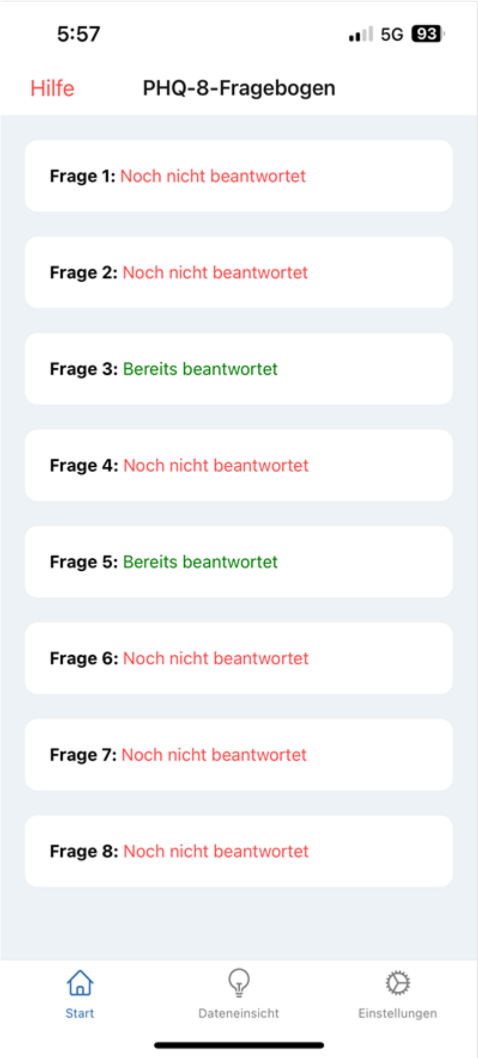
Frage 5 von 8

Wie oft fühlten Sie sich im Verlauf der letzten 2 Wochen durch die folgenden Beschwerden beeinträchtigt:

Verminderter Appetit oder übermäßiges Bedürfnis zu essen?

- ○ Überhaupt nicht
- ○ An einzelnen Tagen
- ● An mehr als der Hälfte der Tage
- ○ Beinahe jeden Tag

Figure 28: PHQ-8 Overview Screen (own illustration)



Frage 1: Noch nicht beantwortet

Frage 2: Noch nicht beantwortet

Frage 3: Bereits beantwortet

Frage 4: Noch nicht beantwortet

Frage 5: Bereits beantwortet

Frage 6: Noch nicht beantwortet

Frage 7: Noch nicht beantwortet

Frage 8: Noch nicht beantwortet

The patient is shown the eight questions on individual pages after clicking on the PHQ-8 questionnaire on the app's home screen. If the patient is interrupted, they can continue where they left off. At the end of the questionnaire, the patient is shown a summary that provides an overview of the questions answered. If a question is skipped, it is marked as incomplete at the end. The patient can then return to this question and complete it (Figure 29).

6.4.1.5. Mood Barometer

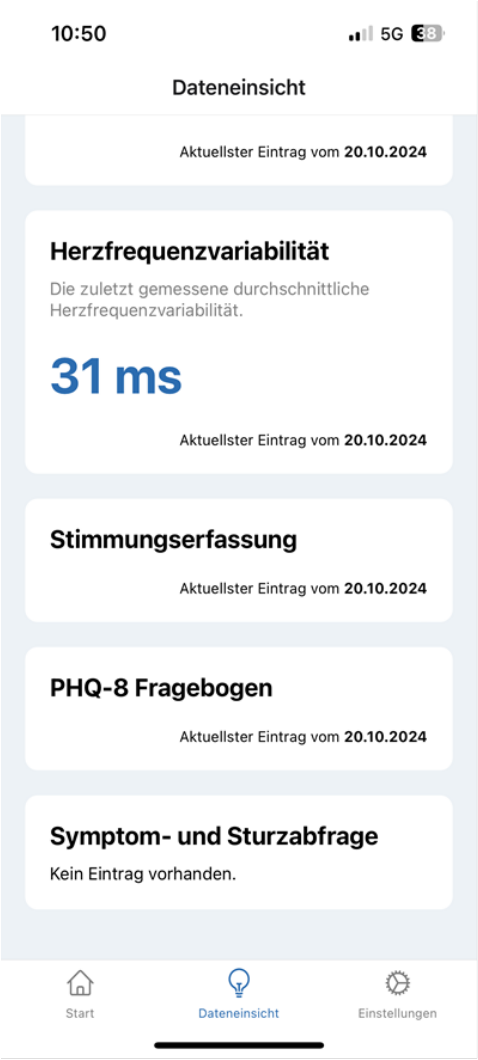
We have also developed a component for assessing the patient's mood. On the home screen, patients are asked, "How are you feeling today?” The rating system for patients is based on a Likert scale that has been transferred to smileys, so the selection ranges from a sad red smiley to a happy green one. This is to make it easier for patients to select. The top of Figure 27 shows the options.

6.4.1.6. Patient Insights

We have added a feature to our app that displays the data collected to provide direct feedback. This is intended to help patients better understand their physical and mental health, but it should not replace discussing the data with their GP. We have integrated five displays for the data points of steps, sleep duration, time to fall asleep, heart rate at rest, and heart rate variability into the application. After completing the PHQ-8 or mood the last completion date is displayed for the mood and PHQ-8 results (Figure 30).

For the five displayed data values, the patients are shown the data for the past day or, in the case of data relating to the night, the past night. Examples of these displays can be seen in Figure 32. When implementing these views, we decided against a history view because, during our qualitative research, a significant concern was that the data could unsettle patients without a detailed explanation.

Figure 31: Patient Insights with PHQ-8 and Mood completed (own illustration)



Dateneinsicht

Aktuellster Eintrag vom **20.10.2024**

Herzfrequenzvariabilität

Die zuletzt gemessene durchschnittliche Herzfrequenzvariabilität.

31 ms

Aktuellster Eintrag vom **20.10.2024**

Stimmungserfassung

Aktuellster Eintrag vom **20.10.2024**

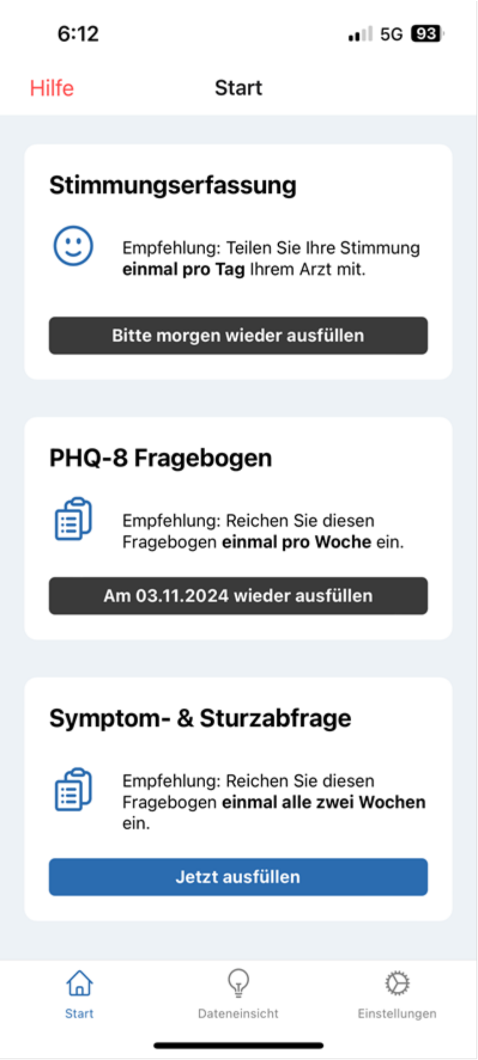
PHQ-8 Fragebogen

Aktuellster Eintrag vom **20.10.2024**

Symptom- und Sturzabfrage

Kein Eintrag vorhanden.

Figure 30: Home screen with PHQ-8 and mood filled in (own illustration)



Start

Stimmungserfassung

Empfehlung: Teilen Sie Ihre Stimmung **einmal pro Tag** Ihrem Arzt mit.

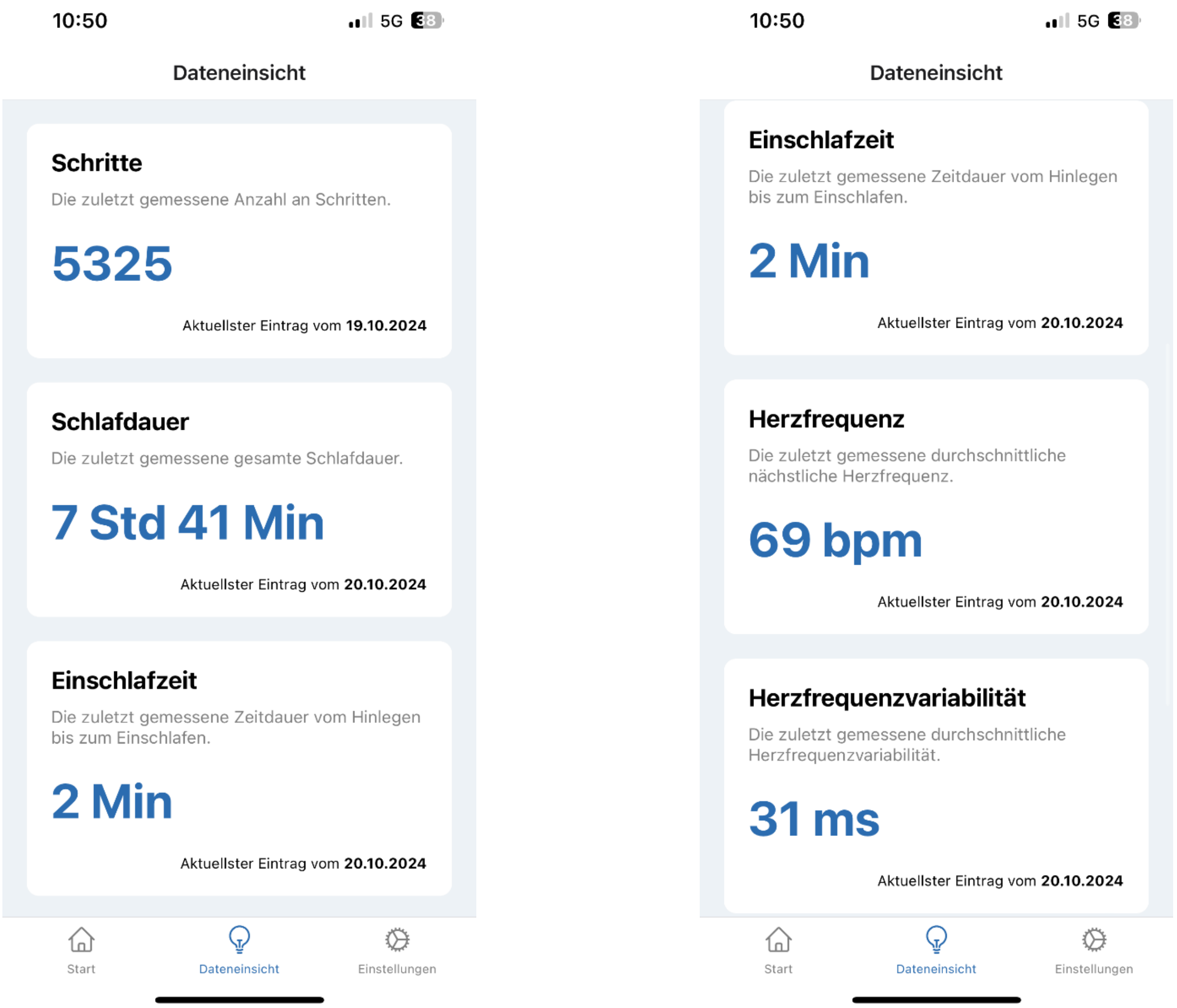
PHQ-8 Fragebogen

Empfehlung: Reichen Sie diesen Fragebogen **einmal pro Woche** ein.

Symptom- & Sturzabfrage

Empfehlung: Reichen Sie diesen Fragebogen **einmal alle zwei Wochen** ein.

Figure 32: Patient Insights (own illustration)



10:50 5G 38

Dateneinsicht

Schritte

Die zuletzt gemessene Anzahl an Schritten.

5325

Aktuellster Eintrag vom **19.10.2024**

Schlafdauer

Die zuletzt gemessene gesamte Schlafdauer.

7 Std 41 Min

Aktuellster Eintrag vom **20.10.2024**

Einschlafzeit

Die zuletzt gemessene Zeitdauer vom Hinlegen bis zum Einschlafen.

2 Min

Aktuellster Eintrag vom **20.10.2024**

10:50 5G 38

Dateneinsicht

Einschlafzeit

Die zuletzt gemessene Zeitdauer vom Hinlegen bis zum Einschlafen.

2 Min

Aktuellster Eintrag vom **20.10.2024**

Herzfrequenz

Die zuletzt gemessene durchschnittliche nächstliche Herzfrequenz.

69 bpm

Aktuellster Eintrag vom **20.10.2024**

Herzfrequenzvariabilität

Die zuletzt gemessene durchschnittliche Herzfrequenzvariabilität.

31 ms

Aktuellster Eintrag vom **20.10.2024**

6.4.2 Technical Realization

The system comprises the POKALConnect app, developed with React Native, and connects to two essential external services. It connects to the Oura API to obtain health data and integrates with clinicians' web-based platform. The POKALConnect app facilitates user registration and displays critical health data to identify significant patterns, sourcing this information from the Oura API. Users control the data transfer process; they must manually approve data sharing from the POKALConnect app to the clinician's platform. This connection improves security by enabling controlled data exchanges with the database, reducing security risks in such transfers.

React Native Framework

The React Native framework allows our application to function seamlessly on iOS and Android platforms using a single code base. This approach significantly reduces the development time for our robust, out-of-the-box mobile application. It allows us to ensure a high level of user experience on both Android and iOS. React Native is built on the React JavaScript library. Our project has specific native applications for iOS and Android, both of which can function independently. The iOS application, for example, can be run in Xcode and will function as though it were written in Swift. Similarly, the Android application can run independently, though it appears to have been developed in Kotlin. This efficient framework makes it possible to deploy both native applications quickly (Meta, 2024).

