

**Regulation for Innovation or Innovation despite Regulation?
Lessons from Germany's DiGA Fast-Track for Digital Health Innovation**

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Sara Gehder

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Gutachter:

Prof. Dr. Moritz Göldner

Prof. Dr. Jochen Klucken

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Preface

It does not happen often that an entirely new reimbursement category is introduced into an established healthcare system. When Germany launched the Digital Health Application (DiGA) Fast-Track in 2020, it did more than create a new pathway for digital medical devices. For the first time, eligible digital health applications could become part of routine care and be prescribed by physicians and psychotherapists, with reimbursement through statutory health insurance. This presented a real chance to fill some gaps in our expensive but inefficient healthcare system. For researchers interested in digital health innovation, regulation, and reimbursement, this presented a unique opportunity to observe the development of a new market and regulatory framework.

Sara Gehder was therefore at the right place at the right time when she started her work in early 2023. Her dissertation, *“Regulation for Innovation or Innovation despite Regulation? Lessons from Germany’s DiGA Fast-Track for Digital Health Innovation,”* accompanies the DiGA system through an important phase of its early development and examines what can be learned from this regulatory innovation for digital health more broadly.

The central question underlying her work is particularly relevant as regulation and innovation are frequently portrayed as opposing forces. Regulation is often discussed as something that slows innovation, increases costs, and creates barriers to market entry. The DiGA Fast-Track provides an interesting counterpoint to this perspective. By combining regulatory requirements with a clearly defined route to reimbursement and an overall start-up friendly mindset, the German framework actively created a market for a new category of digital health technologies. Sara’s work demonstrates, however, that establishing such a pathway is only the beginning. Whether regulation actually enables innovation depends on how its individual mechanisms are interpreted, implemented, adapted and used by the actors involved.

This cumulative dissertation addresses these questions through four scientific publications, all published in renowned outlets between 2024 and 2026. Together, they provide a coherent perspective at the intersection of innovation management, health policy, and digital medicine, moving from an analysis of the emerging DiGA market toward a more detailed examination of specific mechanisms within the regulatory framework. The first study provides a comprehensive data-driven analysis of the development of the DiGA market, including its market structure, uptake, pricing, and evidence base. Building on this broader perspective, the subsequent studies focus on two particularly promising, yet still insufficiently used, elements of the DiGA framework. First, Sara examines patient-relevant structural and procedural improvements (*patientenrelevante Struktur- und Verfahrensverbesserungen*, pSVV), both as a novel approach to defining patient-relevant

value beyond direct medical outcomes and from an innovation systems perspective that considers the institutional and stakeholder conditions influencing its adoption. Second, she turns to real-world data (RWD) and its potential to complement conventional approaches to evidence generation by evaluating digital health technologies under routine conditions. Taken together, the four studies move beyond describing the DiGA Fast-Track as a regulatory innovation and critically examine how its underlying mechanisms function in practice, where their potential remains underused, and what can be learned from the German experience for the regulation, reimbursement, and evaluation of digital health innovation more broadly. Methodologically, the dissertation is equally compelling. By combining qualitative research with the analysis of a comprehensive dataset on DiGA drawn from the official DiGA directory and app stores, as well as a systematic scoping review of the literature, Sara approaches her research questions from complementary empirical and methodological perspectives. This methodological breadth allows her to connect stakeholder experiences and institutional mechanisms with observable market developments and the broader scientific evidence base.

Taken together, the four papers tell an interesting story about regulatory innovation. The DiGA Fast-Track demonstrates that regulation can do more than constrain innovation: when regulation provides a predictable route into reimbursed healthcare, it can actively stimulate market formation and technological development. At the same time, Sara's research shows that creating regulatory possibilities does not automatically mean that they will be used. The experiences with pSVV and RWD illustrate the importance of clear incentives, methodological guidance, institutional alignment, and acceptance among the different actors of the healthcare system.

What I will remember most about working with Sara is not only the scientific progress we made, but also the many conversations, conference trips, and moments of fun that accompanied it. Our exchange was always open, constructive, and intellectually stimulating, and I greatly valued her curiosity, reliability, and critical perspective on digital health and the German healthcare system. As my first external PhD student, she also made this project a new experience for me personally. It has been a genuine pleasure to see her develop into an increasingly independent and thoughtful researcher over the past three years, and I am very grateful for the productive and enjoyable journey we shared and will continue to share.

Sara's dissertation is therefore both timely and forward-looking. It captures an exceptional period in German digital health policy while addressing questions that extend far beyond the specific case of DiGA. How should regulation be designed to enable innovation while maintaining appropriate standards of evidence? How can reimbursement create incentives for technologies that generate meaningful value for

patients? And how can digital technologies use the data they generate to continuously improve the evidence on their effectiveness in routine care?

These questions will remain highly relevant as healthcare systems increasingly integrate digital technologies into standard care. Sara's work provides important empirical evidence and conceptual insights for answering them. I am very pleased to have accompanied her on this journey and am confident that this dissertation will provide a valuable foundation for future research on regulation, reimbursement, evidence generation, and digital health innovation.

Hamburg, August 2026

Prof. Dr. Moritz Göldner

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My sincere gratitude goes to my supervisor, Moritz, whose experience, advice, and encouragement have shaped this journey in countless ways. He opened doors, made valuable connections, and was an excellent sparring partner on all matters related to digital health and entrepreneurship. At the same time, he gave me the freedom to find my own path. He also made this dissertation more colorful — quite literally, in the case of its figures, and figuratively through the many enjoyable moments we shared along the way. I am deeply grateful for his trust and for a collaboration that has grown into a friendship.

I would also like to thank all the interview participants who generously shared their time, experiences, and perspectives with me. Their openness and willingness to engage in thoughtful conversations made an essential contribution to this research.

My thanks also go to my parents. I am profoundly grateful to them for giving me the curiosity, confidence, and sense of security that allowed me to embark on this adventure in the first place. My mother taught me precision, determination, and the conviction that all humans can accomplish formidable things. My father gave me openness, lightness, and an enduring enthusiasm for exploring new ideas. I also thank my sister, my brother and my friends for their patience, understanding, and continued presence, even when this dissertation claimed rather more of my attention than was entirely reasonable.

My greatest thanks go to my husband, my most enthusiastic supporter and most honest critic. He inspires me, supports me with his unconditional love, and has shown me that ambition can be both serious and genuinely enjoyable.

Above all, I feel fortunate to have been surrounded by people who never questioned why I wanted to take on this challenge but simply believed that I could. Thank you for believing in me!

Summary

Digital health technologies are increasingly integrated into healthcare systems as software-based tools for prevention, diagnosis, treatment, and care coordination. Their rapid development cycles and capacity to generate continuous user data challenge traditional regulatory and evaluation models. Regulators therefore face the task of enabling innovation while ensuring safety, methodological rigor, and sustainable reimbursement.

Germany's Digital Health Applications (DiGA) Fast-Track, introduced in 2019, represents one of the first reimbursement pathways for software-based medical devices within statutory health insurance. A key feature of the framework is its broadened value concept: positive healthcare effects can be demonstrated either through traditional medical benefit or through patient-relevant structural and procedural improvements (pSVV). In addition, the pathway anticipates the use of alternative evidence strategies and real-world data in evaluating digital interventions.

This dissertation examines to what extent regulation can act as a driver of innovation in digital health using the DiGA Fast-Track as an empirical case. It analyzes (1) the development of the DiGA market, (2) how value categories such as pSVV are interpreted and operationalized by stakeholders, and (3) how real-world data are currently used to evaluate mHealth effectiveness. A multi-method research design is applied. Descriptive analyses of regulatory and market data examine the development of the DiGA ecosystem. Qualitative interviews with stakeholders are analyzed using grounded theory and the Gioia methodology to reconstruct interpretive patterns surrounding pSVV and regulatory processes. These findings are interpreted within a technological innovation systems framework. In addition, a systematic scoping review following PRISMA-ScR guidelines analyzes the use of real-world data in evaluations of patient-facing mHealth applications.

The findings show that the DiGA Fast-Track successfully established a reimbursed category for digital health applications and enabled structured market formation. However, regulatory innovation in value definition has not materialized. Although pSVV formally broadens the concept of positive healthcare effects, it is not used as a primary endpoint due to methodological ambiguity, limited precedents, and economic risk considerations that favor established medical-benefit strategies. In parallel, the scoping review demonstrates that real-world data are widely generated but selectively integrated into effectiveness evaluations. Overall, the dissertation shows that regulation can effectively create markets for digital health technologies, while deeper transformation of value frameworks and evidence practices depends on additional systemic conditions such as methodological clarity, aligned incentives, and supportive data infrastructures.

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IV. List of Abbreviations

AbEM – Anwendungsbegleitende Erfolgsmessung (English: Continuous Effectiveness Evaluation during Application)

BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte (English: Federal Institute for Drugs and Medical Devices)

COREQ – Consolidated Criteria for Reporting Qualitative Research

DiGA – Digitale Gesundheitsanwendung (English: Digital Health Application)

DiGAV – Digitale-Gesundheitsanwendungen-Verordnung (English: Digital Health Applications Ordinance)

DigiG – Digital-Gesetz (English: Digital Act)

DiMe – Digital Medicine Society

DiPA – Digitale Pflegeanwendung (English: Digital Care Application)

DVG – Digitale-Versorgung-Gesetz (English: Digital Healthcare Act)

EHDS – European Health Data Space

EHR – Electronic Health Record

EU – European Union

FDA – Food and Drug Administration (United States)

GKV – Gesetzliche Krankenversicherung (English: Statutory Health Insurance)

MDR – Medical Device Regulation (European Union)

mHealth – Mobile Health

NICE – National Institute for Health and Care Excellence (United Kingdom)

OECBM – Oxford Centre for Evidence-Based Medicine

OECD – Organization for Economic Co-operation and Development

PECAN – Prise en charge anticipée numérique (English: Early Access Reimbursement Scheme for Digital Health Technologies, France)

PRISMA-ScR – Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

PRO – Patient-Reported Outcome

pSVV – Patientenrelevante Struktur- und Verfahrensverbesserungen (English: Patient-Relevant Structural and Procedural Improvements)

RCT – Randomized Controlled Trial

RQ – Research Question

RWD – Real-World Data

RWE – Real-World Evidence

SaMD – Software as a Medical Device

SGB V – German Social Code Book V

TIS – Technological Innovation Systems

WHO – World Health Organization

1. Introduction

Healthcare systems are increasingly confronted with structural pressures that challenge their capacity to deliver accessible, high-quality, and financially sustainable care. Demographic change, rising healthcare expenditures, workforce constraints, and fragmented health information systems place growing demands on existing healthcare infrastructures (Chen et al., 2023; Endalamaw et al., 2025). In response, digital health technologies are widely discussed as a potential means to improve access to care, enhance efficiency in healthcare processes, and support data-driven decision-making in clinical practice and public health (Badr et al., 2024; Stoumpos et al., 2023; World Health Organization, 2011). These expectations have contributed to a growing policy focus on how digital innovation can be integrated into healthcare systems.

Digital health is increasingly shaped by regulatory frameworks that seek to balance safety, effectiveness, and innovation (Colloud et al., 2023; Diao et al., 2022; Essén et al., 2022; Keutzer and Simonsson, 2020; Koop and Lodge, 2017; Mathias et al., 2024; Torous et al., 2022). While regulation can create clear pathways, reduce uncertainty, and build trust, it can also impede innovation when requirements are rigid, ambiguous, or misaligned with technological development (Blind and Münch, 2024; Gerke et al., 2020; Stern, 2017). Recent policy work, including by the OECD, highlights that regulation can function both as a mechanism of control and as a deliberate instrument to support innovation by shaping incentives and market conditions (Blind, 2012; OECD, 2025). This produces a form of regulatory ambivalence - innovation for regulation when regulatory design enables development, and innovation despite regulation when actors must adapt to, work around, or compensate for regulatory constraints. In this thesis, regulation is not understood merely as an external constraint on innovation but as a constitutive framework that defines the conditions under which innovation becomes legitimate, evidence-based, and reimbursable.