Expo

Expo is a platform of tools and services that simplifies the creation, development, and deployment of React Native applications. We chose Expo over the React Native CLI for several reasons. The easy-to-use framework includes numerous pre-built libraries that simplify the learning process. Expo also makes it easy to deploy updates without re-downloading the app or publishing a new version. It provides an efficient deployment solution that can be tested immediately using the Expo Go app. Expo compiles the app and generates a QR code, allowing easy testing on Android and iOS platforms (Expo, 2024).

Axios

React Native Axios is a widely used HTTP client for React Native applications that can be used in various environments such as browsers and Node.js. It supports the Promise API, automates the conversion of JSON data, and allows the interception of requests and responses. It is also integrated into the Expo platform libraries, enabling seamless integration into our mobile application. We chose Axios because it is user-friendly, simple, and equipped with basic features. Alternatively, the React Native library offers the Fetch API, suitable for smaller projects with basic network requirements. However, in our case, where we initially needed to connect to a backend platform with a Node.js server implementation, Axios proved more advantageous. Although the Fetch API reduces maintenance and security concerns, Axios was the better solution for our use case. We use this third-party library to retrieve health data from the Oura API and then send it to the database. This process demonstrates the practical application of the library in our project (Axios, 2024).

React Native App Auth Library

React Native App Auth is a well-known OAuth client that enables a secure connection between the POKALConnect app and the Oura API. This library is an intermediary for AppAuth-iOS and AppAuth-Android, making communicating with OAuth 2.0 providers, particularly the Oura API, easier. Although it is a third-party library not included in Expo, we found a solution to integrate it into our app despite its status as a native library. The library's main features illustrate its advantages. One key feature is simplifying the OAuth 2 process into basic, user-friendly methods. It efficiently manages token storage and enables easy recovery. It is also compatible with Android and iOS platforms. However, specific configuration adjustments are required in our case due to the standard authentication flow in Expo (Expo, 2024; Meta, 2024).

Oura API

The Oura API is an external service in our infrastructure and links the app and the data of the Oura rings. Consequently, all passively collected PGHD, heart rate, heart rate variability, sleep duration, sleep duration, and steps displayed in the POKALConnect app come from the Oura API. This information is then transmitted to the backend. The API complies with the industrystandard OAuth 2 protocol. To connect to this API, the patient must set up an Oura account and register our application on the Oura API website to get the necessary personal token (Oura, 2024b).

6.5 Deployment

The platform is deployed on multiple servers for stability and security reasons. The database is installed on the same device as the backend service. Since the backend service needs access to the report service output directory to provide professional users with their patients' reports, it is also on the same device. The database is not accessible from outside the device (i.e., the remote host) and is protected by basic authentication. The backend runs in a NodeJS process. The entry point to the backend is an Apache web server running on the Ubuntu host. Proxy requests from the web server begin with /api/ and are forwarded to the backend process. This proxy requires an SSL connection, so the backend can only be accessed via SSL because the NodeJS process runs on a port that is not accessible from outside the host. The ReactJS web frontend is integrated into a static output generator. It is published on a second Ubuntu server via an Apache web server configured similarly to the backend service and enforces the SSL standard. Back and web frontend services are redeployed when pushed to the main or merge server. The PokalAPI is built with an updated version code and pushed to the NPM repository. The reporting service is redeployed by removing the old cron job and adding a new one with the updated path to the new executable.

6.6 GP Platform Evaluation

To evaluate and improve the developed artifact, we interviewed medical professionals, including GPs and psychotherapists (see Table 24 for details of the participants). This step aimed to review the usability, visualization of data, and possible information overload caused by PGHD. To do this, we developed an interview guide for semi-structured interviews, which we then conducted with eight medical professionals. We split the interviews. In the first step, we asked the participants for their assessment of types of PGHD for depression care. In the second step, we presented the participants with the types of PGHD we had identified and used them to check the relevance of these PGHD. In the last step of the interview, we presented the participants with the prototype we had created. The prototype used at this point was filled with dummy data (Figure 33). We asked seven participants to complete the System Usability Scale to gain a general insight into the platform's usability. We then presented the participants with an alternative version of the prototype that included eight types of PGHD to see if the participants preferred more or fewer types of PGHD in the web platform (Figure 34). In the presentation of the platform evaluation, we focus primarily on the artifact-specific results.

Table 24: Participants - Interviews Prototype Evaluation

Profession	Gender	Age
Doctor	Male	29
Doctor	Female	59
Psychotherapist	Female	30
Doctor	Male	Prefer not to say
Psychiatrist	Female	Prefer not to say
Doctor	Male	28
Doctor	Male	Prefer not to say
Doctor	Male	Prefer not to say

6.6.1 Usability of the GP Platform

Participants found the platform user-friendly and free of unnecessary complexity and confirmed that they could use it independently without technical assistance. They were able to quickly search the assigned patients and efficiently use the available data to get an overview of the level of depression and general health of the example patient. Participants also found it effortless to change the view and access detailed information on individual data points. They highlighted the usefulness of the color indicators in focusing on critical topics during patient interviews without having to filter data manually. One participant's statement is indicative of the usability of the platform:

> *"Excellent. Very clear, intuitive to use, and gets right to the facts. The various tools enable us to grasp different aspects of depression and develop tailored therapies quickly." (GP)*

The SUS results showed that the participants did not identify any inconsistencies and found the system easy to learn, especially concerning severity assessment. They praised the platform's assessment methodology for its robustness and flexibility and appreciated the explanatory fields for transparency. This transparency enabled them to trust and integrate the platform more effectively into their treatment processes. Participants indicated that they would proactively contact patients identified by the system as having an increasing severity, as they felt this was a clear advantage over in-person visits.

> *"Especially for those weeks after discharge, such a digital platform would be beneficial in monitoring positive developments at best or intervening if necessary. This would enable us to call patients for follow-up care, and based on the platform results, we would already have an impression instead of relying entirely on the patient's subjective impression. Overall, I see a great opportunity to use such platforms to support the previous experience-driven approach of doctors with objective data analysis. This combination can only improve quality in case of doubt." (GP)*

The participants did not express any specific criticisms, reflected in the high SUS scores. The SUS overall score is above average, with an overall average value of 92.3 (Table 25). In summary, the results show the high quality of the developed design object and confirm the implementation of the requirements identified in the relevance cycle.

Table 25: SUS-Scores for the GP Platform

Participant	No. Participants	Mean	Min	Max	Standard Deviation
Healthcare Professionals	7	92.3	78	100	8.67

6.6.2 Data Visualization

Participants praised the intuitive and effective presentation and graphics of the PGHD, particularly the graphical representation of PHQ-9 scores over time. This feature solves a common problem for GPs who rely on patient memory. Participants also confirmed the relevance of the selected PGHD categories – physical activity, cardiac parameters, sleep, and PHQ-9 – as important markers they already use. They viewed the continuous monitoring and evaluation of this data through the DP platform as a significant improvement in depression management. Participants reported that the graphs helped track progress and provided valuable insights into patients' behavioral changes.

The view of the PHQ-9 questionnaire was highly praised, particularly by the participating GPs. It allowed progress monitoring and provided a detailed breakdown of individual questionnaires. This enables doctors to estimate the onset of depression or the onset of deterioration even before the patient presents for the first time by examining the progression of PHQ-9 scores if the patient records the data in advance. The automatic analysis of the questionnaires and the literature-based assessment of the severity of the depression meant a significant time saving for GPs, who often struggle to find time for a thorough analysis of the questionnaires, as two GPs expressed:

> *"I find the evaluation of the PHQ-9 data very good because I don't have time to collect and evaluate such questionnaires during a normal treatment. " (GP)*

> *"If I have to do these evaluations, I don't have time for them. Otherwise, it's a clear win." (GP)*

Another aspect that the respondents emphasized as particularly positive was the progress displayed on the platform. This feature gave participants a clear overview of the progress and development of the patient's health, which was perceived as very helpful and motivating. In addition, the participants suggested extending the period to 14 days (at the time of the evaluation, the platform still contained a 7-day period, which we adjusted based on the feedback).

> *"The 90-day period seems to be a good solution for the base value. The aggregated assessment period of 7 days is good for preventing a single day from having too much influence as an outlier. This period could increase to 14 days to obtain an even more stable value." (GP)*

Overall, the visualization of the data in the GP Platform was found to be positive. Particular emphasis was placed on the progress display, providing clear insight into the patient's condition.

6.6.3 **Information Overload**

A major concern with using PGHD in the clinical setting is the burden of information overload on treating healthcare professionals. When implementing our platform, we decided to counteract this potential information overload by limiting ourselves to selected PGHDs relevant to the treatment of depression. To test whether a larger number of PGHDs than those implemented in the platform (at the time of testing, only sleep, activity, cardiac parameters, and PHQ-9 were implemented in the platform) would lead to reduced usability of the platform, we created a second version of the platform that contained a total of eight PGHD types in the patient summary. In addition to sleep, activity, cardiac parameters, and PHQ-9, this platform included blood pressure, daily schedule, online behavior, and vital signs as additional tiles. During the evaluation interviews, we showed the participants the second version of the platform in terms of its user-friendliness after they had tested the standard version.

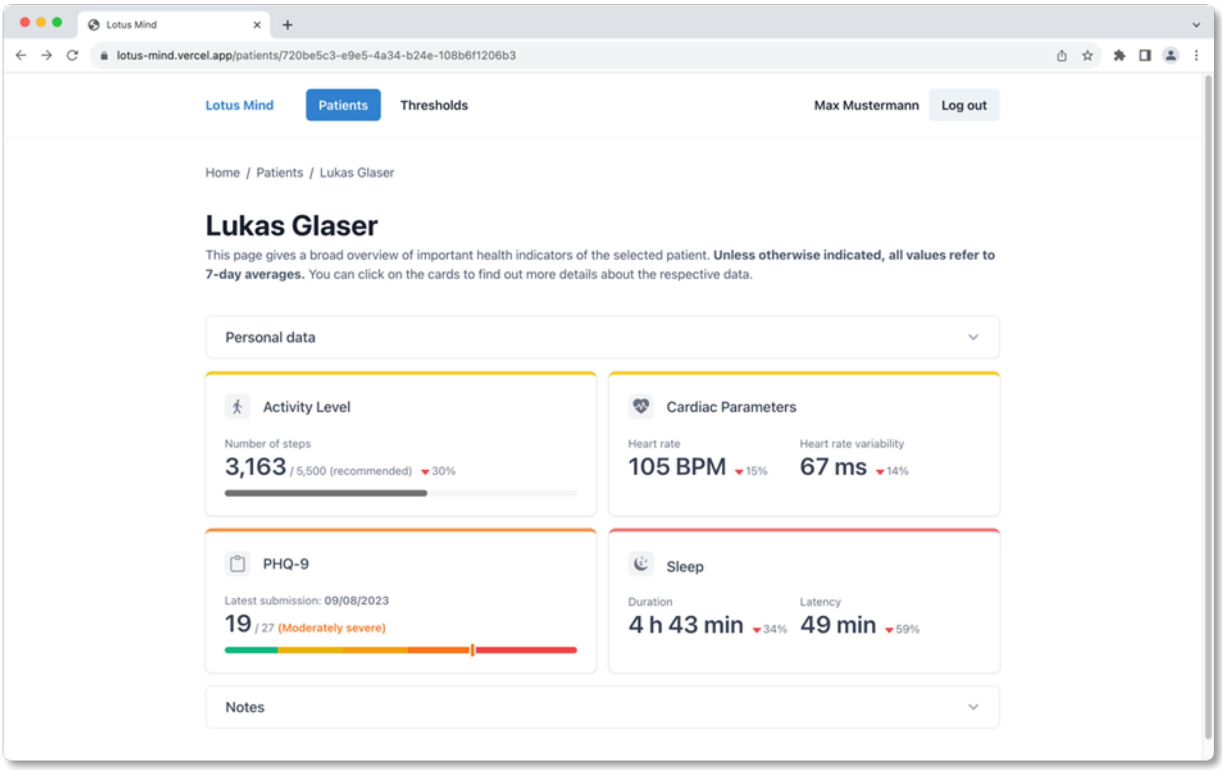
When comparing the two platforms, the participants expressed different opinions on various aspects of the two versions. We focused on two aspects of the platform in particular. The clarity and comprehensibility of the platform in the presentation of PGHD and the usefulness of the platforms in the treatment of depression

(1) Clarity: Participants felt the first platform had a more transparent structure. The limited number of PGHD types allowed seamless navigation without scrolling (especially on small screens), allowing participants to access all features briefly. The participants stated that they could recognize the values that were relevant to them more quickly. This leads us to conclude that the cognitive load on users is lower for the version with less PGHD. In addition, participants emphasized that the structured presentation of the data helped them to make faster and more informed health decisions, as the comparison of individual data points was more intuitive and more straightforward.

(2) Usefulness of the platform: Participants noted that with the platform displaying eight types of PGHD, it would be beneficial to “leave out less relevant information tools”. Participating GPs rated the daily schedule, online behavior, and personal view of vital signs and blood pressure less critical to their work. One suggestion for improvement was to combine or provide a detailed view that includes vital signs and cardiac parameters, as well as the blood pressure view. Participants repeatedly expressed that not all data points in the demo version with eight types were relevant for the treatment of depression. They appreciated the helpful features but acknowledged that some did not meet their needs.

The results show that reducing the PGHD displayed to only relevant ones in our clinician platform can significantly reduce user information overload. Specifically, participants found that the platform with fewer but more appropriate data types (sleep, activity, cardiac parameters, and PHQ-9) resulted in lower cognitive load and improved navigation. In contrast, participants reported that introducing additional, less relevant data made it more difficult to identify essential information, increasing the risk of information overload. This underlines the importance of carefully selecting relevant data to avoid overload in clinical settings.

Figure 33: Patient Summary during Evaluation (own illustration)



Lukas Glaser

This page gives a broad overview of important health indicators of the selected patient. **Unless otherwise indicated, all values refer to 7-day averages.** You can click on the cards to find out more details about the respective data.

Activity Level

Number of steps
3,163 / 5,500 (recommended) ▼30%

Cardiac Parameters

Heart rate
105 BPM ▼15%

Heart rate variability
67 ms ▼14%

PHQ-9

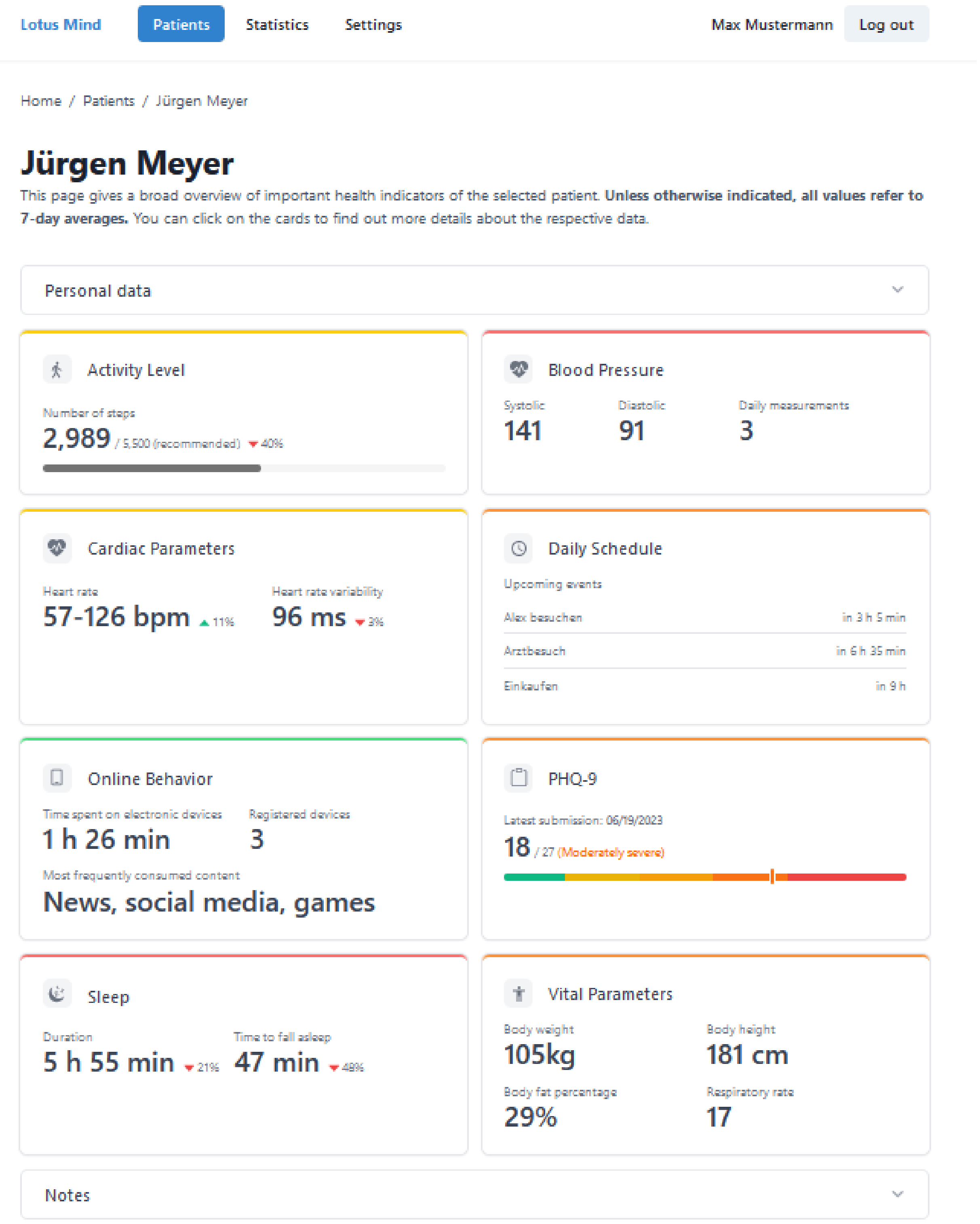
Latest submission: **09/08/2023**
19 / 27 (Moderately severe)

Sleep

Duration
4 h 43 min ▼34%

Latency
49 min ▼59%

Figure 34: Prototype with eight Types of Data (own illustration)



Jürgen Meyer

This page gives a broad overview of important health indicators of the selected patient. **Unless otherwise indicated, all values refer to 7-day averages.** You can click on the cards to find out more details about the respective data.

Personal data

Activity Level

Number of steps
2,989 / 5,500 (recommended) ▼ 40%

Blood Pressure

Systolic: 141
Diastolic: 91
Daily measurements: 3

Cardiac Parameters

Heart rate: 57-126 bpm ▲ 11%
Heart rate variability: 96 ms ▼ 3%

Daily Schedule

Upcoming events

Alex besuchen	in 3 h 5 min
Arztbesuch	in 6 h 35 min
Einkaufen	in 9 h

Online Behavior

Time spent on electronic devices: 1 h 26 min
Registered devices: 3
Most frequently consumed content: News, social media, games

PHQ-9

Latest submission: 06/19/2023
18 / 27 (Moderately severe)

Sleep

Duration: 5 h 55 min ▼ 21%
Time to fall asleep: 47 min ▼ 48%

Vital Parameters

Body weight: 105kg
Body height: 181 cm
Body fat percentage: 29%
Respiratory rate: 17

Notes

6.7 **Patient App Evaluation**

Our evaluation of the patient prototype began with a qualitative pilot study. This study was instrumental in testing the first version of the developed prototype and checking its basic user-friendliness. The collected functionalities were evaluated in this step. For this evaluation, we used the first version of the application, which differed from the final version of the patient app and was only available for iOS.

We evaluated the developed artifact using the SUS questionnaire and open-ended questions to assess the components for patients and clinicians. We evaluated the implemented artifact to understand better the needs of users and medical professionals who use a mental health app to track and communicate PGHD. We chose the SUS questionnaire because it is reliable and robust in measuring subjective usability. In addition, we added open-ended questions to the questionnaire to explore further aspects of such applications. We divided the evaluation into two parts, with the first evaluating the patient component and the second evaluating the entire system from the perspective of caregivers and other researchers. First, we familiarized the participants with the app and asked them to complete several typical tasks, including registering, logging in, and accepting the terms of use. We then showed them the app's core functions, such as the charts, filling out a questionnaire, and contacting caregivers, and introduced them to the charting function. In addition, we presented the clinical side of the application to the medical professionals. These tasks served to determine whether the app meets the usability objectives. After completing the tasks, we asked the participants to complete the questionnaire and answer the additional questions.

We recruited 30 participants with potential interest in such an application. The recruited group consists of potential end users and healthcare professionals. For the end-user group, we recruited 26 participants. The participants were between 21 and 35 years old and came from different backgrounds, most of whom were students. In addition, four healthcare professionals with expertise in mental health treatment participated in this evaluation process. They are psychotherapists in training, GPs, and medical researchers.

An overview of the distribution of participants and the SUS results is shown in Table 26.

Table 26 System Usability Scale Results

Participant	No. Participants	Mean	Min	Max	Standard Deviation
End-User	26	82.8	50	95	11.67
Professionals	4	86.25	75	92.5	7.18

6.7.1 **End-User Evaluation**

We present an overview of the evaluation results in Table 27. We first asked participants to suggest additional features for the open-ended questions for such an application. Based on the users' suggestions, such a mental health app should include several features to improve the user experience. A help page and quick contact information for relevant services such as prevention and hotlines should be provided, along with a view that displays only the most essential contact information. We subsequently implemented this by setting up a help page that can be accessed via the “Help” symbol in the patient app at the top right. The questionnaire should include reminders and push notifications for upcoming questionnaires. In the further developed version of the application, we finally added notifications that can be set in the options. After activation, the user receives notifications for the mood barometer and for completing the PHQ-8 questionnaires. A diary function should also be included to record feelings and insights daily and monitor mood using emojis. For this, we developed mood tracking based on “smileys.” Finally, for a better introduction without a healthcare professional, the app should provide a short tutorial video on how the app works. For this, we developed an online tutorial that can be accessed via the help button.

In the second question, users were asked what changes they would like to see made to such an application. Participants suggested that the answer's slider should have a default value to avoid confusion. Here, we decided to change the slider to a selection. In addition, the participants pointed out that the diagrams should not contain animations because they can slow down the use of the app. Some users also said that the daily questions were too numerous and monotonous and that fewer questions would improve interaction. Another critical point was that features such as consistency tracking could be distressing for some users, especially those with severe depression, because incomplete days could make them anxious. There were also concerns about collecting health data, which we addressed through appropriate communication to build user trust. Finally, there was a desire for an emergency number to be visible for acute crises, which we also considered.

The first line of Table 26, provides an overview of the detailed user results. A SUS value of 82.8 is generally considered a good rating for an application's usability.

Table 27: User-Feedback for Patient Application

Question	Answer
Which further functionality should be added to this mobile application?	U1: Include a help page and a quick page with contact information for relevant services such as prevention and hotlines. U2: Use emoji as a mood detection tool instead of scores. U5: Add reminders and push notifications for upcoming questionnaires. U7: A view that only displays contact information to essential hotlines. U19: Use mood monitoring through emoji. U20: The onboarding should have a small tutorial on how the app works.
What would you like to change in this mobile application?	U6: Questionnaire with fewer questions. The same questions will get boring over time. U6: Not sure if the tracking functionality may harm users with major depression who do not feel like doing anything. U8: It was not clear that the slider that represents the answer has no default value but must be moved U9: A function to change the username. U9: Did not know that you have first to touch the slider. U16: The consistency tracking functionality should be removed because seeing uncompleted days would make the user anxious. U19: Too many questions to answer every day, fewer questions. U19: Charts should have no animations because they slow down the use of the app. U22: Was not okay with health data being collected.

6.7.2 **Healthcare Professional Evaluation**

The second row of Table 26 shows the SUS results of the medical professionals. Alongside the end users' results, the score of 86.25 for the medical professionals can be considered reasonable. First, we asked the medical professionals what features should be added to make the app suitable for practical use. They suggested implementing a personal questionnaire module to monitor mood, physical activity, and emotions and allowing doctors to adjust the frequency. Some recommended replacing the questionnaires with a simple daily mood tracker and displaying sleep charts and other data from health apps. Another suggestion is to register patients using a QR code provided by doctors. They also suggested capturing data on heart rate, blood pressure, hours slept, and sleep stages and displaying weekly summaries of the correlation between questionnaire results and health data. To incorporate these suggestions, we implemented the OTP process for registration and introduced the weekly reports for the GPs.

When we asked about the app's strengths, participants praised connecting doctors and patients through monitoring, as this encouraged patient engagement in treatment. Many also appreciated the intuitive design and the ability to track patient progress over time. The “light mode” design and the feature for adjusting the time frame for visualized data were also positively highlighted. Users particularly praised the activity and questionnaire data overview and the ability to contact clinicians directly.

Regarding possible improvements, the desire for a shorter version of the PHQ-9 for daily use was again expressed, along with the desire for additional monitoring options, such as customizable questionnaires and the ability to provide feedback after completing a questionnaire. Finally, there were suggestions to reduce the number of daily questions and to ensure that certain features, such as consistency tracking, do not cause additional anxiety in users with severe depression.

We provide an overview of the results in Table 28.

Table 28: Healthcare Professional Feedback for Patient Application

Question	Answer
Which functionality should be added to this mobile application to make it suitable for practical use?	P1: Add the functionality to implement a personal questionnaire for mood monitoring, physical activity, and emotion monitoring.
	P2: Instead of questionnaires, use a simple daily mood tracker. Display the sleeping charts and other data from the health app. The patient or clinician can edit the frequency of the questionnaire.
	P3: Add the functionality to register patients via a QR Code that the clinicians own.
	P4: Collect data on heart rate, blood pressure, hours of sleep, and sleep phases. Show a weekly summary of the correlation between questionnaire scores and health data to inform the user. Add the functionality for the patient to give feedback after completing a questionnaire.
Do you think there is a better way of monitoring depression than screening with the PHQ-9?	P1: Clinicians commonly use BDI (twenty items), but the psychometric is not too great. PHQ-9 might be better for daily use as it has only nine questions.
	P2: PHQ-9 is the safest way to diagnose. A simple mood tracker might not be reliable but is more practical for daily use.
What did you like about the mobile application?	P1: The overview and the idea to connect the monitoring process between clinician and patient as a relationship. The idea behind the application is that self-managing patients are more committed. Liked the idea of seeing the progress of patients to treatment from medication. Completing the questionnaire from the patients will show their commitment to intervention and provide self-awareness. The possibility of connecting directly to the clinician. The naming and logo. The overview of the activity and questionnaire.
	P2: Intuitive and easy-to-use overview of the patient. There are many ways to get in contact with the clinician. The possibility of the patient to track his progress and detect tendencies. The light mode design. The ability to change the plot’s time frames without becoming overwhelming.
	P3: Very intuitive to use. Good overview for the clinician.
	P4: The app is intuitive.
What parts of the mobile application do you think need improvement?	P1: Use the PHQ-9 weekly. For daily use, try to implement a mood tracker. Include various questionnaires that the clinician can choose for his patients. Add more monitoring options. Add feedback functionality after the patient fills out the questionnaire.
	P2: Offer a shorter version of the PHQ-9 for the daily questionnaire.

6.7.3 Evaluation Summary

This section overviews the feedback received during the evaluation and highlights the leading suggestions. The app was well received, with high SUS scores from end users and healthcare professionals. To encourage daily use, participants suggested adding features such as a simple mood tracker, gamification elements, and reminders via push notifications. For better accessibility, users recommended providing a help page and quick access to contact details for relevant services, such as suicide prevention hotlines.

Healthcare professionals emphasized the need for additional features, such as mood monitoring, to expand the collection of PGHD. They also suggested that the app should support treatment planning and appointment scheduling features, which would be particularly beneficial in remote care.