Digital health provides a particularly relevant domain for examining this regulatory ambivalence because digital health technologies often evolve faster than traditional regulatory cycles, rely on iterative updates, and depend on data-driven functionalities that challenge conventional evidence models (Barth et al., 2021; Grenier et al., 2019; Kadakia et al., 2020; Torous et al., 2022). These characteristics make the field an instructive setting for analyzing how regulatory design enables, shapes, or constrains innovation in practice.

The German Digital Health Applications (Digitale Gesundheitsanwendungen, DiGA) Fast-Track (Federal Institute for Drugs and Medical Devices (BfArM), 2022) exemplifies this

dynamic. Introduced in 2019 and subsequently expanded through several legislative amendments, the pathway establishes a regulated route by which certain software-based medical devices can be prescribed and reimbursed within statutory health insurance following assessment by the Federal Institute for Drugs and Medical Devices (BfArM). The pathway is widely regarded as a regulatory innovation (Stern et al., 2020) because it introduces a new reimbursable product category (DiGA), allows positive healthcare effects to be demonstrated either through medical benefit or patient-relevant structural and procedural improvements (pSVV), and anticipates the use of real-world data to support ongoing evaluation. At the same time, early implementation has revealed uncertainties in how these value categories are interpreted, how evidence requirements are operationalized, and how market participation unfolds in practice (Gerke et al., 2020; Schmidt et al., 2024).

Building on this broader discussion of regulatory ambivalence, the thesis uses the DiGA Fast-Track as an empirical case to explore how regulatory design shapes innovation in practice. It analyzes the conditions created by the DiGA Fast-Track under which innovative Digital Health Technologies are listed, evaluated, and legitimized in routine care. The focus is on the market structures that emerge under the innovative regulatory pathway, the interpretation and use of innovative value categories such as pSVV, and the role of clinical and real-world data in demonstrating effectiveness.

The following sections introduce the conceptual background for the analysis, situating the DiGA Fast-Track within international developments, outlining its design and value framework, and contextualizing current approaches to evidence generation in digital health.

1.1. Regulation for Innovation

Regulation is frequently understood as a mechanism for constraining or monitoring economic activity. From this perspective, regulation is seen as a burden that increases compliance costs, delays market entry, and restricts entrepreneurial flexibility (Cunha and Donadelli, 2025; Ford, 2017; Jurczak et al., 2025). However, more recent work highlights that regulation can also enable innovation by creating clear expectations, reducing uncertainty, opening new markets, and directing innovation toward socially desirable goals (Ambec and Barla, 2002; Engberg and Altmann, 2015; OECD, 2025). This shift underpins the concept of regulation for innovation (OECD, 2025), which refers to regulatory frameworks designed not only to safeguard public interests but also to actively shape the direction, incentives, and pace of technological development.

A central insight from this literature is the ambivalence of regulatory effects. As Blind (Blind, 2012) demonstrates in a cross-country analysis, regulatory measures can impose

short-term compliance costs that reduce firms' capacity to invest in innovation, while simultaneously generating long-term incentives by defining market standards, ensuring trust, or protecting intellectual property. The effect of regulation therefore depends not only on its content but also on its implementation, timing, and its alignment with wider institutional conditions (Butenko and Larouche, 2015; Parker et al., 2024).

Three broad forms of regulation are relevant in this context: economic regulation (e.g., market entry and pricing rules), social regulation (e.g., safety and quality requirements), and institutional regulation (e.g., liability regimes and intellectual property protection). Each of these can either hinder or foster innovation depending on how clearly they are defined and how predictably they are enforced (Bessen and Hunt, 2007; Jaffe et al., 2002). Importantly, regulatory uncertainty -manifesting in unclear expectations, variable approval timelines, or inconsistent guidance- has been shown to deter first-movers in health technology fields by increasing investment risk (Stern, 2017).

Taken together, the relationship between regulation and innovation is best understood as a dynamic interaction that evolves over time and differs across technological domains. Regulation can restrict some forms of innovation while enabling others; it can hinder innovation in the short term while fostering it in the long term; and its effects depend heavily on institutional capacity and clarity of implementation.

Digital health provides a particularly salient context for examining these dynamics because software-based health technologies develop under overlapping regulatory spheres, including medical device regulation, data protection law, software engineering standards, and healthcare reimbursement structures (Maresova, 2023; Torous et al., 2022). Early mobile health applications were largely distributed through commercial app stores with limited health-specific regulatory oversight. As applications began to claim medical functionality, they were increasingly classified as medical devices under the European Medical Device Directive (MDD), followed by more comprehensive regulation under the Medical Device Regulation (MDR) (Sadare et al., 2023; Svempe, 2025). More recently, several countries have introduced regulated market access pathways for digital health technologies to be prescribed and financed within healthcare systems to be prescribed and financed within the healthcare system (Essén et al., 2022). These instruments are designed to balance safety and accountability with the goal of enabling innovation in routine care.

In this dissertation, regulation is not understood merely as a set of legal constraints, but as the deliberate design of a socio-technical market access architecture. It defines entry conditions, value criteria, evidence requirements, pricing mechanisms, and procedural

timelines. As such, regulation functions as a structural component of the innovation system rather than as an external constraint.

Before examining a regulated market access pathway in digital health in detail, it is necessary to situate these developments within a broader international context. The next section therefore outlines selected regulatory initiatives for digital health in different health systems. This provides the conceptual and empirical background needed to understand how the design of a regulated market access pathway can shape the conditions under which digital health innovations emerge and are integrated into healthcare.

1.2. Terminology and Scope

Digital health technologies are digital systems that use software, connectivity, computing platforms, or sensors to support healthcare activities such as prevention, diagnosis, treatment, and care delivery (U.S. Department of Health and Human Services Food and Drug Administration et al., 2023). Within this broad field, *mobile health (mHealth)* refers to the use of mobile and wireless technologies to support health objectives (World Health Organization, 2011). Independently of the delivery platform, software intended to achieve a medical purpose is regulated as *Software as a Medical Device (SaMD)* (IMDRF SaMD Working Group, 2013). In Germany, *Digital Health Applications (Digitale Gesundheitsanwendungen, DiGA)* constitute a specific, legally defined subset of SaMD: they are Class I, IIa or IIb medical devices whose primary function is digital and that must demonstrate positive healthcare effects to qualify for prescription and reimbursement under statutory health insurance (Federal Institute for Drugs and Medical Devices (BfArM), 2022; Sippli et al., 2025). The hierarchical relationship between these concepts is illustrated in Figure 1.

This distinction defines the analytical scope of this thesis. The analysis focuses on DiGA as an early and internationally significant example of a regulated and reimbursed access pathway for digital health technologies. In addition, the discussion considers mHealth applications intended for direct patient use, which represent a broader category of digital health technologies relevant for the generation and use of real-world data in this thesis' context.

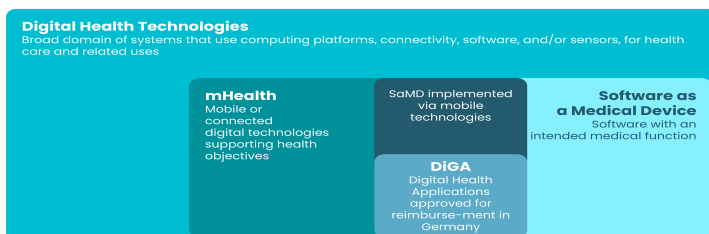


Figure 1 - Hierarchical relationship between key terminology used in this thesis. Digital health technologies refer to the broad field of digital tools in healthcare (U.S. Department of Health and Human Services Food and Drug Administration et al., 2023). mHealth denotes the subset delivered via mobile and wireless technologies (World Health Organization, 2011). Software intended to achieve a medical purpose is classified as Software as a Medical Device (SaMD) (IMDRF SaMD Working Group, 2013). DiGA represent a legally defined subset of SaMD in Germany eligible for prescription and reimbursement under statutory health insurance (Federal Institute for Drugs and Medical Devices (BfArM), 2022; Sippli et al., 2025).

1.3. Global Regulatory Initiatives in mHealth

Several health systems have recently introduced structured pathways intended to support the safe and evidence-based integration of digital health technologies into routine care. These initiatives reflect a shared policy shift: rather than treating digital health as an add-on or consumer technology, health systems increasingly view it as a component of reimbursed care that requires regulatory clarity, predictable evaluation rules, and alignment with clinical practice (Essén et al., 2022; Gordon et al., 2020; Torous et al., 2022; van Kessel et al., 2023). At the same time, the iterative development cycles of software-based interventions and their dependence on patient engagement challenge regulatory models originally designed for pharmaceuticals and high-risk devices (Mathias et al., 2024).

In response, several countries have established dedicated frameworks to evaluate and integrate digital health technologies into their healthcare systems. In France, the PECAN scheme provides temporary reimbursement for digital health technologies contingent on real-world evidence generation, linking early access with post-market data collection (Martin et al., 2024). Belgium's mHealthBelgium framework uses a staged validation model in which technologies progress through levels that assess technical robustness, interoperability, and evidence of clinical benefit (San Miguel et al., 2023). In the United Kingdom, the NICE Evidence Standards Framework specify requirements for data

governance, usability, and differentiated levels of evidence depending on patient risk and intended clinical function (Unsworth et al., 2021; Visram et al., 2024). In the United States, the FDA has explored adaptive regulatory approaches for digital health, most notably through the Digital Health Software Precertification (Pre-Cert) Program, which piloted an organization-level certification model before being discontinued in 2022 as insights were integrated into existing review processes (U.S. Food and Drug Administration, 2022).

Beyond national initiatives, several European efforts aim to improve the harmonization of evaluation approaches for digital health technologies across member states. While the regulatory approval of software-based medical devices is governed by the European Union's Medical Device Regulation (MDR), the assessment of clinical value and reimbursement eligibility remains largely a national responsibility. As a result, evaluation criteria, evidence expectations, and pathways for market access differ substantially across countries. Recent collaborative initiatives therefore seek to develop shared taxonomies and methodological frameworks to support more consistent evaluation practices across European health technology assessment systems. For example, the European Taskforce for Harmonized Evaluation of Digital Medical Devices has proposed a classification grid and associated evidence matrix designed to align evaluation approaches across national agencies and to facilitate cross-country learning (Boers et al., 2025). Such initiatives reflect broader policy efforts to reduce fragmentation in the European digital health landscape while preserving national autonomy in reimbursement and implementation decisions.

These examples do not represent an exhaustive set of models but illustrate different regulatory strategies for balancing innovation and assurance of clinical relevance. Although each system seeks to reduce uncertainty, they differ in how they define and operationalize value and evidence: some prioritize traditional clinical endpoints, whereas others also recognize process-oriented or patient-centered outcomes; some emphasize real-world performance data, while others rely primarily on pre-market evaluations (Essén et al., 2022; van Kessel et al., 2023).

These differences illustrate that regulatory design is not neutral. It shapes which forms of innovation are viable, which outcomes are considered meaningful, and which evaluation strategies developers of digital health technologies adopt. While additional factors -such as reimbursement models, clinician uptake, and integration into care pathways (Brückner et al., 2025; Gilbert et al., 2023a)- also influence adoption, this thesis focuses specifically on how value categories and evidence requirements are defined and applied in regulatory frameworks for digital health technologies.

Within this diverse regulatory landscape, Germany introduced the DiGA Fast-Track as a structured pathway for the evaluation and reimbursement of digital health applications.

The pathway represents one of the earliest fully implemented attempts to combine structured market entry, a differentiated value framework, and the anticipated use of real-world data in routine care evaluation (Lantzsch et al., 2022; Mäder et al., 2023). The next section therefore introduces the design and logic of the DiGA Fast-Track as the empirical setting for this thesis.