Participants praised the app's intuitive design and ability to monitor progress over time. They also appreciated the app's customization options and ability to engage directly with clinicians. However, some areas for improvement were identified, such as reducing the number of daily questions, offering a shorter version of the PHQ-9 for frequent use, and ensuring that certain features, such as consistency tracking, do not trigger additional anxiety in users with significant depression.

6.8 Summary

In this chapter, we have presented the design elements and constructs of PGHD platforms using the patient-clinician platform POKALConnect, which we implemented. POKALConnect was created based on our postulated design guidelines. First, we presented the architecture and the PERN stack on which It is based.

Further, we presented the backend’s functionalities, technical implementation, and data structure. In the following chapters, we presented the implemented design elements for the GP platform and the patient application based on the design principles. In doing so, we presented both the functionalities and the technical implementation. Finally, we explained the platform's deployment.

At the end of the chapter, we evaluated the GP platform and the patient app. We assessed the GP platform with eight healthcare professionals in semi-structured interviews, during which we presented it to them. The GP platform received good feedback regarding usability, data visualization, and possible information overload. We evaluated the patient app with 26 potential end users and four healthcare professionals. The patient app also received excellent feedback, especially regarding usability. Concerning both evaluations, we used the feedback from the interviews to improve POKALConnect further.

7 Discussion

In this section, we review the results of this dissertation and place them in the context of current research and theories. To this end, we first present the core findings of this dissertation. We then consider the theoretical contributions of our findings. We then present the contributions to practice and identify the limitations of our research. Finally, we set out an agenda for future research.

7.1 Key Findings

In this section, we will discuss the key findings of this thesis. First, we will discuss the results of our literature review on the challenges and opportunities of PGHD in healthcare. We then review our findings on relevant types of PGHD for the treatment of depression and discuss the relevance of these findings for depression care. We will then discuss the integration of PGHD into clinical workflows. We will present this integration based on the identified processes and the implemented prototype. We will discuss the incorporation of PGHD into PCFs, data integration, training on PGHD, and barriers to integration. We then discuss our design principles and how they support the implementation and use of PGHD in GP depression care. Finally, we present our results on the implemented design elements and constructs of the POKALConnect platform and explain how these contribute to improved depression care.

7.1.1 Opportunities and Barriers of PGHD in Primary Care

The first research question of this dissertation deals with the opportunities and obstacles of PGHD in healthcare systems. To this end, we conducted a systematic literature review. The large number of articles considered relevant for this literature search concerning the number of articles found in our search shows the importance of the topic. We were able to identify three phases of PGHD use in clinical settings that are important to the use of PGHD in healthcare systems:

1. The collection of PGHD
2. The introduction of PGHD into clinical workflows
3. The interaction between patient and clinician

Therefore, in the following sections, we will outline our key findings on the opportunities and barriers of PGHD in healthcare.

One finding from the systematic literature review is that new technologies are changing the way PGHDs are recorded. The research on PGHDs shows how there has been a transition from handwritten files (White 3rd et al., 1982) to modern solutions in recent decades. These modern technologies are mainly represented by smartphones (Panda et al., 2020), platforms (Karnati et al., 2021), and wearables (Bove, 2019). These new modern technologies expand the possibilities for the use of PGHD. They enable the use of actively collected data documented by patients and the passive tracking of PGHD.

While data collection methods have become increasingly sophisticated over the past few decades due to the rise of digitalization, we have also seen a shift from data collection methods that require active patient participation to more passive data collection. These passive data collection methods (mainly represented by wearables and smart sensors) can offer new possibilities for data collection, even in patients with chronic illnesses who do not allow or restrict active follow-up (Hartmann et al., 2019). It is vital to balance actively and passively tracking and recording PGHD. The concept of "partially passive" follow-up, in which we combine active and passive methods, is a valuable approach to follow-up. On the one hand, this mix of active and passive methods encourages patients to participate actively in data collection and, on the other hand, enables the continuous recording of relevant types of PGHD for treating depression, such as sleep or activity. For example, in CCM, actively engaging patients in data collection and, thus, in their disease management aims to improve patient care and increase their involvement in their therapy (Wagner et al., 1996). Passive data collection, on the other hand, can provide around-the-clock data collection and more reliable data. In addition, it can provide insights into patients' lives that would not have been possible before (Wood et al., 2015).

Furthermore, we would like to elaborate on our findings regarding the benefits and challenges of integrating PGHD into clinical workflows. We approached the topic from two different angles. First, we wanted to discuss the technical perspective. Here, we provided insights into the introduction of PGHD into the EHR. There are currently many efforts underway to facilitate this process. From our point of view, it should be noted that the use of EHR is presently not very widespread and that the problem of integrating and standardizing EHR in healthcare must also be addressed (Jha et al., 2009). This structural problem can nevertheless be circumvented by using EHR-compatible data formats so that essential data can be attached to the EHR. Second, we investigated how this integration changes the workflow. In doing so, we uncovered crucial areas for improvement in integrating PGHD. Our literature review found that technical integration by EHR for clinicians is insufficient to use the provided PGHD in their consultations. We identified that the information provided must be easily accessible for clinicians (Holt et al., 2020) and visualized in an easy-to-understand way (Akram et al., 2017).

Finally, we provided insights into how the introduction of PGHD into clinical workflows can change patient and clinician interactions. A key finding from this phase of PGHD utilization is that the introduction of PGHD can create value for both the patient and the treating GP. Overall, we have shown that both parties can benefit from the introduction of PGHD, although there are still some challenges to overcome to realize its full potential. The most significant potential arises daily for SDM in therapy (E. Austin et al., 2020; Bourke et al., 2020). Here, the GPs must trust and not oppose the collected PGHD (Burns et al., 2019). It is equally essential that the PGHDs are selected in such a way that they add value and do not overburden the doctors. This increases the risk of technostress and information overload, which must be considered in Patient Clinician Platforms (Holt et al., 2020; Ye, 2021).

In summary, we found different challenges and opportunities for using PGHD in healthcare settings. We were able to show a shift from active to passive data collection methods, such as wearables, and identify opportunities for a combined approach. Integration challenges in GP workflows include integrating PGHD into the technical systems of PCFs and ensuring easy access and presentation of data for clinicians. In addition, PGHD can support SDM and personalized therapy, although risks such as technostress and information overload must be considered.

7.1.2 PGHD for Depression Care in Primary Care

An essential outcome of this work, relevant to answering research question 2, is the type of PGHD data relevant to the use of PGHD for depression treatment in primary care from the GPs' perspective and the correlation with the recognizability of these types from the patient's perspective. In this section, we present our key findings from the surveys of GPs and those of the patients. Therefore, we primarily focus on the data types likely to be highly relevant for treating depression by GPs. Furthermore, we discuss these types of PGHD in terms of their survey effort.

Data types with High Relevance and Low Effort

The main PGHD types considered crucial by GPs for the treatment of depression include sleep patterns, activity levels, cardiac parameters, vital signs, and online behavior. We found similar results on the patient side in the focus groups. Sleep and activity data were also found to be highly relevant. This data is collected passively, requiring patients to carry devices such as smartphones, smartwatches, or fitness trackers to monitor their sleep and activity (Ng et al., 2019). Nowadays, smartwatches can record most cardiac parameters, except blood pressure, which requires active patient participation using a blood pressure monitor and entering the data into a smartphone or dedicated app (Bourke et al., 2020). While some vital signs can be collected passively via smart sensors, patients must use a body or body fat scale. Online behavioral data, such as screen time and app usage, can be collected passively (Rooksby et al., 2016). These methods of data collection, which allow passive data tracking, were also rated as acceptable by patients. In focus groups with patients, smartphones, apps, and wearables such as smartwatches or smart rings are preferred for recording PGHD due to their ease of use and accessibility.

Passive data collection is convenient for patients but does not involve them actively in treatment. Patient involvement in treatment is often emphasized in the literature, and the use of PGHD aims to improve care and increase patient participation in their treatment (Danis, 2016; Wagner et al., 1996). Here, recording PGHD can help to activate patients. As depression patients may have difficulties with active data collection due to symptoms such as lethargy or chronic fatigue, it is recommended that the threshold for data collection is set low. This prioritizes accessible data collection from patients, especially in the acute stage of the disease (Fava et al., 2014). This can be achieved by using passive methods of PGHD collection, as these allow patients to collect data reliably and without a significant (time) investment. This will enable patients to be involved in their therapy at an early stage of treatment without the risk of missing specific data points. It should also be at the clinician's discretion to request active collection of PGHD if this can improve the patient's treatment, considering their health status.

Data types with High Relevance and High Effort

In addition to the types of PGHD that we identified as relevant and accessible to collect, we were able to identify other kinds of PGHD that are relevant for depression care but require more effort to collect. From the GPs' perspective, this data primarily includes information on mental health, everyday life, and social behavior. The patients also classified data on mental health and medication or medication intake in this category.

First, the survey on suicidal tendencies and the recording of the “degree of depression” using depression questionnaires should be emphasized. Both types of data can provide valuable insights into the patient's state of mind and, in the worst case (prevalent suicidality), prevent a suicide attempt by enabling caregivers (e.g., doctors, nurses, etc.) to act quickly. The collection of this data was already considered complex by healthcare professionals, which was confirmed in the focus groups with patients. It is important to emphasize that measuring suicidality is particularly challenging (Franklin et al., 2017). Nevertheless, various measures, particularly in the context of psychological questionnaires, can be used to assess suicidality (Kroenke et al., 2001).

Mental health questionnaires are the most common and established method for collecting this type of data. So far, this data can only be collected using questionnaires, even remotely. In the case of our prototype implementation, the PHQ-8 questionnaire offers the possibility to assess both levels of depression with only eight questions. Although this data type is challenging to collect, its benefits outweigh the difficulties. The PHQ-8 is usually completed every two weeks and covers two weeks. This makes it easy to track progress and recognize mood swings. Trends over time can be identified so that GPs can react quickly to improvements or deterioration. Patients also rated stress levels and mood data as relevant in this context. Mood, for example, can be collected daily at very short intervals, providing an even more accurate picture of the patient's fluctuating condition.

The highest-rated data type in the quantitative survey with patients, 'medication tracking,' can have several benefits in the treatment of depression. Medication adherence can provide GPs with valuable insights into patient adherence to treatment, and in this way, for example, medication tracking can help improve patient adherence to treatment (Park et al., 2019).

Other types of data that are relevant but difficult to collect include data on daily routines, social behavior, and sexual behavior. Like healthcare professionals, survey participants rated these data types as challenging to collect. However, involving patients in the data collection process is crucial. Combining the three data points would make the survey more accessible to patients. Patients could keep a diary in which they write down what happened to them during the day concerning all three data points - it would be conceivable to ask specific, essential questions about these three data points (e.g., What was your daily routine like today? Did you meet with friends today?). Although this would mean that these points would be asked retrospectively, it could make the survey easier, as keeping a diary can also be a therapeutic measure for depression.

Relevance for Depression Care

The main types of PGHD relevant to the treatment of depression are, therefore: sleep, activity level, cardiac parameters, vital signs, media action, and mental health data. The following highly rated data types on mood, stress, and sleep (as well as mental health questionnaire data) are related to depression and are, therefore, well-established in questionnaires and data collection (Cummins, 2013; Sano et al., 2018; Tsuno et al., 2005). Data on vital parameters (Onyike et al., 2003; Scott et al., 2008), cardiac parameters (Carney & Freedland, 2017), medication (Lam et al., 2012), and activity (Paluska & Schwenk, 2000) are partly related to depression. They can usefully supplement the overall picture of the patient's condition.

The potential of technology in data collection is vast and promising. Sleep and activity levels can be monitored using smartphones, smartwatches, or fitness trackers (Ng et al., 2019). Smartwatches can also record most cardiac parameters, although blood pressure data must be actively recorded by patients using a monitor, and the data must be entered into a smartphone or dedicated app (Bourke et al., 2020). Some vital signs, such as respiratory rate, can be measured passively with smart sensors, but scales are required for weight and body fat percentage. Online behavioral data, such as screen time and applications, can be collected passively (Rooksby et al., 2016).

While passive data collection reduces the burden on patients, patients are not actively involved in their treatment. Scientific literature emphasizes the importance of patient involvement in their therapy (Danis, 2016; Wagner et al., 1996). PGHD aims to provide healthcare professionals with better insights and involve patients more closely in their treatment (Kim & Lee, 2017). While passive data collection is convenient, it partially ignores the benefits of active patient involvement. Given the lethargy and chronic fatigue that often accompany depression (Fava et al., 2014), it is essential to keep barriers to data collection low, especially in the acute stage of the illness.

We conclude that relevant PGHD can be used to develop holistic and personalized health solutions that incorporate valuable data types for more effective treatment of depression. These solutions can provide a more comprehensive approach to therapy by considering medication, mood, physical activity, sleep, vital and cardiac parameters, and psychological questionnaires. We, therefore, emphasize the importance of aiming for a combination of active and passive data to utilize both types of data collection.

7.1.3 Integration into Clinical Workflows

The results of our systematic literature review and our surveys of healthcare professionals have shown problems with integrating PGHDs into clinical workflows (Lavallee et al., 2020; Omoloja & Vundavalli, 2021). While our findings suggest that PGHDs in depression treatment can add value to treatment, it is essential that PGHDs can be integrated into clinical workflows without significant problems. In this section, we therefore discuss various findings from this work on the integration of PGHDs into GP practices for the treatment of depression.

Incorporating PGHD into PCFs

The integration of PGHD into PCFs varies depending on whether the patient receives ongoing treatment for a chronic condition or brings newly collected data at an initial office visit. While regular data collection and use is partially established for chronic conditions, PGHD collected is used inconsistently, especially when presented by patients bringing such data to the practice for the first time. A lack of standardized procedures for integrating PGHD into existing workflows leads to data processing inconsistencies. Introducing guidelines and protocols for PGHD documentation could make workflows more efficient, reduce staff burden, and ensure consistent documentation in (digital) patient records.