1.4. The DiGA Fast-Track in Germany

The DiGA Fast-Track was established in Germany in 2019 by the Digitale-Versorgung-Gesetz (DVG), which introduced §§ 33a and 139e into the Social Code Book V (SGB V) to regulate reimbursement and the DiGA directory, managed by the Federal Institute for Drugs and Medical Devices (BfArM). It establishes a regulated pathway through which certain software-based medical devices with a primary digital function may be prescribed by physicians or psychotherapists and reimbursed within statutory health insurance after assessment and inclusion in the DiGA directory. Initially limited to devices of risk classes I and IIa, the Fast-Track was expanded to include class IIb devices through the Digital-Act (Digital Gesetz, DigiG), which entered into force on 26 March 2024. The Fast-Track is designed to enable timely access to digital health innovations while maintaining requirements for safety, data protection, and demonstrable positive healthcare effects (Federal Institute for Drugs and Medical Devices (BfArM), 2023; Lantzsch et al., 2022). In parallel, the DVG also introduced a comparable framework for digital care applications (Digitale Pflegeanwendungen, DiPA) within long-term care insurance under the Social Code Book XI; however, the present analysis focuses on DiGA. The following section reflects the regulatory framework of the DiGA Fast-Track as of 2026, including recent amendments introduced through the Digital Act and subsequent regulatory adjustments.

The DiGA Fast-Track is widely recognized as a regulatory innovation because it does not merely evaluate digital health applications for safety and performance but creates a new reimbursable product category within routine care (Essén et al., 2022; Gerke et al., 2020; Stern et al., 2020; van Kessel et al., 2023). This distinguishes it from many international digital health assessment approaches, which focus primarily on certification or quality assurance without linking evaluation directly to reimbursement. The German pathway therefore functions not only as a regulatory mechanism but also as a market access and adoption instrument, enabling digital therapeutics to be integrated into clinical care pathways and financed through existing insurance structures.

Several innovative mechanisms have been introduced by the DiGA Fast-Track. A central feature of the pathway is a provisional listing mechanism. Applications may enter the DiGA Directory on a temporary basis if a plausible evaluation concept is submitted, allowing an initial twelve months of reimbursement while evidence is still being generated

(extendable up to 24 months under defined conditions). Permanent listing requires submission of evidence demonstrating positive healthcare effects according to the approved evaluation plan (Federal Institute for Drugs and Medical Devices (BfArM), 2023). This staged approach reflects an effort to balance timely patient access with evidence-based evaluation, acknowledging that the generation of robust evidence takes time.

A second distinctive element concerns pricing. During the first year following listing in the DiGA Directory, manufacturers are permitted to set the price of the application independently. After this initial period, the reimbursement price is negotiated between the manufacturer and the statutory health insurance funds, represented by the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband). This mechanism is intended to lower barriers to market entry for innovative digital health technologies while subsequently introducing cost control through negotiated reimbursement.

A third mechanism relates to methodological flexibility in the generation of evidence. While randomized controlled trials remain an important standard for demonstrating clinical benefit, the DiGA framework allows for alternative study designs where appropriate. These may include pragmatic trials or other forms of real-world evidence generation that capture outcomes under routine conditions of use. This flexibility reflects the specific characteristics of digital health interventions, which often evolve iteratively and may require continuous updates, making long and rigid trial structures difficult to implement. It also acknowledges that meaningful outcome data may only emerge once applications are used in everyday care contexts. (Gilbert et al., 2023b; Stern et al., 2022).

Recent amendments to the DiGA regulation have further strengthened the emphasis on real-world performance monitoring. The introduction of the *Anwendungsbegleitende Erfolgsmessung* (AbEM; English: Continuous Effectiveness Evaluation during Application) establishes a structured framework for the continuous measurement of outcomes during routine use of certain DiGA. Under this approach, predefined indicators are collected during the period of use to monitor whether the application achieves the expected positive healthcare effects in real-world settings. In addition, the revised framework allows a portion of the reimbursement to be linked to these outcome measures, with up to 20% of the remuneration potentially tied to the achievement of defined performance targets. This mechanism introduces an element of outcome-based reimbursement into the DiGA pathway and further integrates evidence generation with routine care delivery.

The pathway also incorporates a dual framework for demonstrating positive healthcare effects. To receive permanent listing, manufacturers must provide evidence of either medical benefit (e.g., symptom improvement, health outcomes) or patient-relevant structural and procedural improvements (patientenrelevante Struktur- und

Verfahrensverbesserungen, pSVV), such as enhanced treatment adherence, improved disease self-management, or improved coordination of care (Federal Institute for Drugs and Medical Devices (BfArM), 2023), or a combination of both. This second category represents an explicit attempt to broaden what counts as “value” in digital health, recognizing that digital interventions can act by modifying care processes as well as producing direct clinical endpoints.

Since its introduction, the DiGA Fast-Track has resulted in a steadily expanding portfolio of reimbursable digital health applications. According to the most recent report of the National Association of Statutory Health Insurance Funds, more than one million DiGA prescriptions or approvals had been recorded by the end of 2024, reflecting rapidly increasing utilization within statutory health insurance (GKV-Spitzenverband, 2025). As of March 2026, a total of 78 applications has entered the DiGA directory, of which 61 remain listed while others have been withdrawn or delisted. Figure 2 illustrates this development. Panel A shows the number of DiGA by year of first inclusion and current listing status, illustrating the expansion of the DiGA directory and the current composition of listed and withdrawn applications. Panel B summarizes how positive healthcare effects are currently operationalized among listed DiGA, showing that all listed applications demonstrate medical benefit as the primary endpoint, while a subset additionally reports pSVV as a secondary endpoint.

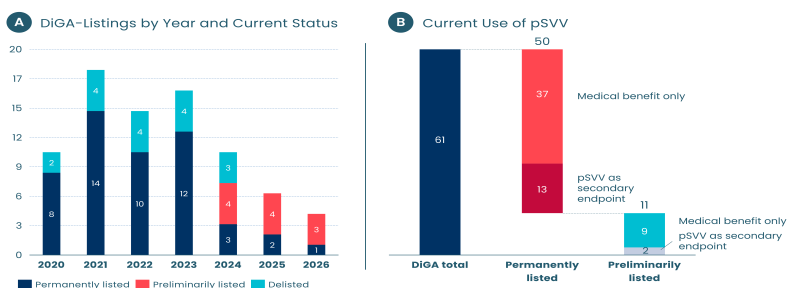


Figure 2 - DiGA listings and use of pSVV in the BfArM directory (data as of March 2026). (A) DiGA by year of first inclusion and current listing status. (B) Distribution of positive healthcare effects, showing medical benefit and pSVV use among permanently and preliminarily listed DiGA.

The observed development of the DiGA market must be understood in relation to the regulatory architecture that structures market entry, value assessment, and evidence generation. For analytical clarity, the key mechanisms of the DiGA Fast-Track can be

grouped into three dimensions of regulatory innovation that extend beyond conventional medical device regulation: market innovation, value innovation, and evidence innovation (Figure 3). Market innovation refers to instruments that facilitate market entry and reimbursement for digital health applications. Value innovation relates to the expansion of outcome categories used to assess the benefits of DiGA. Evidence innovation concerns adaptations of evaluation methods and evidence generation to the specific characteristics of digital health technologies. These dimensions correspond to three central challenges in integrating digital therapeutics into healthcare systems: enabling market access, defining relevant forms of value and generating appropriate evidence. Existing work on digital health evaluation frameworks highlights the difficulty decision-makers face in assessing rapidly evolving digital technologies given heterogeneous evidence standards and evolving value criteria (Haig et al., 2023).

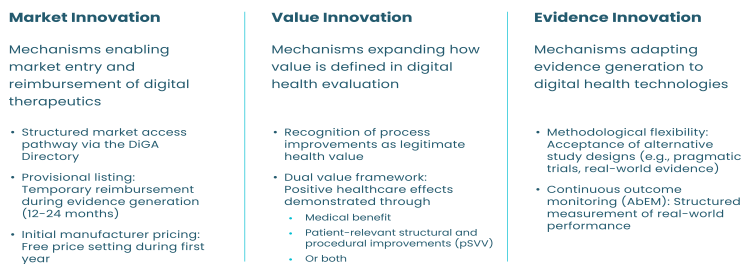


Figure 3 - Dimensions of regulatory innovation in the DiGA Fast-Track. The key mechanisms of the DiGA Fast-Track can be grouped into three dimensions: market innovation, value innovation, and evidence innovation. These dimensions reflect how the regulatory framework shapes market access, expands the definition of value in digital health evaluation, and adapts evidence generation to the characteristics of digital health technologies.

Taken together, these design features position the DiGA Fast-Track as a structured market access pathway that operationalizes regulation not solely as a gatekeeping function, but as a tool for shaping market formation, value definition and evaluation practices in digital health. The design of the DiGA Fast-Track has evolved notably since its introduction through the DVG in 2019. Subsequent legislative and regulatory amendments -including substantial changes introduced by the DigiG in 2024 and further adjustments implemented in 2026- have modified elements of the pathway, particularly regarding evidence generation, outcome monitoring, and reimbursement mechanisms. These modifications illustrate an iterative approach to regulatory design in which the framework

is gradually refined based on implementation experience and stakeholder feedback. Such adaptive governance reflects the challenge of regulating rapidly evolving digital health technologies within institutional structures traditionally designed for more stable forms of medical innovation.

However, several elements of the pathway -including the interpretation of pSVV and the role of real-world data in evidence generation- remain under active implementation and negotiation among manufacturers, payers, clinicians, patients, and regulators (Dittrich et al., 2023; Schlieter et al., 2023). These aspects form the basis of the subsequent sections of this chapter and the research questions of this thesis.

The following chapter focuses in detail on pSVV and examines how this value category is defined, interpreted, and applied in the evaluation of DiGA.

1.5. Patient-Relevant Structural and Procedural Improvements (pSVV)

As introduced in the previous section, within the DiGA Fast-Track, manufacturers may demonstrate a positive healthcare effect either by showing medical benefit or by demonstrating patient-relevant structural and procedural improvements (patientenrelevante Struktur- und Verfahrensverbesserungen, pSVV) (Federal Institute for Drugs and Medical Devices (BfArM), 2023), or both. Whereas medical benefit refers to changes in clinical outcomes, pSVV is defined as improvements in the organization, delivery, or experience of care that are meaningful to patients, even when they do not directly alter medical endpoints. As one of the three dimensions of regulatory innovation introduced in the previous section and given its comparatively limited use among listed DiGA shown in Figure 2B, the concept of pSVV warrants closer examination.

The pSVV value category reflects recognition that many digital health technologies exert their impact through support for disease management, coordination, communication, and engagement, rather than through direct physiological mechanisms. Traditional health technology assessment approaches prioritize clinical outcomes observable in randomized trials, yet digital interventions often shape everyday practices of care, influencing adherence, autonomy, and interaction within health systems (Dang et al., 2020; Wang et al., 2023; Wedlund and Kvedar, 2021). pSVV therefore aligns regulatory evaluation with the mechanisms through which digital interventions often deliver benefit.

The current BfArM guidance gives nine examples of what a positive healthcare effect in the form of pSVV may be (Federal Institute for Drugs and Medical Devices (BfArM), 2023):

- coordination of treatment procedures
- alignment of treatment with guidelines and recognized standards

-
- adherence
 - facilitating access to care
 - patient safety
 - health literacy
 - patient autonomy
 - coping with illness-related difficulties in everyday life
 - reduction of therapy-related efforts and strains for patients and their relatives

These domains specify which forms of improvement are considered patient-relevant, but they do not prescribe specific endpoints or measurement instruments; these must be justified and empirically demonstrated (Federal Institute for Drugs and Medical Devices (BfArM), 2023).

To obtain permanent listing, manufacturers must provide evidence that the observed improvement is attributable to the application, is relevant from the patient perspective, and is observable under routine conditions (Federal Institute for Drugs and Medical Devices (BfArM), 2023). This places methodological demands on endpoint selection, study design, and measurement strategy, particularly in relation to patient-reported outcomes, adherence metrics, and care process indicators (Gerke et al., 2020; Schlieter et al., 2023). The regulatory logic of pSVV therefore directly intersects with questions of how value is defined and made evidencable in digital health.

This thesis does not intend to evaluate whether pSVV is successfully implemented, nor does it assess the clinical effectiveness of individual DiGA. Rather, it examines how pSVV is interpreted and used in practice within the DiGA Fast-Track, how stakeholders understand its meaning, and which structural and methodological conditions influence whether and how this value category is taken up. This is investigated empirically in the second and third publications of this thesis.

1.6. Evidence generation for mHealth

Evaluating the effectiveness of mHealth applications presents distinct methodological and regulatory challenges. Software-based health interventions evolve iteratively, are personalized in their use, and depend on sustained engagement in everyday environments. These characteristics can complicate the use of traditional randomized controlled trials (RCTs), which were designed to evaluate stable interventions delivered in controlled settings (Byambasuren et al., 2018; Gilbert et al., 2023b; Maaß et al., 2023; Pham et al., 2016). Additionally, blinding and the development of suitable digital control conditions are often difficult to achieve, and sham or placebo app designs remain an emerging methodological area requiring further investigation (Bos et al., 2023).

In parallel, mHealth applications routinely generate real-world (RWD), defined as routinely collected, longitudinal health data from everyday clinical or user interactions (U.S. Food & Drug Administration, 2018), such as symptom entries, behavioral logs, usage patterns, or sensor-derived measurements. Such data can, under appropriate conditions, contribute to real-world evidence (RWE), defined as “the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD” (U.S. Food & Drug Administration, 2018), supporting assessments of benefit, safety, and performance in everyday practice (Han Wong et al., 2022; Mathias et al., 2024; Stern et al., 2022)

However, the value of RWE depends on how it is generated and analyzed. Key considerations include whether measures are validated, whether data collection is embedded into routine use rather than introduced solely for research purposes, and whether study designs enable causal interpretation rather than descriptive observation (OCEBM Table of Evidence Working Group et al., 2011; Silberman et al., 2023; U.S. Food & Drug Administration, 2019). Frameworks in several health systems, including Germany, France, the United Kingdom, and the United States, increasingly acknowledge the potential role of ongoing data collection to support decision-making across the lifecycle of digital health technologies (Federal Institute for Drugs and Medical Devices (BfArM), 2019; Unsworth et al., 2021; U.S. Food & Drug Administration, 2018). As discussed in Section 1.4, the German DiGA Fast-Track reflects this approach by opening evaluation possibilities beyond traditional randomized controlled trial designs, by allowing data generation during the provisional listing period, and by introducing mechanisms for ongoing outcome monitoring such as the Anwendungsbegleitende Erfolgsmessung (AbEM).

Paper 4 in this thesis examines this issue by systematically reviewing how real-world data is currently used to evaluate the effectiveness of patient-facing mHealth applications in scientific research. The review provides conceptual grounding for understanding the methodological and practical considerations involved in generating evidence for digital health technologies intended for routine care.

1.7. Rationale and Research Objectives

This thesis is motivated by the increasing institutionalization of digital health within healthcare systems and the recognition that regulatory frameworks do not only constrain innovation but also shape the conditions under which it emerges. The German DiGA Fast-Track provides a particularly relevant setting in this regard. As one of the earliest fully implemented reimbursement pathways for Software as a Medical Device, it offers a structured mechanism for market entry and evaluation and therefore creates observable

dynamics in this digital health innovation system. Studying this pathway enables examination of how regulatory design influences market composition, how value is defined and made assessable, and how evidence practices evolve in response to regulatory requirements.

While the DiGA Fast-Track has been widely discussed as a novel reimbursement mechanism for digital therapeutics, less is known about how its regulatory architecture operates in practice. It remains unclear how the DiGA market has developed since its introduction, how emerging value categories such as patient-relevant structural and procedural improvements (pSVV) are interpreted and operationalized by stakeholders, and how evolving evidence practices are applied in the evaluation of digital interventions. Addressing these questions is essential for understanding how regulatory frameworks shape innovation processes in digital health systems.

At the same time, digital health technologies operate in everyday environments and evolve iteratively, which raises methodological questions that extend beyond the DiGA context. In particular, the increasing role of real-world data in evaluating digital interventions requires consideration of how evidence is generated outside of controlled trial settings and how such evidence is interpreted in practice. While the first two research questions therefore examine the DiGA Fast-Track as a case of regulated digital health market formation, the third research question adopts a broader perspective on patient-facing mHealth to understand current approaches to real-world data use and the methodological challenges associated with it.

Accordingly, the thesis is guided by three research questions:

- (1) How has the DiGA market evolved over time with respect to market structure, value frameworks, evidence strategies, and regulatory pathway dynamics under the Fast-Track system?
- (2) How are value categories for demonstrating positive healthcare effects interpreted and negotiated among stakeholders within the DiGA pathway, and which structural, institutional, and methodological conditions influence the use of innovative forms of value, patient-relevant structural and procedural improvements (pSVV)?
- (3) How is real-world data currently used to evaluate the effectiveness of mHealth applications, and what constraints and opportunities shape its role in evidence generation?

The research questions are addressed in sequential analytical progression (Figure 4). The first question provides a descriptive assessment of the development of the DiGA market

and the observable outcomes of the regulatory framework since its introduction. This analysis identifies empirical patterns in the use of value categories and evidence practices within the DiGA pathway. Building on this empirical overview, the second research question examines how value innovation is interpreted and applied by actors within the regulatory system. The third research question then broadens the analytical perspective by examining the methodological landscape of evidence innovation beyond the DiGA context, focusing on the use of real-world data in mHealth evaluation.

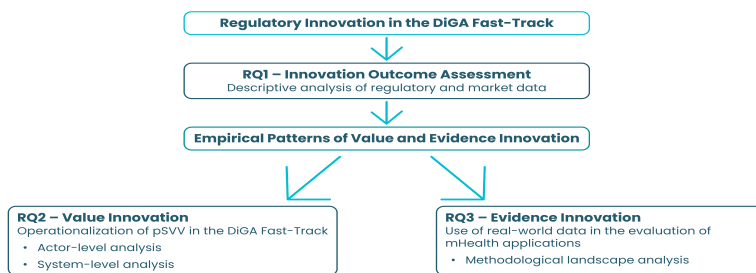


Figure 4 - Analytical progression of the dissertation. The dissertation begins with a descriptive assessment of innovation outcomes within the DiGA pathway (RQ1). Building on this empirical overview, the subsequent research questions examine two key dimensions of regulatory innovation: value innovation through the operationalization of patient-relevant structural and procedural improvements (pSVV) (RQ2) and evidence innovation through the use of real-world data in mHealth evaluation (RQ3).

Taken together, the research aims to contribute to understanding how regulatory frameworks shape digital health innovation, how value is made evidentially legible, and how real-world data practices evolve in the context of software-based health interventions. In particular, the study interrogates the broader policy question: To what extent does the digital health market evolve because of regulation -enabled and structured by the design of the DiGA Fast-Track- or despite regulation, requiring actors to adapt to, work around, or compensate for regulatory constraints?

The following chapter outlines the methodological approaches used to address each research question.

2. Methodology

This cumulative dissertation is based on a multi-method research design that combines descriptive analyses of regulatory and market data, qualitative interviews with key stakeholders, a functional–structural innovation system analysis and a systematic scoping review of scientific literature (Figure 5). This methodological pluralism reflects the complexity of regulatory innovation in digital health and was chosen to capture the phenomenon from complementary perspectives: empirical adoption patterns, stakeholder experiences, systemic performance factors and methodological landscapes of evidence generation.

At the empirical foundation, descriptive analyses of publicly available secondary data were conducted. These included structured extractions from the DiGA directory, annual reports of statutory health insurance funds, app store ratings, and clinical trial registries. The analyses focused on applications, approvals, withdrawals, pricing dynamics, and the types of evidence submitted to regulatory authorities. By synthesizing these heterogeneous data sources at consistent reference points, the descriptive strand provided a comprehensive overview of the uptake and evidence practices within the DiGA framework.

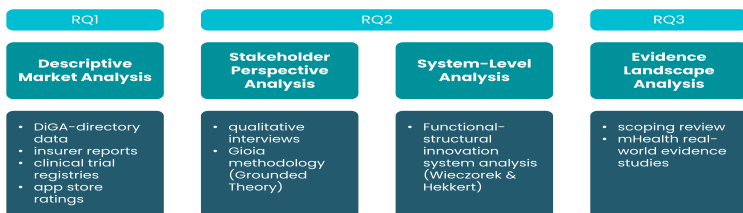


Figure 5 - Multi-method research design of the dissertation. The study combines four complementary analytical approaches. Descriptive analysis of regulatory and market data provides an empirical overview of the DiGA ecosystem. Qualitative interviews capture stakeholder interpretations of value categories within the regulatory process. Innovation system analysis contextualizes these findings at the system level. A scoping review maps the methodological landscape of real-world evidence in mHealth research.

To explore the perspectives of stakeholders directly involved in digital health regulation, a qualitative study was undertaken. Semi-structured interviews were conducted with decision-makers from DiGA manufacturers, consultancies, and institutions linked to the approval process. The study followed principles of Grounded Theory (Strauss and Corbin,

1998) and applied the Gioia methodology (Gioia et al., 2013), allowing inductive theory-building from first-order concepts to second-order themes and aggregate dimensions. Data collection and analysis were reported in line with the COREQ-32 checklist (Tong et al., 2007), ensuring transparency and rigor. Reliability was strengthened by consensus-building within the research team and triangulation with expert discussions. This qualitative component illuminated the interpretive frames, perceived barriers, and logics of action that shaped regulatory adoption.

The findings were integrated into a systemic perspective through a functional–structural innovation system analysis (Wieczorek and Hekkert, 2012). Drawing on established frameworks in innovation studies, empirical data were mapped against core system functions and structural elements. This allowed the identification of systemic problems as well as the derivation of strategic performance factors relevant to digital health regulation. By embedding empirical insights in a broader theoretical lens, this approach enabled a conceptual generalization of the dissertation’s findings beyond the German case.

Complementing the empirical perspectives, a scoping review (Peters et al., 2020) was conducted to map the methodological landscape of evidence generation for patient-facing mHealth applications. The review adhered to the PRISMA-ScR guideline (Tricco et al., 2018), with a protocol registered prospectively, and applied a comprehensive multi-database search strategy. Studies were included if they evaluated app effectiveness using naturally occurring real-world data generated during routine app use. Screening and extraction were performed by two reviewers using a structured framework, and the synthesis was descriptive, classifying study designs, data sources, and outcomes in relation to international evidence hierarchies (OCEBM Table of Evidence Working Group et al., 2011; Swift et al., 2018; Unsworth et al., 2021) and regulatory guidance. This review positioned the dissertation within the global methodological debate on real-world evidence for digital health.

Taken together, the methodological design ensures robustness through triangulation across diverse data sources and analytic strategies. Transparency and rigor were supported by adherence to established reporting standards such as PRISMA-ScR and COREQ. Ethical standards were met by obtaining informed consent from interviewees.

In sum, the dissertation combines descriptive, qualitative, systemic and systematic methods to generate a multi-layered understanding of regulation as a driver of innovation in digital health. This integrated approach ensures that the findings are empirically grounded, theoretically informed, and of practical relevance for both policymakers and stakeholders in digital health innovation.

3. Publications

This cumulative dissertation consists of four peer-reviewed publications that address the research questions from complementary analytical perspectives. Together, the papers examine the development of the DiGA market, the interpretation and operationalization of value categories within the regulatory framework, and the methodological use of real-world data in mHealth evaluation. Table 1 provides an overview of the included publications, their authorship and publication outlets. Each publication aims to address a specific aspect of the dissertation's research questions, as indicated by its title and analytical focus.

Table 1 - Overview of the included publications.

No	Title	Authors	Journal	DOI	Pages
1	Digital Health Applications (DiGAs) on a Fast Track: Insights From a Data-Driven Analysis of Prescribable Digital Therapeutics in Germany From 2020 to Mid-2024	Moritz Goeldner, Sara Gehder	Journal of Medical Internet Research (JMIR)	10.2196/59013	16
2	Structural benefits on prescription? Exploring potentials and challenges of the pSVV concept in the approval process of digital health applications in Germany	Sara Gehder, Moritz Goeldner	Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen (ZEFQ)	10.1016/j.zefq.2024.11.003	10
3	Unpacking Performance Factors of Innovation Systems and Studying Germany's Attempt to Foster the Role of the Patient Through a Market Access Pathway for	Sara Gehder, Moritz Goeldner	Journal of Medical Internet Research (JMIR)	10.2196/66356	18

	Digital Health Applications (DiGAs): Exploratory Mixed Methods Study				
4	A Scoping Review on Using Real-World Data to Evaluate the Effectiveness of mHealth Applications	Sara Gehder, Stefanie Brückner, Stephen Gilbert, Moritz Goeldner	npj Digital Medicine	10.1038/s41746-026-02562-0	12

3.1. Author Contributions

A detailed description of the author's contributions is provided separately in each paper. Sara Gehder is the single first author of Publication 2 and 3 and shares the first authorship in publication 4. She developed or co-developed the concepts of the manuscripts with Moritz Goeldner, conducted the research and wrote the initial draft of the manuscripts. Sara Gehder additionally handled the submission process and acted as corresponding author for publications 3 and 4.