Data integration

Logistical barriers complicate the integration of PGHD, such as the data format (analog vs. digital) and the lack of standardized transmission methods, such as health applications. These issues lead to inconsistent workflows where manual entry and scanning dominate, often limiting the usefulness of PGHD. There are still fundamental problems with the digitization of PCFs (Albrecht et al., 2023) that either do not allow digital PGHD or make it very difficult. For example, only around a quarter of all PCFs in Germany communicate mainly or entirely digitally with their patients. Another reason for the slow integration of digital applications could be that most PCFs have had bad experiences with digital solutions. Therefore, we believe that the first step to integrate PGHD into GPs' workflows and processes successfully is to develop structural digitalization in PCFs further, and that solutions should integrate interfaces for PGHD to facilitate the integration of PGHD.

Training on PGHD

Even though GPs are not necessarily the end users of health apps but rather prescribe them (or use the data collected), they need to be familiarized with the functions and features of the app. Providing comprehensive guidance or training could help convince healthcare professionals of the benefits of health apps. The concerns of primary care staff go beyond a lack of information and include fears about data protection and privacy breaches. This is consistent with previous findings and highlights healthcare providers' concerns about data protection and privacy (Ye, 2021). Incorporating appropriate security measures, particularly around data protection, could facilitate the seamless integration of PGHD into PCF workflows.

Barriers to PGHD Integration

Further, we identified barriers to the integration and utilization of PGHD in PCFs for depression care. Our findings partially confirm previous research. For example, we identified barriers to data accuracy (West et al., 2018) and data security (Rooksby et al., 2016) that have already been discussed and described in the literature. We identified the other barriers primarily in our specific context of primary care. Through the patient-centered approach to primary care, we identified three barriers that mainly consider the patient's perspective from the point of view of healthcare professionals. The main concerns of GPs and healthcare professionals are that a higher frequency of visits will unsettle patients and that the practice will be overcrowded. Our proposed design principles are intended to address these barriers and avoid potential problems arising from using PGHD in PCFs.

7.1.4 **Design Principles for PGHD Platforms**

The main result of answering the second research question is the postulation of 17 design principles for implementing PGHD platforms for treating depression by GPs. Translating insights from earlier analyses into design principles that meet the complex requirements for using PGHD in treating depression. We developed these design principles as theoretical guidelines and practical solutions that consider the different needs of clinicians and patients. We structured these design principles into three dimensions:

- General principles
- Principles for GP platforms
- Principles for patient applications

We will structure our presentation of the main results according to these three dimensions.

General Principles

Based on our requirements analysis process, we identified general principles for implementing and using PGHD platforms for patients and clinicians to treat depression. Therefore, paying particular attention to data protection, patient trust, and using PGHD platforms is essential. The sensitivity of health data, especially mental health, means that without solid data protection measures, patients may be hesitant to share their data, and clinicians may be reluctant to rely on it. For clinical usability, it was, therefore, essential to use precise data (Cohen et al., 2016; Ye, 2021). Treating depression requires reliable and interpretable data that clinicians can use to make informed decisions. Inaccurate data can lead to misinterpretation and reduce the usefulness of PGHD in patient care (Cho et al., 2021; Zhu et al., 2016). Furthermore, when developing such platforms, care should always be taken to ensure that the platforms take ethical and social aspects into account. In particular, care should be taken to ensure that the platforms do not provide a basis for discrimination and that users' rights are protected. This should further strengthen trust in such platforms.

These principles provide the foundation for a trustworthy, accurate, ethical, and user-centered platform that meets the needs of patients and clinicians and supports the safe, effective, and engaging use of PGHD in depression care.

Principles for GP Platforms

The needs assessment provided essential insights into the needs of GPs for effectively integrating PGHD into clinical workflows and treating depression. Doctors emphasized data reliability and trust in data collection methods, as PGHD must provide accurate, verifiable information to be clinically helpful. Misinterpreted or inaccurate data could lead to ineffective treatment decisions, so high data accuracy and consistency standards are essential. Furthermore, clinicians expressed concerns about possible information overload leading to cognitive overload (Ye, 2021). Therefore, PGHD platforms must integrate seamlessly into existing healthcare systems and provide accurate and easy-to-interpret data to avoid additional cognitive load during patient consultations. Hence, the design principles we postulate aim to ensure the relevance of the PGHDs introduced and trust in the data collection methods. Furthermore, data visualization and system integration principles are crucial as they enable optimized and rapid interpretation of the data in clinical workflows, reduce potential disruption, and improve decision-making without overwhelming clinicians. This is important as these applications should support GPs in their work and improve patient therapy so that using such platforms should not be challenging for GPs (Gotz & Borland, 2016; Khan et al., 2017).

For GPs to use PGHD to treat depression, the platform's development must ensure that data is accurate and presented in formats that minimize cognitive effort. Integration with existing clinical infrastructure or EHRs and intuitive visualizations are essential to ensure workflow efficiency and build trust in the data's reliability.

Principles for Patient Applications

Our qualitative and quantitative research has allowed us to identify patient-specific requirements, particularly regarding data protection, user-friendliness, and positive data communication. Patients with depression are particularly aware of what happens to their health data. How PGHD is managed and shared is particularly important here, as mental illness is often stigmatized (Fox et al., 2018; Halter, 2004). Therefore, patients require strict data protection precautions to trust and use PGHD platforms (Cohen et al., 2016; Wu et al., 2020). Furthermore, the platforms need to be user-friendly and provide an intuitive interface for all technological competence levels. Finally, positive data communication is essential, as overly antagonistic or judgmental feedback on health data can unintentionally affect mental health. Instead, data should be communicated neutrally or positively to promote engagement and reduce stress.

Therefore, PGHD platforms need to focus on collecting data that is both clinically relevant and accepted by patients. Furthermore, principles should be established to ensure that the applications are accessible and can be used by many people with a high level of usability. Patient-oriented PGHD platforms play a unique role in the treatment of depression. Patients use these to collect and integrate data into clinical processes. Data collection and provision can improve patient involvement and self-management (Chiauzzi et al., 2015).

The design principles we postulate are tailored to the specific requirements of GPs and patients in the particular context of primary care depression care. The design principles for GPs ensure that the platform provides reliable, accurate, and relevant data and can be integrated into the existing practice infrastructure without overburdening them in their work. For patients, these principles ensure that value is placed on privacy, positive engagement, and accessibility, creating an environment in which they feel safe and able to share sensitive health information. Ultimately, these principles aim to improve the quality and effectiveness of primary care by creating PGHD platforms that support the safe and effective management of mental health. In doing so, they contribute to a more robust, adaptable, and patient-centered primary care environment better equipped to handle the complexities of mental health.

7.1.5 **Design Elements and Constructs**

To answer research question 3, we developed the PGHD-based patient-clinician platform “POKALConnect” based on our analysis of the requirements analysis. In the implementation, we followed the design principles we formulated. The design and development of the POKALConnect platform highlights several aspects necessary for the effective integration of PGHD into primary care workflows for depression treatment. The core elements of the POKALConnect platform focus on the constructs for data collection and presentation, mechanisms for severity assessment and feedback, and user-centered design and security protocols. Each construct has been designed to meet the specific requirements of depression treatment in primary care. The aim is to support clinical decision-making and improve patient outcomes through the targeted use of PGHD.

Data Collection Constructs

A key challenge in using PGHD for clinical decision-making is finding the right balance between data volume and ease of use. The POKALConnect platform solves this problem by integrating active and passive data collection methods, creating a comprehensive dataset of patient physical and mental health indicators critical to the assessment of depression. The platform obtains a nuanced picture of patients' health trajectories by combining active tools such as PHQ-8 and mood measurement with passive wearable data (e.g., heart rate variability and sleep duration). This approach makes it possible to generate a detailed insight into each patient's health status. These data points can help understand the patient's condition through patterns and subtle changes over time, often more revealing than individual data points.

The active data collection methods used in POKALConnect, PHQ-8 questionnaire, and mood assessment, in particular, help GPs to gain a comprehensive picture of the patient's mental state. These subjective insights of the patients provide insights (Nowell et al., 2019). The POKALConnect platform also uses the opportunity to involve patients in their therapy through active collection methods, allowing patients to take an active role in their therapy (E. Austin et al., 2020).

At the same time, passive data collection through wearables, such as measuring cardiac parameters, physical activity, and sleep via the Oura ring, allows the platform to monitor without the patient having to actively collect data continuously. This reduces the patient burden of passive data collection as no daily interaction is required, ensuring more consistent data availability - especially during periods of low patient motivation, which is common in depression (Nittas et al., 2019). These PGHD provide objective insights into aspects such as sleep quality or exercise that have links to depression (Paluska & Schwenk, 2000; Tsuno et al., 2005). As sleep disturbances are common in depression, continuous passive monitoring enables early detection of physical changes that may accompany or herald mental health shifts.

By combining active symptom queries with passive physiological monitoring, the platform creates a comprehensive data set that provides clinicians with both subjective and objective perspectives on a patient's condition. POKALConnect balances data diversity and clinical usability by generating multi-layered insights. Combining this data for GPs can solve the problem of contextualizing the data (West et al., 2018). The passively collected data is thus given an extended subjective context through the actively collected data on mental health. This allows the data to be better interpreted and provides an improved treatment environment (Ng et al., 2022).

Data Visualization Constructs

The PGHD collected is presented to GPs with POKALConnect in a visually accessible format that includes color-coded indicators and progression charts. This gives clinicians a quick overview of the patient's health status without being overwhelmed with too much detail. This aligns with research findings emphasizing the importance of user-friendly data visualizations in a clinical context. Several barriers exist to using PGHD and visual analytics effectively in a clinical context. Clinically, PGHD is often unstructured, voluminous, and low-quality, making it much more difficult to gain insights. Clinicians and patients frequently desire direct interaction rather than analyzing data during brief clinical visits (Ryokai et al., 2015). Furthermore, the issues go beyond data collection to include visualization challenges, such as presenting comprehensive patient stories, creating engaging user interfaces, and preparing data for all users. Communicating PGHD effectively through visual aids is complex and requires considering different user perspectives and recognizing that a universally perfect solution is impossible. Resolving these issues requires navigating and optimizing trade-offs between various aspects of health data use (Belle et al., 2015). Based on our extensive requirements gathering with GPs, we developed POKALConnect, a solution that can provide PGHD for depression care to GPs through easy-to-understand data visualization. The high SUS ratings show that the minimalist approach we chose with a traffic light system and progression charts represents an approach for the presentation of PGHD in depression care.

In the patient app area, the design of POKALConnect avoids overwhelming patients by not displaying historical trends but instead offering daily insights. Patients only see current data (e.g., steps, sleep duration last night). This gives patients access to their data and the context of their current condition without overloading them with detailed historical data. This design decision was based on feedback from the qualitative focus groups that an extensive data history can lead to anxiety in patients with depression.

Severity Assessment and Feedback Mechanisms

Another essential feature of POKALConnect is the severity assessment approach, which includes absolute and relative scoring models. This design allows GPs to assess the intensity of a patient's symptoms against evaluated thresholds (PHQ-8) and track their trends over time, thus accounting for intra-individual variability (e.g., sleep, activity). These severity ratings are precious in primary care, where treatment of depression requires frequent adjustments based on symptom development (Lewandowski et al., 2013). The model, coupled with weekly feedback, empowers GPs to make more proactive decisions and reduce the need for acute interventions by recognizing worsening symptoms early. This feedback loop aligns with best practice in clinical informatics, where actionable insights from individual patient data are fundamental to preventative care.

User-Centered Design

Finally, the platform's design emphasizes usability, addressing a common barrier to using PGHD in a clinical context: Information overload (Choe et al., 2018; Cronin et al., 2018; Reading & Merrill, 2018; West et al., 2018). By focusing on the core PGHD areas relevant to depression treatment (e.g., sleep, cardiac parameters, activity level, depression level, and mood), POKALConnect minimizes the risk of information overload, which has been shown to reduce clinical productivity (Ye, 2021). This “less is more” approach reduces the burden on patients and allows healthcare professionals to obtain the specific data they need more efficiently.

Based on the problem of information overload (Choe et al., 2018; Cronin et al., 2018; Reading & Merrill, 2018; West et al., 2018), we hypothesize that clearer utilization of the platform can be achieved by reducing and limiting the types of data to the most relevant and essential. Therefore, this thesis promotes the understanding that a large amount of information or data in the form of PGHD does not automatically add value in depression prevention or clinical contexts. PGHD types that have minimal impact on the diagnosis and treatment of depression can potentially be excluded from the platform. This reduction in data types is critical in improving depression treatment in two ways: The first impact is that clinicians are only presented with information that they consider helpful for the treatment of depression or that helps them in the differential diagnosis and exclusion of other diseases. This reduces the burden on clinicians when presenting the patient, as relevant PGHD is already available before clinical contextual data is collected and during disease monitoring during treatment and therapy. Consequently, clinicians can use the data to prepare for patient appointments and maximize the value of their limited time with patients. The second impact is that reducing the types of PGHDs that need to be collected helps to reduce the burden on patients. Targeting the collection of data points from a few data clusters rather than accumulating as much data as possible will ease the burden on patients, improving their willingness to collect PGHDs, especially those that require active collection.

In POKALConnect, we have implemented a data organization and presentation structure limited to the most critical data based on requirement engineering. By implementing effective data categorization and visualization techniques, healthcare providers can find and interpret relevant information faster without being overwhelmed by excess data. We achieve this by implementing the Patient Overview, which ranks PGHDs from their highest importance for depression to their (comparatively) lowest importance, summarizes all critical information about a patient, displays data history in charts, and analyzes patient trends by calculating z-scores. GPs can quickly identify changes, trends, and patterns in a patient's health status using these tools.

This clear and concise data presentation improves the efficiency of GPs’ information processing and thus reduces the time needed to select the right data for the patient-clinician session. The correct arrangement of data (prioritization) in the overview ensures that clinicians receive the most critical data first, which improves the efficiency and effectiveness of clinical decisions. In addition, the time spent on data interpretation can be minimized through efficient presentation with charts and pre-built analyses, minimizing the risk of errors and improving decision-making.

As a result, a PGHD platform can significantly reduce the challenges associated with information overload in depression treatment, leading to more effective and efficient patient management and better overall outcomes.