- 3.2. Publication 1 - Digital Health Applications (DiGAs) on a Fast Track: Insights From a Data-Driven Analysis of Prescribable Digital Therapeutics in Germany From 2020 to Mid-2024

[Original Paper](#)

Digital Health Applications (DiGAs) on a Fast Track: Insights From a Data-Driven Analysis of Prescribable Digital Therapeutics in Germany From 2020 to Mid-2024

Moritz Goeldner, Prof Dr; Sara Gehder, MSc

Working Group for Data-Driven Innovation, Hamburg University of Technology, Hamburg, Germany

Corresponding Author:

Moritz Goeldner, Prof Dr

Working Group for Data-Driven Innovation

Hamburg University of Technology

Am Schwarzenberg-Campus 4

Hamburg, 21073

Germany

Phone: 49 40428784777

Email: moritz.goeldner@tuhh.de

Abstract

Background: This study aimed to analyze the rapidly evolving ecosystem of digital health applications (*Digitale Gesundheitsanwendung*; DiGAs) in Germany, spurred by the 2019 Digital Healthcare Act. With over 73 million people in Germany now having access to DiGAs, these prescribable digital health apps and web-based applications represent a substantial stride in health care modernization, supporting both patients and health care providers with digital solutions for disease management and care improvement.

Objective: Through a data-driven approach, this research aimed to unpack the complexities of DiGA market dynamics, economic factors, and clinical evidence, offering insights into their impact over the past years.

Methods: The analysis draws from a range of public data sources, including the DiGA directory, statutory health insurance reports, app store feedback, and clinical study results.

Results: As of July 1, 2024, there are 56 DiGAs listed by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte), divided into 35 permanently and 21 preliminarily listed applications. Our findings reveal that a majority of DiGAs extend beyond the intended 1-year period to achieve permanent listing, reflecting the extensive effort required to demonstrate clinical efficacy. Economic analysis uncovered a dynamic pricing landscape, with initial prices ranging from approximately €200 to €700 (€1=US \$1.07), averaging at a median of €514 for a 3-month DiGA prescription. Following negotiations or arbitration board decisions, prices typically see a 50% reduction, settling at a median of €221. Prescription data offer valuable insights into DiGA acceptance, with total prescriptions jumping from around 41,000 in the first period to 209,000 in the latest reporting period. The analysis of the top 15 DiGAs, representing 82% of the total prescriptions, shows that these best-performing apps receive from a minimum of 8 to a maximum of 77 daily prescriptions, with native apps and early market entrants achieving higher rates. Clinical evidence from all 35 permanently listed DiGAs indicates a uniform preference for randomized controlled trials to validate primary end points, with no noteworthy use of alternative study designs encouraged in the Digital Healthcare Act and related regulations. Moreover, all evaluated DiGAs focused on medical benefits, with health status improvement as a key end point, suggesting an underuse of patient-relevant structural and procedural improvement in demonstrating health care impact.

Conclusions: This study highlights the growth and challenges within the DiGA sector, suggesting areas for future research, such as the exploration of new study designs and the potential impact of patient-relevant structural and procedural improvements. For DiGA manufacturers, the strategic advantage of early market entry is emphasized. Overall, this paper underscores the evolving landscape of digital health, advocating for a nuanced understanding of digital health technology integration in Germany and beyond.

(*J Med Internet Res* 2024;26:e59013) doi: [10.2196/59013](https://doi.org/10.2196/59013)

KEYWORDS

digital health application; DiGA; data-driven analysis; clinical evidence; health economics; positive care effect; medical benefit; patient-relevant structural and procedural improvements; pSVV; digital health care act

Introduction

Background

While Germany continues to navigate the complex challenges of digital transformation within its health care system, the reimbursement of digital medical devices by statutory health insurance represents a pivotal milestone in this journey. The 2019 Digital Healthcare Act (Digitale-Versorgung-Gesetz) marks a substantial legislative milestone, incorporating digital health applications (German: *Digitale Gesundheitsanwendung*; DiGA) into the benefits catalog of statutory health insurance in Germany [1-4]. Since September 2020, the first DiGAs have been officially listed in the DiGA directory of the Federal Institute for Drugs and Medical Devices (German: Bundesinstitut für Arzneimittel und Medizinprodukte; BfArM), thereby becoming accessible to more than 73 million individuals in Germany. DiGAs are digital medical devices of risk classes I and IIa, or IIb (a recent regulatory update—the Digital Law—has made class IIb medical devices eligible for DiGA listing, albeit imposing more stringent criteria for demonstrating evidence and proving the positive care effect) that are primarily based on digital technologies and aim at assisting both insured individuals and health care professionals by enhancing the detection, monitoring, treatment, or alleviation of diseases, as well as the identification of, treatment of, alleviation of, or compensation for injuries or disabilities. DiGAs listed in the DiGA directory may be prescribed by physicians and psychotherapists or directly provided by the statutory health insurances under certain requirements [5,6].

Compared with existing approval procedures in health care, the legislator has integrated 3 regulatory innovations. First, a 12-month trial phase allows DiGA manufacturers to initially introduce their DiGA to the market on a provisional basis and subsequently provide the final proof of effectiveness [6]. During this phase, the price for using the DiGA can be set by the manufacturer within defined maximum limits. Second, the approval was designed as a fast-track-procedure, meaning the BfArM's review of the application takes a maximum of 3 months. Third, the concept of "therapeutic benefit," crucial in drug approval, has been expanded to the more comprehensive concept of a "positive care effect" (German: *Positiver Versorgungseffekt*; pVE). This can be demonstrated either by proving a "medical benefit" (German: *medizinischer Nutzen*), that is, an improvement in health status or enhancement of quality of life, or a "patient-relevant structural and procedural improvement" (German: *patientenrelevante Struktur- und Verfahrensverbesserung*; pSVV) focusing on optimizing the interaction between patients and health care providers as well as supporting the patient [6-8]. To prove the positive care effect, each DiGA requires conducting a clinical trial within Germany. In addition, a preliminary study demonstrating the DiGA's basic features is required before preliminary listing as well.

After almost 4 years into the implementation of the DiGA framework, we seek to investigate the evolving landscape of the DiGA market. Other European countries, such as France and Belgium, are adopting comparable approaches for digital medical device reimbursement [9,10], though they have not reached the same scale yet. Thus, our primary aim was to unpack the dynamics that have shaped this market in Germany, quantifying the economic aspects of DiGAs, and identifying the characteristics of successful DiGA implementations based on the data available. Moreover, this study aimed to provide a comprehensive understanding of the clinical evidence surrounding DiGA that has been generated and was assessed by BfArM.

Objectives

To achieve these objectives, we adopt a data-driven approach, leveraging publicly available data sets to craft a coherent and detailed picture of the DiGA ecosystem. This methodology allows us to explore various facets of the DiGA landscape, from market trends and economic impact to clinical effectiveness and regulatory outcomes. Through this analysis, we aimed to uncover insights into the factors that contribute to the success of DiGA, the challenges they face in the market, and the broader implications for health care professionals, policy makers, and patients within the (digital) health care system.

Methods

To provide a comprehensive analysis of the DiGA ecosystem in Germany, our study leveraged publicly available data sources. The following data sources were obtained during the analysis.

DiGA Directory Data

Access to this data was facilitated via the DiGA application programming interface provided by BfArM, enabling up-to-date insights into the range and characteristics of each individual DiGA ever listed. The data were accessed using a custom-developed script using the cloud-based integrated development environment Replit.

Annual Reports of Statutory Health Insurance Funds

We analyzed 3 annual reports on DiGAs from the National Association of Statutory Health Insurance Funds (German: GKV-SV), which provided valuable information on the adoption rates and prescription trends for DiGAs [11-13]. It is important to consider that this data set does not include privately insured patients who use DiGAs, potentially underrepresenting total use. In Germany, about 10% of the population is privately insured [14].

App Store Ratings

To gauge user reception and satisfaction, we accessed app rating data from the Apple App Store (Apple, Inc) [15-17]. This was achieved through an application programming interface and a custom-developed Google Sheets (Alphabet, Inc) script, allowing for the automated collection of ratings data. Similarly,

app ratings from the Google Play Store were manually accessed to complement the data gathered from the Apple App Store, ensuring a comprehensive view of user feedback across major mobile platforms [18].

Accessing Clinical Studies

We conducted manual searches for all studies pertaining to permanently listed DiGAs that were identified as relevant for the “assessment decision by the BfArM” according to the DiGA directory. These studies were registered either in the German Clinical Trials Register, ClinicalTrials.gov (maintained by the National Library of Medicine at the National Institutes of Health), or the International Standard Randomised Controlled Trial Number registry (maintained by BioMed Central, part of Springer Nature). In addition, respective publications, study reports and protocols for each study were reviewed to assess the clinical evidence base supporting the use of these DiGAs. Our analysis encompassed a thorough review of study designs, measuring instruments, and dropout rates, analyzing the ratio of observation duration, sample size, and the length of the trial phase, and comparing age and gender of the participants with demographic data.

To ensure a uniform perspective across the collected data, our analysis specifically used information from the DiGA directory as of July 1, 2024. This approach provided us with a comprehensive data set encompassing 3 full years, in addition to approximately 3 months and a few days, since the first DiGA was introduced in late September 2020 and 6 months in 2024. It is important to note, however, that the data from the GKV-SV, particularly concerning the number of prescriptions, were segmented into 3 terms, with each term spanning from October to September of the following year. This discrepancy in the data collection periods has been carefully addressed in our analysis to ensure clarity and accuracy in our findings.

All data were consolidated into a single database. Basic calculations were performed using SPSS Statistics (version 29; IBM, Corp), and visualizations were created with flourish.studio (Canva UK Operations Ltd) and ThinkCell (think-cell Software GmbH). Given the nascent state of the DiGA market and the limited number of apps available, our study did not use statistical analysis. The market’s current size does not support such an approach; however, this is anticipated to change as the market matures. Consequently, our results are primarily descriptive, offering insights into the present landscape of DiGAs, their use, user feedback, and the clinical evidence supporting their efficacy and utility.

Ethical Considerations

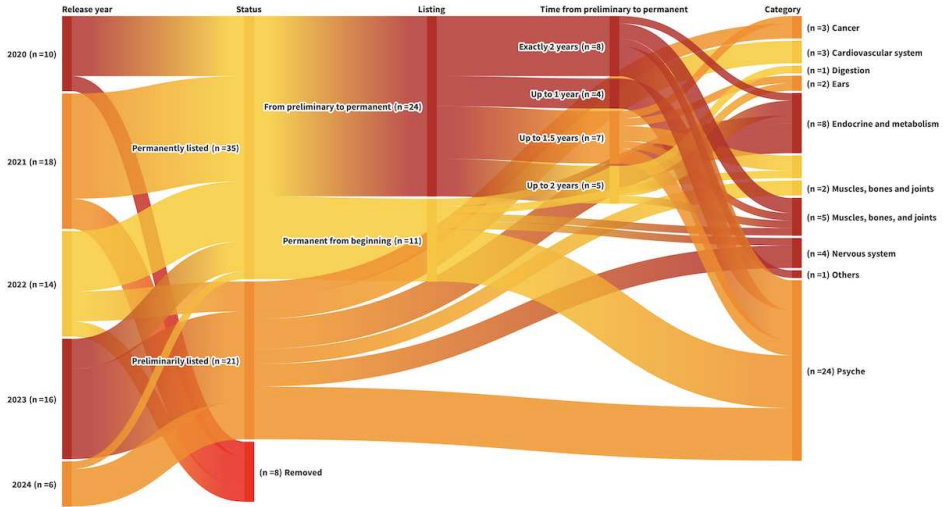
Ethics approval does not apply to this study, as we evaluated publicly available, deidentified data on DiGA prescriptions [11-13] and did not involve any human participants during data collection.

Results

Descriptive Data on DiGAs

As of July 1, 2024, a total of 64 DiGAs have been approved by the BfArM. Currently, 35 DiGAs are permanently listed, 21 are preliminarily listed (still required to submit clinical evidence for permanent listing), and 8 DiGAs have been removed from the directory. Among the 35 permanently listed DiGAs, 11 (31%) were initially approved for permanent listing, whereas 24 (69%) initially received preliminary approval and were later granted permanent listing. While the regulator allows up to 1 year for this process, an extension to 2 years is permissible (Figure 1).

Figure 1. Overview of digital health application (Digitale Gesundheitsanwendung; DiGA) categories and preliminary or permanent listings. Only 1 therapeutic category is indicated for each DiGA.



Our analysis indicated that most DiGAs necessitate considerably longer than 1 year to complete this transition, with one-third precisely requiring 2 years (including the period for BfArM to assess the submitted data). Moving forward, we have excluded the 8 removed DiGAs from all subsequent analyses, concentrating on the 56 DiGAs that remained accessible.

The therapeutic areas for DiGAs span 12 categories as defined by the BfArM, with the largest being the *psyche* category. This category includes 26 DiGAs designed to address various psychological conditions, predominantly through cognitive behavioral therapy. The *endocrine and metabolism* category follows with 8 DiGAs. The *muscles, bones, and joints* category is represented by 7 DiGAs, and *nervous system* with 4 DiGAs (notably, 5 DiGAs are linked to 2 categories each, resulting in a total of 61 categorizations).

The new concept of positive care effect is the pivotal point in the assessment of clinical evidence for DiGA. Despite the regulator introducing a new framework, the pSVV, its uptake remained modest. Among the 56 DiGAs, 55 (98%) had a medical benefit as primary end point, while only 1 (2%) DiGA (ProHerz, ProCurement GmbH) had a pSVV as primary end point. In addition, 10 (18%) DiGAs with a medical benefit as primary end point incorporated pSVV as an additional end point in their studies.

To qualify for DiGA listing, a product must be certified as a medical device. Among the 56 DiGAs, 32 (57%) were still recognized under the Medical Device Directive (MDD) as class I medical devices—a regulation that officially expired in May 2021, with a current transition period in effect. The remaining 24 (43%) DiGAs complied with the Medical Device Regulation (MDR), the updated European standardized regulation where the assessment process for digital medical devices has changed (refer to rule 11 of MDR), resulting in a more rigorous review of their risk classes [19]. Within this group, 21 (87%) were classified as class I medical devices, and 3 (13%) were class IIa medical devices, which necessitate certification from a notified body for approval. Until July 2024, no class IIb medical device was certified as a DiGA, because applications for DiGAs in this risk class only became possible after the new regulation took effect at the end of March 2024. While MDR certification certainly enhances the safety of (digital) medical devices by requiring premarket testing and continuous postmarket surveillance of medical devices, it also represents a significant financial and time-consuming burden, particularly when it comes to class IIa or IIb medical devices because notified bodies are a veritable bottleneck within this process [19,20]. Variations were observed in relation to the federal states hosting the headquarters of DiGA manufacturers. From Hamburg, 20 DiGAs (from 8 manufacturers) emerge, with an approximately equal distribution between MDR (11 DiGAs) and MDD (9 DiGAs) classifications. In Berlin, 11 DiGAs (from 6 manufacturers) fall

exclusively under the category of MDD-regulated medical devices, with only 1 DiGA listed in 2024 being classified under the MDR. Such disparities are not evident in other federal states. While we found no reason for this discrepancy in our data, we assumed that the state authorities in the city-states of Berlin and Hamburg have different approaches to accepting class I MDR medical devices under rule 11 of MDR.

DiGAs are mandated to use digital technologies, which means they are not restricted to app formats alone. However, our observations show that 27 DiGAs, originating from 24 manufacturers, were available as native apps (unlike web applications, native apps are developed for a specific platform, such as the Apple App Store or the Google Play Store) in both the Apple App Store and Google Play Store. In addition, 10 DiGAs, from 6 manufacturers, provided access through both app and web application formats, whereas 19 DiGAs, from 7 manufacturers, were exclusively accessible via websites.

Analysis of Initial and Final Prices

During the first year following the initial listing, whether preliminary or permanent, DiGA manufacturers have considerable freedom in setting prices, subject to certain criteria based on the demonstrated positive care effect (medical benefit, pSVV, or both), the *International Classification of Diseases, Tenth Edition (ICD-10)* category, and the pricing of existing DiGAs within that category [2,21]. Upon final listing—or after 12 months for DiGAs already permanently listed—price negotiations with the GKV-SV commence, with 3 meetings planned to reach an agreement. Should these negotiations fail, an arbitration board is engaged to reach a definitive decision. Thus, not all permanently listed DiGAs have an established final price yet. As of July 1, 2024, among the 35 permanently listed DiGAs in our data set, 30 (86%) had received their final pricing. These final prices were markedly less than the initial prices, spanning from 29% to 93% of the initial price, averaging at 50% of the initial amount.

DiGA manufacturers also have the option to adjust (ie, increase) the price once within the first year, although this occurs infrequently and was not further considered in our data set. In addition, our analysis did not account for varying prices between the initial and subsequent prescriptions, as this pricing strategy is seldom implemented.

Typically, a DiGA is prescribed for 3 months of use. To date, only 1 preliminary listed DiGA, levidex, offered a lifetime license at a substantially higher cost of €2077.40 (€1=US \$1.07). This DiGA will be excluded from the following analysis. The prices for the rest of the DiGAs were effective for a period of 3 months and ranged from approximately €200 to €700, with a median price of €535.49. One can observe that the initial pricing has trended upward over time (Figure 2). The median was €487 in the first year, increased to €567 in 2022, and adjusted to €547 in 2024 (Table 1).

Figure 2. Initial prices of digital health applications (Digitale Gesundheitsanwendung [DiGA]; n=55) plotted per year of initial listing. One preliminary listed DiGA (levidex) with a lifetime license was excluded.

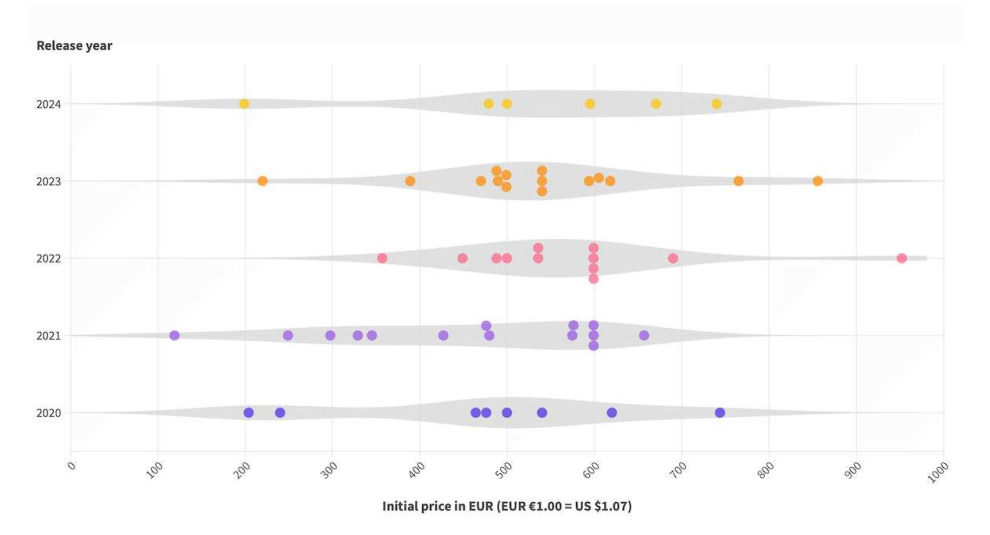


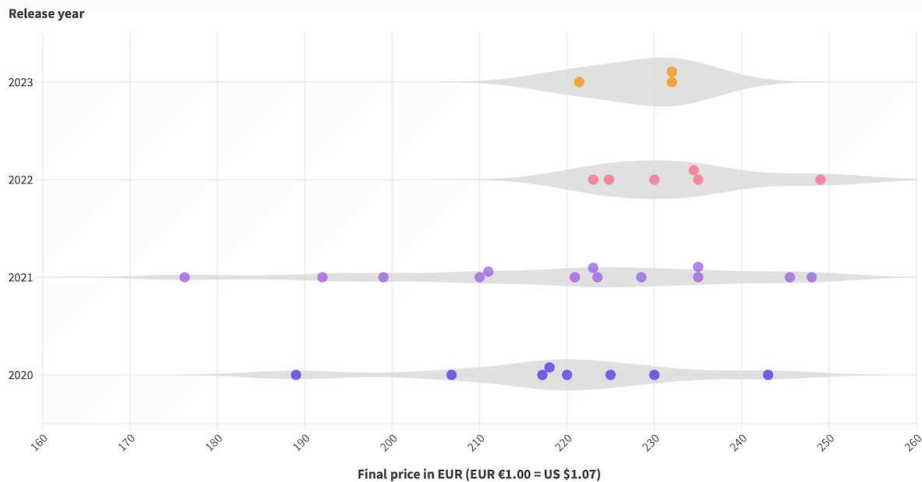
Table 1. Initial and final prices of digital health applications (DiGAs) per release year. One preliminary listed DiGA (levidex) with a lifetime license was excluded.

Release year	Price (€ ^a), mean (SD)	Price (€), median (IQR)
Initial prices		
2020 (n=8)	473 (180)	488 (296-600)
2021 (n=14)	452 (162)	478 (321-599)
2022 (n=12)	575 (147)	567 (491-599)
2023 (n=15)	541 (147)	540 (488-605)
2024 (n=6)	531 (190)	547 (409-688)
All years (n=55)	514 (162)	535 (464-599)
Final prices		
2020 (n=8)	219 (16)	219 (209-229)
2021 (n=13)	219 (21)	223 (204-235)
2022 (n=6)	233 (9)	232 (224-238)
2023 (n=3)	228 (6)	232 (221-232)
All years (n=30)	221 (17)	224 (216-235)

^a€1=US \$1.07.

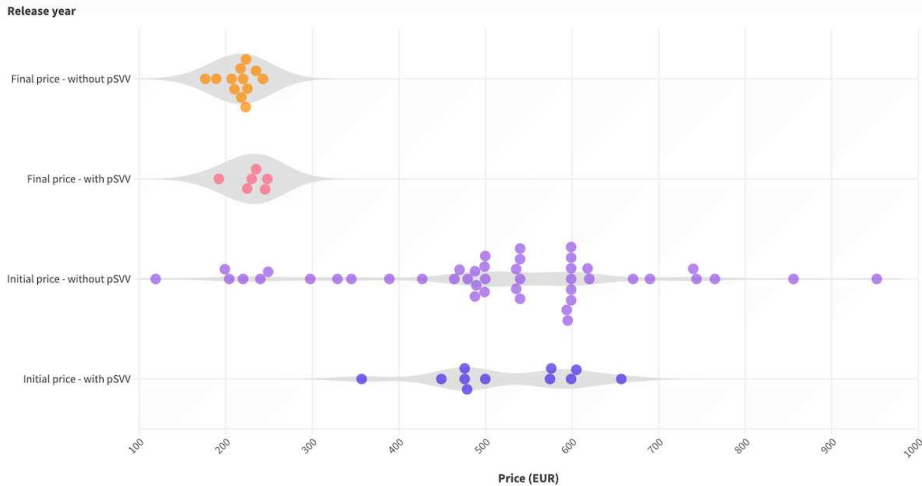
Similarly, the prices negotiated or determined by the arbitration board have seen a gradual rise, moving from a median of €219 for DiGAs initially listed in 2020 to a median of €232 for those listed in 2023 for the first time (refer to [Figure 3](#) for an overview). However, the data reveal low variance from the mean values of final prices.

Figure 3. Final prices of digital health applications (Digitale Gesundheitsanwendung [DiGA]; n=30) plotted per year of initial listing.