Security Constructs

The platform's security measures also ensure that patient data is protected and that secure data exchange between patients and GPs is possible. This is intended to gain the trust of both GPs and patients to increase engagement and compliance with the platform. In addition to security protocols, POKALConnect includes transparent data sharing and consent mechanisms to ensure that patients are fully informed about what data is collected, how it is used, and who can access it. Patients consent via the platform before data is shared, providing a basis for informed decision-making. In addition, patients can independently control access to their data and revoke permissions (such as the doctor connection) if necessary, increasing confidence in protecting their privacy and promoting a sense of data sovereignty.

In summary, the design elements and constructs of the POKALConnect platform can be interpreted as a targeted response to the need for practical integration of PGHD into depression care in primary care. By balancing data richness and ease of use, employing flexible severity assessment, and ensuring safe, patient-centered interactions, the platform meets modern digital health standards while addressing specific challenges in treating depression. Future research could build on these findings by examining the long-term impact of the platform on patient outcomes and analyzing the effectiveness of additional PGHD types in the treatment of depression.

7.2 Theoretical Contribution

This dissertation contributes to various research strands, which, due to the interdisciplinary nature of the work, can be found in information system research, medical informatics, or health services research and confirms, expands, or contextualizes them.

Patient-Generated Health Data

Our findings advance research on PGHD in clinical contexts (E. Austin et al., 2020; Demiris et al., 2019; Nittas et al., 2019; Shapiro et al., 2012). We introduce new types of PGHD relevant to the collection for use in depression treatment. In doing so, we extend the existing literature on types of PGHD in general (Demiris et al., 2019) and on PGHD for depression treatment and mental health care (Bauer et al., 2019; Medina & Isomursu, 2023; Meyerhoff et al., 2021; Ng et al., 2019; Ng et al., 2018; Ng et al., 2022; Wang et al., 2016) in particular. This is particularly important as healthcare providers often encounter irrelevant PGHD (West et al., 2018). In addition to the literature on PGHD types, we extend the strands of research on PGHD utilization (E. Austin et al., 2020). This dissertation addresses known barriers to PGHD utilization (West et al., 2018). It extends them to include specific barriers and concerns as well as benefits in the dimensions of collection (E. Austin et al., 2020; Nittas et al., 2019; Piras, 2019; West et al., 2018), integration into clinical workflows (Akram et al., 2017; Burgermaster et al., 2020; Burns et al., 2019; Holt et al., 2020; Kim et al., 2017), and incorporation of PGHD into patient-clinician interactions (E. Austin et al., 2020; Bourke et al., 2020; Burns et al., 2019; Cahn et al., 2018; Holt et al., 2020; Ye, 2021). We address these barriers by formulating design principles and implementing our patient-clinician platform, POKALConnect, for the use of PGHD in depression in primary care.

As there are a variety of different data collection methods for various diseases (Nittas et al., 2019) and data collection can be cumbersome for many diseases (Piras, 2019), our findings contribute to a better understanding of which methods can be used to capture PGHD in depressed patients. Using the Oura smart ring in POKALConnect, we extend the literature on using smart rings to capture PGHD in a clinical context (Mason et al., 2024; Robbins et al., 2024). Therefore, POKALConnect not only optimizes data collection but also expands knowledge on the nature and accuracy of data captured by advanced sensors in the depression context, which may lead to more accurate diagnoses (Su et al., 2021; Vidal et al., 2012; Wang et al., 2018; Zhou & An, 2022). Using active elicitation methods, we encourage patients to proactively participate in their therapy (E. Austin et al., 2020).

In addition, we developed an exemplary workflow for integrating PGHD into primary care, highlighting ways in which the integration of PGHD into depression treatment can be optimized (Burns et al., 2019; Deering et al., 2013; Holt et al., 2020). As primary care has several unique characteristics (Europe, 2002), our research contributes to a broader understanding of how PGHD can be implemented in this setting and how barriers can be overcome. By formulating design principles based on the identified barriers, we open up the research field to encourage further research in this area, mainly through validating and implementing the design principles.

Information Overload

Second, we contribute to a better understanding of information overload (Chen et al., 2009; O'Reilly III, 1980; Saegert, 1973) by using PGHD (Choe et al., 2018; Cronin et al., 2018; Reading & Merrill, 2018; West et al., 2018; Ye, 2021). Our findings suggest that the number of PGHD types collected and made available to GPs should be reduced to the essential, relevant PGHD types. This should solve the problem of potential information overload for healthcare providers using PGHD in their treatment (West et al., 2018; Wright et al., 2016; Ye, 2021). The design elements for PGHD platforms developed and implemented in this dissertation help to ensure that the relevant information provided can be retrieved efficiently (Ratwani et al., 2018; Wright et al., 2016).

Treatment of Depression and CCM

This dissertation analyzes the features of mental health apps that facilitate data communication, focusing on opportunities for improvement and potential benefits for treating depression (Medina & Isomursu, 2023; Ng et al., 2022). Capturing PGHD and communicating current data to patients is consistent with CCM, where patient involvement in their treatment is essential (Wagner et al., 1996). Mental health apps provide patients access to support and monitoring they may not otherwise have (Borghouts et al., 2021). PGHDs integrated into the clinical system allow GPs to track treatment effectiveness, predict fluctuations in health status, and detect early symptoms of deterioration via the web platform and weekly reports (Nuij et al., 2018). The generally high usability ratings indicate that the healthcare professionals surveyed are willing to use such applications in the future. Addressing end-user concerns and ensuring easy integration into existing treatment processes is crucial to avoid additional burdens that could reduce adherence (Chakrabarti, 2014) and increase patient stress (Wu et al., 2020).

Our results fit into the overall concept of improved depression care in primary care (Gensichen et al., 2022). In addition to current advances in diagnostics (Teusen et al., 2024; Teusen et al., 2022; von Schrottenberg et al., 2024), therapy (Bauer et al., 2019), contextual factors (Schoenweger et al., 2023) and medication management (Brisnik, Rottenkolber, et al., 2024; Brisnik, Vukas, et al., 2024), our results on patient monitoring with PGHD fit into a modern overall concept of depression care in primary care. We extend the classical aspects of depression care by using digital data collected outside the clinical context to create a future-oriented “productive environment” between the treating GP and the patient (Gensichen et al., 2006).

7.3 **Practical Contribution**

Beyond the theoretical contributions, this dissertation was shaped by the goal that the developed artifact POKALConnect is also highly relevant to the real world. Therefore, it is, essential to show how our results can help ensure that PGHD can be used better in GP depression care.

Use of PGHD in Primary Care

Utilizing data-driven insights can significantly improve the diagnosis and treatment options of GPs in depression care, enabling them to provide more effective care. POKALConnect optimizes the presentation of PGHD and aims to achieve a more efficient use of the time doctors and patients spend together. For example, traditional in-person examinations can be supplemented by monitoring the platform between visits to get a better holistic view of the patient's health status. In addition, the platform enables GPs to treat and monitor mild to moderate depression with greater certainty, which could reduce specialists' workload. While many GPs can effectively treat mild to moderate depression, accurate diagnosis and rapid intervention in severe cases are essential to enable timely referral to psychiatrists or psychologists as needed.

With our developed platform, POKALConnect, we improve the introduction of PGHD into clinical processes. Our results show several advantages for the introduction of PGHD into primary care. Using POKALConnect, new and improved personalized treatment approaches based on PGHD can be used (Cahn et al., 2018), and patients' diagnoses and general treatment can be improved (Burgermaster et al., 2020). However, integrating PGHD into clinicians' workflows still poses problems (Hussein et al., 2021). Our results provide further insights into the issues of integrating PGHD into clinical workflows, enabling PCFs to adapt their workflows.

POKALConnect provides easy access to the collected patient data directly at the GP's workplace. By implementing the platform on a web platform, treating clinicians have easy access to the data collected by patients directly from the treatment room. As a result, we have addressed some of the issues identified with integrating the data into the workflow. First, we are improving doctors' access to the data (Hussein et al., 2021). This enables doctors to save time during treatment, as they can access the relevant data for each patient directly at their workplace and do not have to view the data on the patient's device. By integrating the report function, it is also possible for doctors to view the data (without internet access in the treatment room) before the patient interaction and thus also prepare for the patient consultation. This implementation enables GPs to make the integration and use of PGHD more efficient and save time. The generated PDF can be attached to the practice management system by exporting the report.

Types of PGHD for Depression Care

In this dissertation, we were able to identify relevant types of PGHD for use in primary care depression care. From a clinician's perspective, these data provide a basis for GPs who want to treat their patients with PGHD and monitor depression. They can use the results of this dissertation to find out which types of PGHD have been identified as relevant by other medical professionals and then collect them from their patients. This foundation and the presented matrix provide an evaluated basis for collecting data on relevant types of PGHD in the treatment of depression. GPs can then use these impressions to implement tracking of PGHD for the treatment of depression in their practices. Patients, on the other hand, can use our results to track relevant data about their depression for themselves. This is particularly useful if you have not yet started tracking your data but would like to include it in your treatment. On the one hand, they can track the data classified as relevant so that when they present it to their doctor, the doctor does not receive any irrelevant data. Furthermore, patients can use our results to determine which data types are difficult and easier to track. This enables them to decide which kinds of PGHD are more accessible for them to

Use of POKALConnect

In our implemented platform, we limit ourselves to data on sleep, activity, heart parameters, the PHQ-9 questionnaire, and a daily mood survey. In this way, we significantly reduce the number of data points provided to the doctor and try to prevent information overload for the doctor (Chen et al., 2009; Hussein et al., 2021). By standardizing data collection in POKALConnect with smart rings from Oura, we can also dispel concerns about the origin of the data and its validity (Hussein et al., 2021). By limiting ourselves to a standardized data source, we can create the same basis for all patients and make the data comprehensible for doctors. Doctors also know the circumstances of data collection and provision for treatment. Our prototype is a proposal for standardizing data presentation for using PGHD in clinical settings. A significant problem with the current use of PGHD is that it is not presented or used consistently (Hussein et al., 2021) because there are many unconnected programs and platforms. Our platform offers a solution to this problem. Thanks to the structure we have chosen for the web platform, it can be extended to create extensions of the existing platform for different diseases or uses. These platforms can share a common database or implement different databases to ensure better data separation. In the long term, this extensibility ensures that individual data points can be presented similarly, making it easier for treating clinicians to use the platform for different purposes. Our platform can be used directly in doctors' offices to treat and monitor depression, but it can also serve as a template. Developers and practitioners can use our prototype to guide and develop their solutions for using PGHD in clinical settings.

Shared Decision-Making

GPs can use the POKALConnect platform to treat patients with depression. The treating doctor can use POKALConnect to make the interaction between doctor and patient data-driven with the platform's help and to compare subjective patient perceptions with objective, data-based findings. GPs and patients can access and view the data via the platform during the patient consultation. This can improve shared decision-making in the treatment of depression in several ways. The treating GP and the patient have access to all data relevant to the treatment, improving data transparency. Patients are actively involved and can engage with their data before and during treatment. This data transparency shifts access to treatment-relevant information from the GP (who usually only has access to clinically collected data) to a balance between the GP and the patient. The available treatment time can be used more efficiently by using the data as a basis for communication - several aspects of the platform help to reduce the time needed for data aggregation during patient consultation. First, the attending clinician and the patient can prepare in advance at the doctor's office. Both can access the same data, so neither party has more information about the patient's health situation than the other. In addition, the time during the patient consultation can be used more effectively because the data is easily accessible and, thanks to the intuitive presentation, can be easily interpreted by both the doctor and the patient.

Design Principles and Design Elements

The developed design principles are intended primarily to serve as guidelines for developers and researchers to align PGHD platforms with the requirements of depression treatment. The principles can be used to develop PGHD platforms for clinicians and PGHD patient apps. In addition, the principles provide general insights into important topics that must be considered when implementing software development in the medical field. On the one hand, these principles promote a user-centered design that addresses the specific needs of patients and supports clinical goals by enabling a more effective use and integration of health data in the treatment process. On the other hand, the developed principles emphasize the importance of data protection and privacy in the handling of PGHD in general and data from depressed patients in particular.

7.4 Limitations

This dissertation provides valuable insights into integrating PGHD into depression treatment in primary care. However, due to our choice of research methods, we are aware of some limitations of this dissertation.

First, we acknowledge the limitations inherent in our chosen design research approach. In general, design research requires the application of rigorous methods for creating and evaluating artifacts. To that end, we ensured that the iterative design research approach proposed by Hevner (2007) and Hevner et al. (2004) is carefully executed and documented. In addition to implementing the artifact based on the design principles derived from the relevance cycles, we evaluated each part of the artifact with healthcare professionals and potential users to ensure its usability and usefulness in practice and integrated newly emerging requirements into the artifacts. However, it was beyond the scope of this work to evaluate the artifact over a more extended period in the practice of primary care with GPs and patients, which could provide additional insights into their usefulness and indicate the need for changes.

Our literature search may not have covered all relevant studies due to the selection of sources and keywords. Alternative terms for PGHD, such as “patient-reported outcomes,” could yield further relevant articles. Therefore, despite careful methodological execution, we cannot rule out the possibility of inadvertently neglecting studies relevant to our research. Furthermore, we simplified the study results through our coding process to make them more comparable; our results are based on the three main trends identified during the coding process (collection, PGHD integration of PGHD into clinical workflows, and interaction with patients by PGHD). While this may have led to the loss of specific insights, this approach enabled us to analyze the three main trends more thoroughly. Finally, the research gaps and challenges we identified for future research may reflect the authors' perspective, suggesting that further questions exist.

Furthermore, we are aware that our choice of qualitative research methods may have led to limitations. In focus groups, more dominant participants may have pushed the opinions of quieter, more passive participants into the background. Although we tried to design the focus groups to avoid this, it is possible that we unintentionally influenced the participants and distorted the results by the way we designed and conducted the focus groups. In the interviews, we are also aware that our perspective or tone of voice may unconsciously influence the participants' answers and affect objectivity or that participants may have difficulty remembering past experiences accurately, especially in retrospective studies, which could affect the results. Finally, we are aware that participants in the interviews and focus groups may have adapted to the group's or the interviewer's opinion or given answers that they thought were socially acceptable, which could affect authenticity (Bergen & Labonté, 2020).