In our subsequent analysis, we investigate whether the chosen positive care effect (ie, medical benefit or pSVV) impacts pricing. Initial prices showed a statistically insignificant difference (we used a Mann-Whitney *U* test as the data is not normally distributed; $P=.69$) in median values: €518 (IQR €398–€599) for DiGAs without pSVV compared with €479 (IQR €449–€576) for DiGAs with pSVV (Figure 4).

Figure 4. Initial prices of digital health applications (Digitale Gesundheitsanwendung [DiGA]; n=55) and final prices (n=30) with and without patient-relevant structural and procedural improvements (Patientenrelevante Struktur- und Verfahrensverbesserungen; pSVV).



For the final prices, this insignificant difference was reversed; the median was €223 (IQR €212–€232) for DiGAs without pSVV and €232 (IQR €217–€246) for those that include a pSVV.

Analysis of Prescriptions

Although prescription numbers for DiGAs likely offer some of the most compelling insights, these data are not publicly available for all DiGAs. The only official figures are annually published by the GKV-SV, which releases rounded prescription

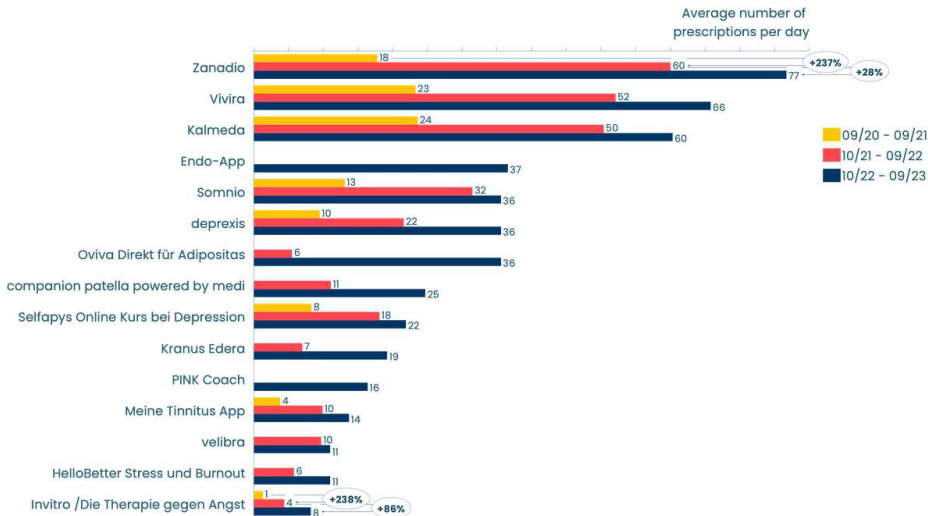
numbers. The total number of prescriptions was approximately 41,000 in the first reporting period (September 2020–September 2021), increased to 124,000 in the subsequent period (October 2021–September 2022), and reached 209,000 prescriptions in the latest period (October 2022–September 2023). Altogether, exactly 374,377 DiGA prescriptions were recorded from the initial availability of the first DiGA in late September 2020 until September 30, 2023. This total number also includes prescriptions of now delisted DiGAs.

However, although data on individual DiGA prescriptions were accessible for all DiGAs exceeding 100 total prescriptions in the first reporting period, this criterion tightened in later periods. In the subsequent period, only DiGAs with over 1000 total prescriptions throughout their life span were featured. The threshold was further elevated in the most recent report to include solely DiGAs with more than 5000 prescriptions over their life span. By the end of September 2023, 15 DiGAs surpassed the threshold of 5000 prescriptions over their lifetime. Hence, our subsequent analyses focused exclusively on these top 15 DiGAs. When available, data from 2021 and 2022 were also incorporated. To ensure consistency and comparability, we

calculated the average daily prescriptions for these 15 DiGAs by taking the number of days listed in the directory from the first listing to the end of the reporting period of the GKV-SV at the end of the third quarter of 2023.

Within the top 15 DiGAs, we observed considerable variability in prescriptions, ranging from 77 per day for zanadio (Sidekick Health Germany GmbH) to 8 per day for Invirtro (Sympatient GmbH). Among these top 15, 8 (53%) DiGAs were released in the first 12 months following the DiGA directory’s launch, 6 (40%) during the second period, and only 1 (7%) DiGA (Endo-App, Endo Health GmbH) during the latest reporting period by the GKV-SV. The average year-on-year growth for these apps across their individual first 2 reporting period was approximately 270%. However, between the second and third reporting periods, the growth rate for these apps decreased to 140% (Figure 5). For example, the growth rate for zanadio was 237% between the first two periods and 28% between the second two periods. Similarly, the growth rates for Invirtro were 238% and 86%, respectively (Figure 5). In total, 308,000 prescriptions were made for these top 15 DiGAs, a substantial share (82%) of the total 374,377 prescriptions.

Figure 5. Average daily prescriptions per digital health application (Digitale Gesundheitsanwendung [DiGA]; n=15).



DiGAs are mandated to use digital technologies, which means they are not restricted to app formats alone. However, our observations showed that 27 DiGAs, originating from 24 manufacturers, were available as native apps in both the Apple App Store and Google Play Store. In addition, 10 DiGAs from 6 manufacturers provided access through both app and web-app formats, whereas 19 DiGAs from 7 manufacturers were exclusively accessible via websites. Within the top 15 DiGAs, it is notable that 9 DiGAs available solely as apps accounted for 210,000 prescriptions. In contrast, 2 DiGAs offering both app and web application formats garnered 46,000 prescriptions,

and 4 DiGAs accessible only through web applications achieved 52,000 prescriptions.

While DiGA prescriptions are commonly associated with those issued by medical doctors or psychotherapists, there is an alternative pathway for patients to receive a DiGA directly from their statutory health insurance. Typically, health insurance providers may request proof that the patient has the condition targeted by the DiGA, though this is not an official requirement. In exploring the ratio of DiGAs distributed by health insurances versus total prescriptions, there are notable differences between the different DiGAs. Notably, Endo-App and Kranus Edera (Kranus Health GmbH), both categorized under *genitals*,

kidneys, and urinary tract, lead health insurance distributions at 40% and 28%, respectively, followed by Oviva Direkt (Oviva AG) at 23%. Conversely, at the spectrum's lower end, Vivira (ViViRA Health Lab GmbH) and Companion Patella (medi

GmbH), focusing on muscles, bones, and joints, each saw only 5% of their distributions through statutory health insurance (Table 2).

Table 2. Digital health application (DiGA) prescriptions based on GKV-SV reporting [11-13].

DiGA name	Prescriptions from September 2020 to September 2021 (n=28,172), n (%)	Prescriptions from October 2021 to September 2022 (n=135,331), n (%)	Prescriptions from October 2022 to September 2023 (n=239,046), n (%)	Authorization by statutory health insurance (%)
Zanadio	6100 (21.65)	21,900 (16.18)	28,000 (11.71)	11
Vivira	8000 (28.4)	19,000 (14.04)	24,000 (10.04)	5
Kalmeda	8600 (30.53)	18,400 (13.6)	22,000 (9.2)	8
Deprexis	2100 (7.45)	7900 (5.84)	13,000 (5.44)	8
Endo-App	— ^a	—	13,000 (5.44)	40
Oviva Direkt	—	2000 (1.48)	13,000 (5.44)	23
Somnio	4500 (15.97)	11,500 (8.5)	13,000 (5.44)	11
Companion Patella	—	4000 (2.96)	9000 (3.76)	5
Selfapys Depression	2400 (8.52)	6600 (4.88)	8000 (3.35)	11
Kranus Edera	—	2000 (1.48)	7000 (2.93)	28
PINK Coach	—	—	6000 (2.51)	13
velibra	1400 (4.97)	3600 (2.66)	5000 (2.09)	8
HelloBetter Stress und Burnout	—	2000 (1.48)	4000 (1.67)	13
Meine Tinnitus App	—	2000 (1.48)	4000 (1.67)	6
Invitro	400 (1.42)	1600 (1.18)	3000 (1.18)	10

^aNot available.

Finally, we also wanted to take into account the user's reviews in the app stores as well as the information if the DiGA was the first within its *ICD-10* category on the market. Therefore, we can only consider the 11 (73%) out of the top 15 DiGAs that are listed as a native smartphone app in the 2 major app stores. App store reviews were collected from both, Apple App Store and Google Play Store and combined, taking the average review (on a 5-star scale) and the number of reviews into account. Again, we used average prescriptions per day to have better comparability.

Unsurprisingly, it was observed that apps with a higher number of prescriptions tended to garner more reviews. Regarding the quality reflected in a 5-star rating system, Vivira, Oviva Direkt, somnio (mementor DE GmbH), and zanadio stood out with the highest reviews, scoring 4.6, 4.5, 4.5, and 4.4, respectively (Figure 6). On the lower spectrum, Kalmeda (3.3; Pohl-Boskamp

Digital Health GmbH) and Selfapy (3.4; Selfapy GmbH; Selfapy provides a single app encompassing all their DiGAs, meaning reviews cannot be uniquely attributed to the app Selfapy Depression alone) were notable.

In addition, we observed that DiGAs received more average prescriptions per day when they were first to the market than when they were second in various categories (Figure 7). This pattern was evident with zanadio leading ahead of Oviva Direkt, Kalmeda outpacing Meine Tinnitus App (BAYOOCARE GmbH), and—on a lower level—velibra (GAIA AG) ahead of Invitro. Only Deprexis (GAIA AG) performed slightly better than Selfapy Depression in terms of prescriptions, but both apps were—similar to velibra and Invitro—released only 2 months apart. While many factors might have contributed to this trend, the first-to-market advantage is worth noting, particularly if there is a long period between being first and second to market.

Figure 6. Average app reviews in app stores (x-axis) and daily prescriptions of digital health applications (Digitale Gesundheitsanwendung [DiGA]; y-axis) among the top 15 that are available as native apps. The size of the bubbles indicates the number of app reviews.

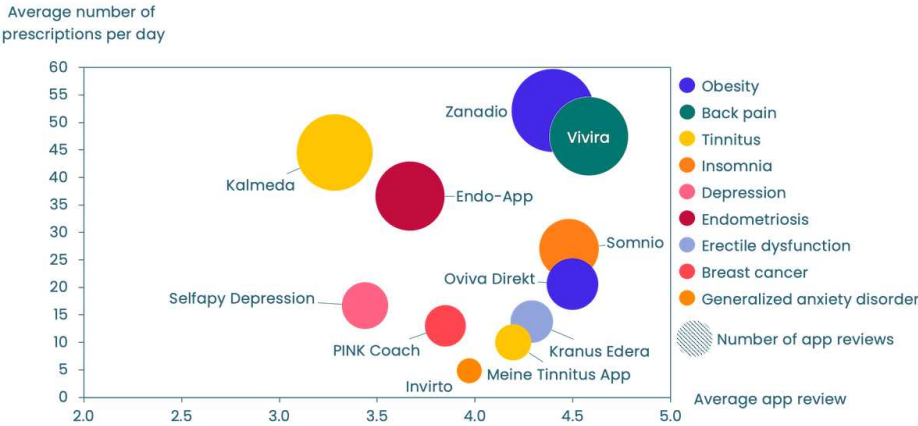
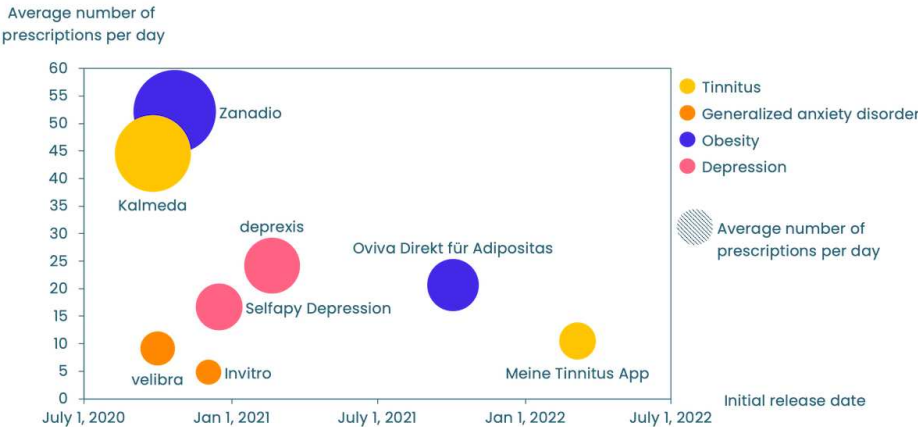


Figure 7. Average prescriptions per day (y-axis) and launch date (x-axis). The bubble size is proportionate to the average number of prescriptions per day.