Furthermore, we need to consider the generalizability of our results. Our results specifically relate to the treatment of depression in primary care. Therefore, our findings have limited applicability to other diseases or care settings. In addition, the platform we developed only uses data identified in our surveys as relevant to the treatment of depression. Therefore, conducting further surveys to determine which types of PGHD are relevant for these diseases makes sense. These can be implemented in a new platform for this disease and made available to the treating clinicians. In other healthcare facilities or hospitals, workflows may differ significantly from those in a primary care practice. When used in these settings, it makes sense to reevaluate and adapt the platform's integration into patient care workflows. These other care areas (e.g., oncology or cardiology) often have different patient monitoring requirements and must be considered separately. Thus, the generalizability of the results must be viewed critically, but this does not mean that our results and the developed platform cannot serve as a basis for creating an adapted monitoring and treatment environment.

7.5 Future Research

This dissertation offers many approaches for future research. Therefore, we would like to highlight several points of interest.

The results of this dissertation are a first step towards improving the treatment of depression in primary care. The results can form the basis for further research in this area. The developed artifact can be used to verify the benefits of PGHD in a clinical study. While this dissertation primarily examined the usability of the designed artifact, our results can be used to verify the effectiveness of the artifact in a clinical study. For this purpose, patients with depression should be treated with PGHD in a primary care practice. In such a study, patients could collect PGHD over a more extended period using POKALConnect and a wearable device. During this time, patient-clinician discussions based on the data collected in the platform could be used to find approaches to improve the patient's therapy. This improved patient care can then be compared to the current care in a clinical intervention study to verify the effectiveness of digitized depression care with PGHD.

One aspect that should be considered when conducting further research based on our findings is that the processes and methods for using the patient-clinician platform continue to develop during treatment. This dissertation provides the framework for developing and integrating PGHD platforms into depression care provided by GPs. The idea presented in this dissertation of using the platform as a basis for communication should be further developed in future qualitative research and implemented in a concrete example process. The aim of this research should then be a clinical guideline for the use of PGHD platforms in depression care. By considering the level of interaction between doctor and patient, further insights can be gained for the effective use of PGHD in the clinical context (E. Austin et al., 2020; Lordon et al., 2020).

In addition to examining the interaction between patients and clinicians based on our results, it is also interesting for future research to look at the interaction of both user groups with the platform on different levels of interaction. On the one hand, this can provide new insights into how clinicians interact with PGHD platforms in a clinical context, and on the other hand, further insights can be gained into how patients interact with PGHD apps. For this purpose, the web platform and the patient app of the developed artifact can be used to assess the aspects of the different interactions.

The results of this study and the postulated design principles provide a basis for improving the adoption and use of PGHD in primary care. The processes and barriers identified in this dissertation are the first step toward improving the care of patients using PGHD. Future research should address the limitations of this dissertation by using more extensive and diverse samples, considering multiple geographic locations, and examining the perspectives of various stakeholders from the digital health ecosystem involved in integrating PGHD into primary care workflows. Further qualitative research promises to further evaluate and expand on the study's findings through expert workshops, particularly involving practitioners from different angles to gain insights into their varying requirements while allowing for group discussions.

Another approach based on which further research can be conducted is the expansion of the developed artifact. The platform developed in this dissertation aimed to improve the care of depressed patients in GP practices. To do this, it is also conceivable that it is not limited to the use of PGHD but also includes other aspects that PGHD supports. For example, extending the platform to include further functionalities is plausible. To develop an extension of the application to control and monitor patients' medication. Here, decisions could be made about adjusting the patient's medication based on the patient's well-being, current medicines, and collected PGHD. The PGHD collected in the patient app could then be further improved by a symptom query to identify possible serious side effects of the current medication or possible interactions due to the simultaneous use of several different drugs. The platform could then highlight the risks for the doctor, and the doctor and patient could jointly decide on and implement an adjustment to the medication (Brisnik, Rottenkolber, et al., 2024; Brisnik, Vukas, et al., 2024).

Our study provides an opportunity to examine how behavioral and lifestyle choices affect the selection and evaluation of PGHD's relevance for depression treatment. Based on this, strategies can be developed to integrate into the survey the types of PGHD that are not considered relevant by patients but are nevertheless crucial for clinicians without losing user acceptance.

With the POKALConnect we developed, further research can be conducted into the barriers to adopting such PGHD platforms in resource-limited or conservative healthcare settings. It is essential to gain insights into how these practices can be achieved by removing the identified barriers to adoption. Conceivable obstacles in this context are those caused by financial, technical or cultural constraints.

8 Conclusion

This dissertation was motivated by the constantly increasing number of depression patients. We were able to identify PGHD as a way to improve depression care in GP practices. The results of this dissertation show opportunities and barriers to the use of PGHD in healthcare settings based on the three dimensions of PGHD collection, PGHD workflow integration, and PGHD in patient-clinician interaction. Through qualitative and quantitative surveys with healthcare professionals and patients, we were able to identify relevant types of depression care, possible collection methods for PGHD, functionalities for the presentation and use of PGHD, and concerns about the use of PGHD. On this basis, we postulated design principles in three categories for implementing PGHD platforms for depression care in GP practices: General Design Principles, Design Principles for Patient Applications, and Design Principles for GP Platforms. Ultimately, we used the design principles to develop a patient-clinician platform for using PGHD in GP care. Using our developed platform, POKALConnect, we present design elements and constructs for implementing the design principles. The evaluation of the platform has demonstrated high usability values for both healthcare professionals and patients. We conclude how future research for the use of PGHD in depression care can be conducted based on our research and can extend our research.

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Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring, and measuring the severity of depression (Kroenke & Spitzer, 2002; Kroenke et al., 2001).

Over the last 2 weeks, how often have you been bothered by any of the following problems?

(Use "✓" to indicate your answer)

Little interest or pleasure in doing things

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

Feeling down, depressed, or hopeless

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

Trouble falling or staying asleep, or sleeping too much

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

Feeling tired or having little energy

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

Poor appetite or overeating

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

Feeling bad about yourself — or that you are a failure or have let yourself or your family down

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

Trouble concentrating on things, such as reading the newspaper or watching television

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

Thoughts that you would be better off dead or of hurting yourself in some way

☐ Not at all

☐ Several days

☐ More than half the days

☐ Nearly every day

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

☐ Not difficult at all

☐ Somewhat difficult

☐ Very difficult

☐ Extremely difficult

Appendix A Healthcare Interviews Questionnaire

Einleitung: *Vorstellung des Interviewers und des Projekts, Ziel dieses Interviews, Klärung der Aufnahmeberechtigung. Außerdem kurze Vorstellung des Interviewpartners und seiner/ihrer Rolle.*

Klinischer Arbeitsablauf:

- Wie sieht der aktuelle Arbeitsablauf für einen ankommenden Patienten aus?
- Wie nützlich ist Technologie bei der Erfassung von Informationen über Patienten und bei der Behandlung?
- Mit welchen Herausforderungen ist man bei der täglichen Behandlung von Patienten konfrontiert?
- Einführung neuer Software und Anwendungen in Kliniken – Hat dies das Leben der Ärzte erleichtert (schnellere Prozesse) oder erschwert (Benutzerfreundlichkeit, Erlernbarkeit usw. einer Software)?
- Was wäre Ihrer Meinung nach der ideale Anwendungsfall von Technologie in der Behandlung?

Alltag eines Hausarztes (diagnostizierte Krankheiten – Einführung in psychische Probleme):

- Mit welchen Krankheiten haben Sie als Hausarzt am häufigsten zu tun?
- Wie sieht es mit psychischen Problemen aus? Diagnostizieren Sie diese derzeit?
- Wenn ja, welche häufigen Symptome stellen Sie bei Patienten fest?
- Wie unterscheiden sie sich von körperlichen Problemen? Ist es einfacher/schwieriger?
- Wie viele Patienten kommen wegen psychischer Probleme?
- Laut Untersuchungen ist es für Hausärzte schwierig, psychische Erkrankungen ohne externe Hilfe zu diagnostizieren. Was kann getan werden, um dies zu erleichtern?

PGHD:

- Was halten Sie von den jüngsten technologischen Entwicklungen zur Behandlung von Patienten (wie mHealth-Apps, Fitness-Tracker usw.)?
- Wie beurteilen Sie die Vertrauenswürdigkeit dieser Geräte in Bezug auf ihre Fähigkeit, genau zu verfolgen und zu messen?
- Was halten Sie von der Verwendung solcher Daten bei der Behandlung von Patienten?
- Welche Hindernisse stehen Ihrer Meinung nach im Weg?
- Glauben Sie, dass es für Depressionspatienten möglich ist, ihre Kalorien/Ernährung zu verfolgen und zu messen?
- Wo sehen Sie das größte Potenzial für diese Daten?
- Welche Art von Daten über die Gesundheit von Patienten wäre für Hausärzte am relevantesten?
- Welche Datenpunkte sind für die Vorhersage von Depressionen nützlich?

Datenvisualisierung:

- Was ist der größte Schwachpunkt bei der Verwendung von Datenvisualisierungen?

- Wie sollten Visualisierungen Ihrer Meinung nach aussehen, damit die Daten schnell verstanden werden können? (Anzahl der Elemente, Lesbarkeit, Design)
- Welche Art von Grafiken/Farben würden Sie gerne sehen?
- Welche Funktionen erwarten Sie von einer Datenplattform, um Erkenntnisse in Bezug auf Benutzerfreundlichkeit, Funktionalität usw. zu gewinnen?

Plattform:

- Gibt es eine Plattform, die Sie derzeit kennen oder für das Hochladen und Visualisieren von Patientendaten verwenden?
- Welche Probleme sehen Sie bei der Nutzung einer solchen Plattform (für Krankenschwestern, Assistenten und Ärzte)?
- Welche Probleme sehen Sie bei der Integration der Plattform in den klinischen Arbeitsablauf?
- Wie würde eine Plattform angesichts dieser Herausforderungen Ihrer Meinung nach angenommen werden?

Zusammenarbeit mit Patienten:

- Was halten Sie von einer stärkeren Einbeziehung von Patienten in die Behandlung?
- Welche Herausforderungen sehen Sie dabei?
- Wie würde ein solches Kooperationsmodell die Behandlung von Depressionen beeinflussen?

Appendix B Patient Interviews Questionnaire

Einleitung: *Vorstellung des Interviewers und des Projekts, Ziel dieses Interviews, Klärung der Aufnahmeberechtigung. Außerdem kurze Vorstellung des Interviewpartners*

Allgemeine Fragen zu Smartphones und den aufgezeichneten Daten:

- Besitzen Sie ein Smartphone? Eine Smartwatch? Benutzen Sie Geräte, um Ihre sportlichen Aktivitäten oder Gesundheitsdaten aufzuzeichnen?
- Welche Arten von Daten fallen Ihnen ein, die von einem Smartphone oder einer Smartwatch aufgezeichnet werden können?
    - Wenn keine Daten einfallen, dann Beispiele geben (Schritte aufzeichnen, Sport tracken, Essen)
- Haben Sie bereits persönliche Daten mithilfe eines Smartphones oder anderer Geräte gesammelt?
    - Wenn ja, haben Sie diese Daten schon einmal zu einem Arzttermin mitgenommen?
    - Wenn nein, könnten Sie sich vorstellen, dass diese Daten für einen Arzt in bestimmten Situationen relevant sein könnten?

Allgemeine Fragen zu patientengenerierten Gesundheitsdaten:

- Haben Sie schon einmal den Begriff "patientengenerierte Gesundheitsdaten" gehört?
- Welche Informationen, die Patienten über ihre Gesundheit oder ihren Lebensstil sammeln können, halten Sie für wertvoll?
    - Beispiele sind Symptome, soziales Verhalten, sexuelles Verhalten, Tagesablauf, Medikamenteneinnahme, Schlaf.
- Können Patienten Ihrer Meinung nach durch aktive Teilnahme an der Erfassung solcher Informationen zu besseren Behandlungsergebnissen beitragen?
    - Wenn ja, wie können sie das tun?
    - Wenn nein, warum nicht?
- Welche Herausforderungen könnten Ihrer Meinung nach bei der Erfassung eigener gesundheitsbezogener Daten auftreten?
- Gibt es bestimmte Ansprechpartner oder Verantwortliche, die bei diesen Herausforderungen helfen könnten?
    - Wenn ja, wie könnten sie helfen?
    - Wenn nein, warum nicht?

Patientengenerierte Gesundheitsdaten zur Diagnose und Behandlung von mentalen Krankheiten:

- Denken Sie, dass patientengenerierte Gesundheitsdaten auch für die Diagnose und Behandlung von mentalen Krankheiten wie Depressionen verwendet werden können?
    - Wenn ja, welche Daten sehen Sie hier als relevant?
    - Wenn ja, sehen Sie Unterschiede oder besondere Herausforderungen bei der Verwendung dieser Informationen für die Diagnose und Behandlung von mentalen Krankheiten?
    - Wenn nein, warum nicht?

- Sehen Sie potenzielle Vorteile bei der Verwendung von patientengenerierten Gesundheitsdaten zur Diagnose und Behandlung von mentalen Erkrankungen?

Fragen zur Art der Datenerfassung:

- Wie stellen Sie sich die Zusammenarbeit zwischen Patienten und Ärzten bei der Erfassung und Nutzung gesundheitsbezogener Daten vor?
    - Was halten Sie für entscheidende Faktoren?
- Gibt es bestimmte Methoden, mit denen Sie sich die Erfassung von gesundheitsbezogenen Informationen besonders einfach vorstellen?
- Gibt es auch Methoden, die für Sie die Datenerfassung besonders schwierig machen würden?
- Könnten Sie sich vorstellen, Ihre Daten auch dann aufzuzeichnen, wenn Sie gesund sind, damit Ihr Arzt Vergleichswerte für den Krankheitsfall hat?
- Wären Sie im Allgemeinen bereit, Informationen über Ihren Gesundheitszustand elektronisch an Ihren Arzt zu senden?
    - Wenn ja, was wäre Ihnen wichtig, damit Sie Ihre Daten elektronisch an Ihren Arzt senden würden?
    - Wenn ja, können Sie sich auch eine kontinuierliche, passive Datenübertragung vorstellen?
    - Wenn nein, warum nicht?
- Wenn Sie eine App hätten, mit der Sie Informationen über Ihre Gesundheit oder körperliche Aktivität eingeben könnten, auf welchem Gerät würden Sie sie am liebsten verwenden?

Patientengenerierte Gesundheitsdaten im eigenen Umfeld:

- Haben Sie in Ihrem Umfeld von Personen gehört, die durch die Nutzung von patientengenerierten Daten Ihre Gesundheit verbessern konnten?
- Haben Sie in Ihrem Umfeld Personen, bei denen Sie sich vorstellen können, dass die Nutzung von patientengenerierten Daten eine positive Auswirkung auf die Gesundheit hätte?
- Was könnten wir aus diesen Erfahrungen lernen?

Appendix C GP Evaluation Questionnaire

Einleitung: *Vorstellung des Interviewers und des Projekts, Ziel dieses Interviews, Klärung der Aufnahmeberechtigung. Außerdem kurze Vorstellung des Interviewpartners und seiner/ihrer Rolle.*

Einleitung:

- Vorstellung und Zweck des Interviews.
- Vertraulichkeit und Zustimmung

Relevanz von patientengenerierten Gesundheitsdaten (PGHD)

- Allgemeine Fragen, um das Verständnis und die Wahrnehmung des Arztes für PGHD im Zusammenhang mit der Behandlung von Depressionen zu ermitteln.
- Kurze Einführung zu PGHD
- Wieso nennen wir das so
- Was ist das - etc
  - Welchen Begriff verwenden Sie für diese Art von Daten?
  - Haben Sie in Ihrer Praxis bereits Erfahrungen mit PGHD gemacht oder sind Sie damit in Berührung gekommen?

Vorstellung Ergebnisse der vorherigen Workshops anhand einer Liste

- Welche dieser Arten von Daten halten Sie für sinnvoll für die Versorgung von Depressionen
- Sind auf der Liste Arten von Daten, die Sie bisher nicht berücksichtigt haben – finden Sie diese sinnvoll?
- Welche aufgelisteten Arten von Daten finden Sie nicht sinnvoll für die Überwachung von Depressionen?

Ansichten des Arztes zu den potenziellen Vorteilen und Herausforderungen, die mit dem Einsatz von PGHD bei der Behandlung von Depressionen verbunden sind.

- Was sind Ihrer Meinung nach die potenziellen Vorteile der Integration von PGHD in die Behandlung von Depressionen?
- Was sind Ihrer Meinung nach die potenziellen Herausforderungen oder Einschränkungen bei der Einbeziehung von PGHD in Ihre Praxis?

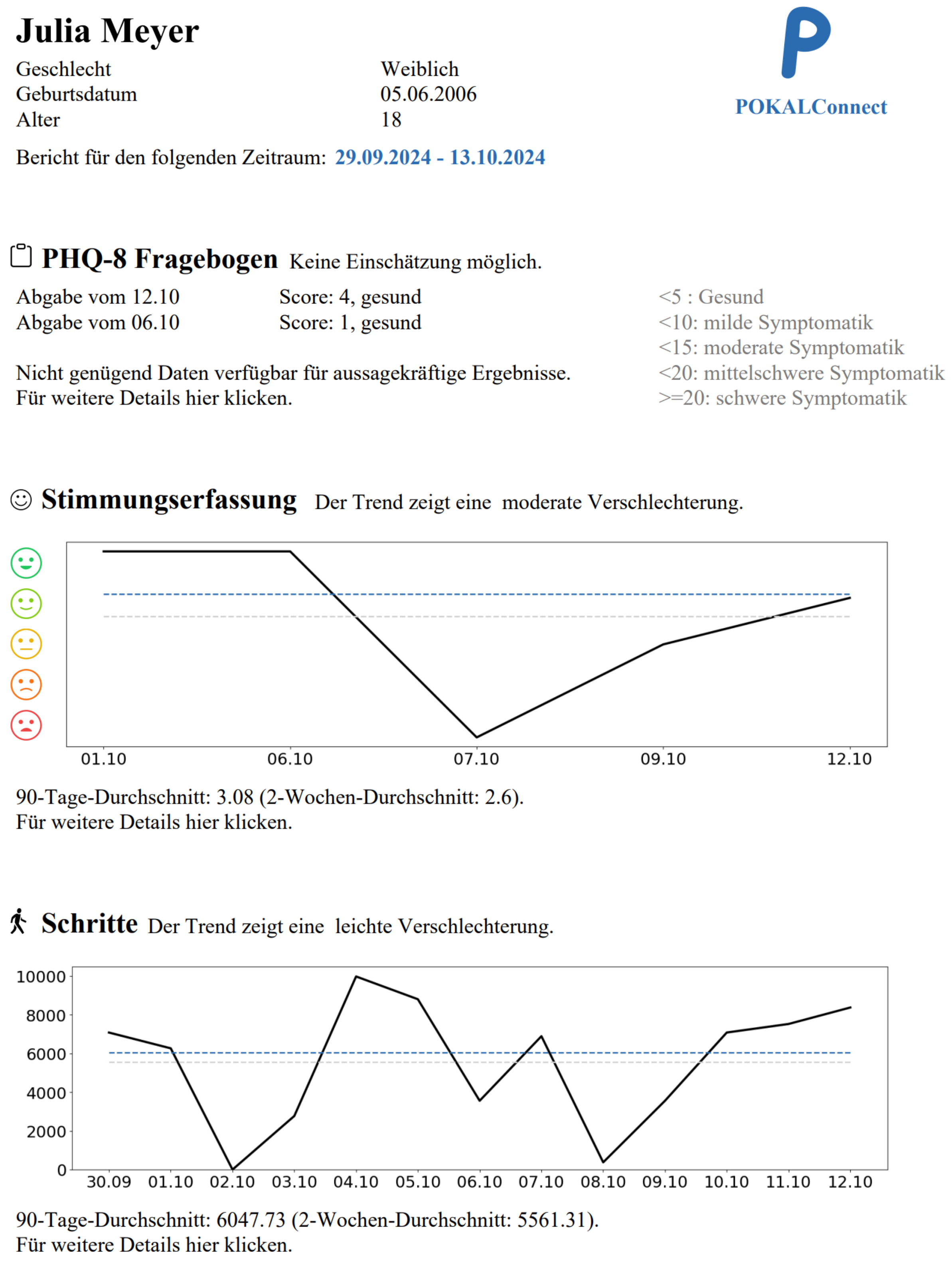
Abschnitt 2: Präsentation von PGHD bei Ärzten anhand des Prototypen

- Vorstellung Prototyp anhand von
  - Datenarten
  - Darstellung
  - Technik

- Was mögen Sie an dem Programm?
- Was mögen Sie nicht an dem Programm?
- Welche der zwei vorgestellten Versionen bevorzugen Sie?
- Welche Arten von Daten würden Sie aus den bestehenden Prototypen entfernen? Welche integrieren?
- Wie sollen diese Arten von Daten erhoben werden?

Appendix D Weekly Report

Figure 35: Weekly Report - Page 1 (own illustration)



Julia Meyer

Geschlecht	Weiblich
Geburtsdatum	05.06.2006
Alter	18

POKALConnect

Bericht für den folgenden Zeitraum: **29.09.2024 - 13.10.2024**

PHQ-8 Fragebogen Keine Einschätzung möglich.

Abgabe vom 12.10	Score: 4, gesund
Abgabe vom 06.10	Score: 1, gesund

<5 : Gesund
<10: milde Symptomatik
<15: moderate Symptomatik
<20: mittelschwere Symptomatik
>=20: schwere Symptomatik

Nicht genügend Daten verfügbar für aussagekräftige Ergebnisse.
Für weitere Details hier klicken.

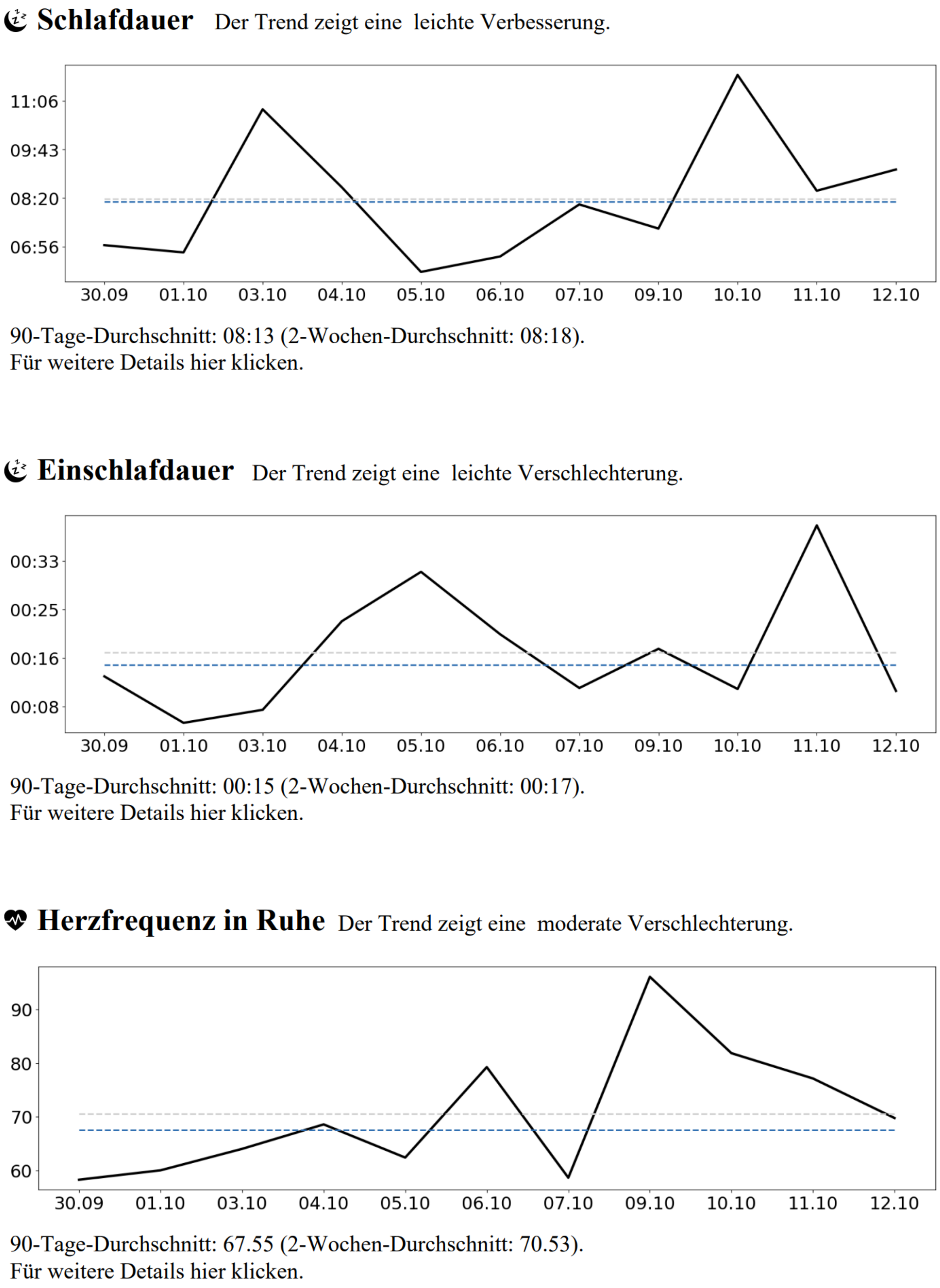
☺ **Stimmungserfassung** Der Trend zeigt eine moderate Verschlechterung.

90-Tage-Durchschnitt: 3.08 (2-Wochen-Durchschnitt: 2.6).
Für weitere Details hier klicken.

Schritte Der Trend zeigt eine leichte Verschlechterung.

90-Tage-Durchschnitt: 6047.73 (2-Wochen-Durchschnitt: 5561.31).
Für weitere Details hier klicken.

Figure 36: Weekly Report - Page 2 (own illustration)



Schlafdauer Der Trend zeigt eine leichte Verbesserung.

90-Tage-Durchschnitt: 08:13 (2-Wochen-Durchschnitt: 08:18).
Für weitere Details hier klicken.

Einschlafdauer Der Trend zeigt eine leichte Verschlechterung.

90-Tage-Durchschnitt: 00:15 (2-Wochen-Durchschnitt: 00:17).
Für weitere Details hier klicken.

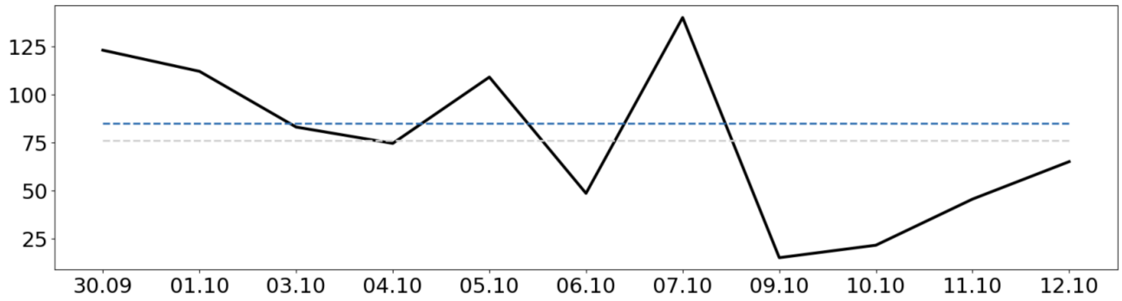
Herzfrequenz in Ruhe Der Trend zeigt eine moderate Verschlechterung.

90-Tage-Durchschnitt: 67.55 (2-Wochen-Durchschnitt: 70.53).
Für weitere Details hier klicken.

Figure 37: Weekly Report - Page 3 (own illustration)

Herzfrequenzvariabilität in Ruhe

Der Trend zeigt eine moderate Verschlechterung.



90-Tage-Durchschnitt: 85.08 (2-Wochen-Durchschnitt: 76.09).
Für weitere Details hier klicken.