Analysis of Clinical Trial Data

To demonstrate a pVE for permanent listing of a DiGA, manufacturers must conduct a clinical trial in Germany that shows one or more end points related to the positive care effect. In this section, we analyzed all permanently listed DiGAs in our sample (refer to [Multimedia Appendix 1](#) for an overview).

Among the 35 DiGAs analyzed, all have proven at least 1 medical benefit, with each opting for *improvement of the state of health* as primary end point. Notably, 23 (66%) of these 35 DiGAs demonstrated this single positive care effect exclusively. Three more DiGAs demonstrated both, *improvement of the state of health* and *improvement in quality of life*. The remaining 9 DiGAs used pSVV as an additional end point in their studies.

In total, 5 DiGAs have evidenced a pSVV along with *improvement of the state of health*, covering aspects such as *health competence*, *reduction of therapy-related efforts and burdens on patients and their relatives*, *alignment of treatment with guidelines and recognized standards*, and *patient sovereignty*. Furthermore, 3 more DiGAs were able to show 2 medical benefits along with a pSVV (with all 3 opting for *patient sovereignty*), and finally, 1 DiGA demonstrated 2 medical benefits in conjunction with 2 additional pSVV (ie, *health competence* and *coping with illness-related difficulties in everyday life*).

Following the permanent listing of a DiGA, manufacturers are required to make available to the public, within 1 year, the study results demonstrating the pVE of the DiGA. As of July 2024, for all 35 permanently listed DiGAs in our data set, at least 1

registered clinical trial was mentioned in the “assessment decision of BfArM” of the DiGA directory. Furthermore, 1 of these 35 DiGAs (Deprexis) cited 2 clinical trials—hence, the subsequent analyses refer to a total of 36 registered trials.

All 36 trials were registered as randomized controlled trials. The study type was registered as interventional across all 36 studies. In 35 (97%) of the studies, the allocation of participants to either the control group or the intervention group was conducted through “parallel distribution,” while 1 (3%) study used a “factorial” design. Furthermore, 15 (42%) studies used masking, 19 (53%) explicitly did not, and 2 (6%) studies did not clarify their use of masking. Where implemented, masking usually concealed the group affiliation (ie, control or intervention) from either the outcome assessors, the statisticians, or both. Exceptionally, 1 study kept patients unaware of their group membership.

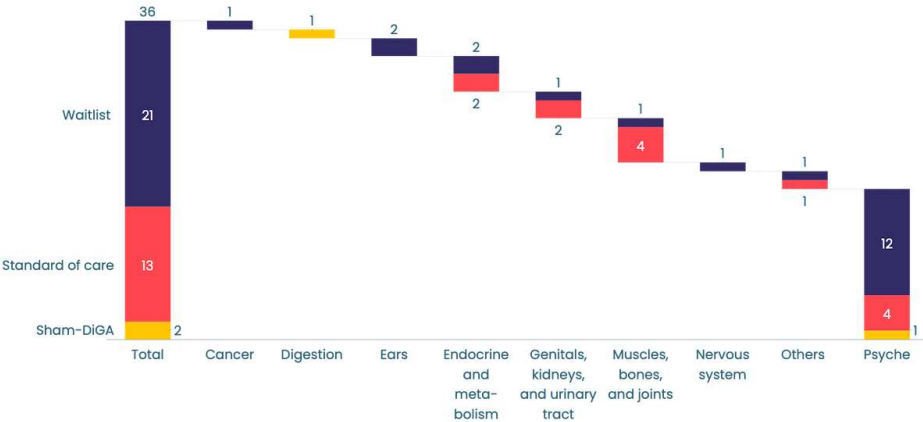
In the 36 conducted trials, 22 different primary end points (such as *depression symptoms*, *tinnitus exposure*, or *pain intensity*) were used. To evidence these primary end points, 29 different measurement instruments (mostly patient-reported outcome measures, but also measures such as weight or HbA_{1C}) were used. Furthermore, 6 end points were used by >1 DiGA

manufacturer—*depression symptoms*, *anxiety symptoms*, *pain intensity*, *body weight*, *reduction of disease-specific symptom severity*, and *tinnitus burden*.

Yet, these primary end points were measured differently by DiGA manufacturers—only within the end points *depression symptoms* and *tinnitus burden*, 2 psychometric tests for measuring the severity of depression (Beck Depression Inventory and Patient Health Questionnaire) and a Tinnitus Questionnaire (Mini-TF-12) were used 2 or 3 times, respectively. Thus, most DiGA manufacturers opted for different measures for the primary end point, even if the same end point has been previously assessed by another DiGA. For secondary end points, we see a variety of measures that were used across DiGA manufacturers.

In total, 22 (61%) of the 36 studies used a waitlist control group, while 12 (33%) studies used *standard of care* as the control. Two DiGAs implemented control groups using apps with reduced functionality (sham DiGAs), featuring versions of the actual DiGA that provided only medically useful tips or survey instruments. There was no obvious pattern linking the design of these control groups with the indication area of the DiGA (Figure 8).

Figure 8. Control groups in clinical studies (n=36) per disease category. Two digital health applications (Digitale Gesundheitsanwendung; DiGAs) are associated with 2 disease categories. In this figure, both are located within the muscle, bones, and joints category; the second category was psyche (waitlist) and injuries (standard of care).



In total, 30 (86%) out of the 35 permanently listed DiGAs recommend a use duration of 3 months. Furthermore, 20 (57%) of these DiGAs correspondingly used an observation period of 3 months in their studies, 5 (14%) of them used a shorter observation period, and 5 (14%) used a longer one. In addition, 2 (6%) DiGAs suggested a use duration exceeding 3 months; 1 (3%) mirrored this with a longer study period, whereas the other did not. Two DiGAs advised a shorter use duration than 3 months and aligned their study duration accordingly.

The description of the study design varied widely among the 36 trials reviewed. A total of 13 (37%) DiGAs included detailed information with a link to a scientific publication in the study

registry. Furthermore, 8 (23%) DiGAs provided a study report within the registry and 3 (9%) DiGAs published their study protocol. In addition, for 2 (6%) DiGAs, links to scientific publications were available in the DiGA directory.

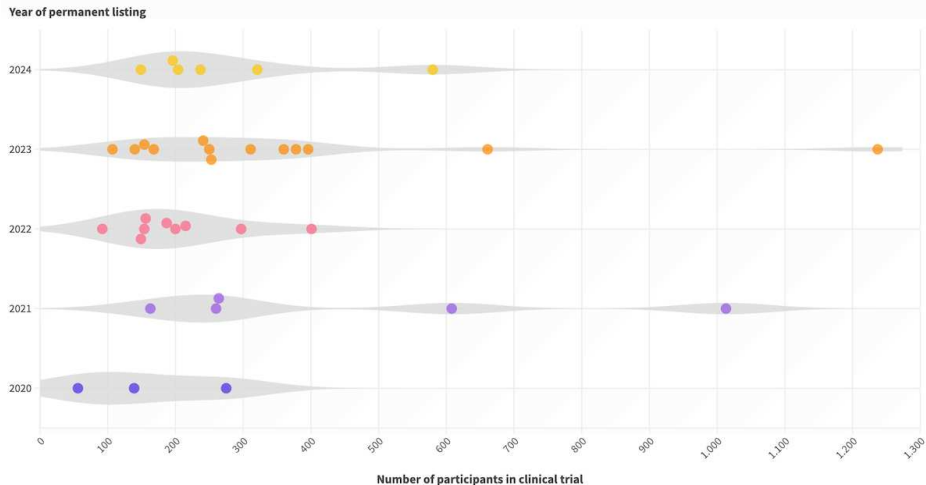
For all 36 studies, the sample size information was provided, ranging from as low as 56 participants to as high as 1237, with the median being 239 participants. There has been a noticeable increase in sample size over the years: DiGAs that were permanently listed within the first 3 months in 2020 had a median of 139 (IQR 56-139) participants (combining both intervention and control groups), which rose to a median of 264 (IQR 211-810) participants in 2021, decreased slightly to 187

(IQR 151-256) in 2022, and then increased again to 253 (IQR 161-387) in 2023 and 220 (IQR 184-386) in 2024 (Figure 9).

Data on the duration of the clinical study were accessible for 30 trials, spanning from 4 months at the minimum to 54 months at the maximum, with a median duration of 17.5 months. Data on the dropout rate were available for 27 of the studies, indicating a median dropout rate of 17.5% among participants.

Gender distribution was reported in 22 studies, revealing that approximately 63% of all study participants for which the gender was reported were female, 37% male, and less than 1% identified as diverse. The average age of participants, provided in 15 studies, had a median of 41.3 years. In comparison, the 2024 annual report of GKV-SV presented a gender distribution of 71% female and 29% male among actual DiGA users, with an average user age of 54 years.

Figure 9. Year of permanent digital health application (Digitale Gesundheitsanwendung; DiGA) listing versus sample size in clinical trials (n=36).



Discussion

Principal Findings and Comparison With Prior Work

In summary, our results paint a picture of the emerging DiGA ecosystem in Germany. Through a data-driven examination, this paper uncovered the complexities and challenges in market dynamics, pricing strategies, prescription trends, and clinical evidence, offering valuable implications for researchers, DiGA manufacturers, regulatory bodies and health care professionals.

As of July 1, 2024, BfArM has approved 64 DiGAs, with 35 being permanently listed, 21 being preliminarily listed, and 8 that were subsequently removed from the directory. This study's analysis, focusing on the 56 currently listed DiGAs, highlights the challenges in transitioning from preliminary to permanent listing. While 75% (24/32) of the DiGAs that were initially preliminarily listed eventually achieved permanent listing, they often exceeded the 1-year timeline provided for this transition, with a third requiring exactly 2 years to complete the process. Although we do not have a rationale for this long timeframe in our data set, we anticipate that the process of evidence generation for digital medical devices is lengthy and that finding more appropriate methodologies for this purpose will require more academic attention in the future [4,6,22,23]. Our analysis reveals a wide therapeutic application of DiGAs across 12 categories, with psychological conditions being the most

addressed, followed by endocrine and metabolic disorders. Despite the introduction of the positive care effect concept to encompass both medical benefits and patient-relevant structural and procedural improvements, the adoption of pSVV remains limited. Our economic analysis shows a steady year-on-year increase in both the initial and final prices of newly listed DiGAs. The appropriateness of these prices remains a topic of ongoing debate [24]. Looking ahead, the introduction of performance-based pricing models is anticipated to address these concerns by aligning costs more closely with the value and effectiveness of DiGAs [2,4].

Prescription analysis reveals a substantial, yet not overwhelming increase in DiGA use, attributed to both the introduction of new DiGAs to the market and the growth of existing DiGAs. Overall, the 15 most successful account for approximately 82% of total prescriptions. The year-on-year growth rate for DiGA prescriptions among the top 15 has shown a decline. Being first to market appears to be a critical factor for achieving substantial sales, although other elements, such as product quality, perceptions of health care professionals on DiGA [25,26], and the extent of sales efforts, obviously play vital roles but could not be analyzed in this study. While the current analysis has not yielded statistically significant results, the expanding market and the anticipated increase in the number of DiGAs suggest that statistically significant findings are likely to emerge in the near future.

The validity of study designs specifically for DiGAs remains a hotly debated topic [27]. The uniformity in choosing randomized controlled trials over alternative study designs for the primary clinical end point underscores an area ripe for exploration. Researchers are encouraged to investigate the impact of new study designs on the validation of digital health technologies [28,29], also with respect to continuous data evaluation [2]. Clinical trials for permanently listed DiGAs uniformly focused on medical benefits as positive care effect, with a universal emphasis on the *improvement of the state of health*. Thus, clinical trials for DiGAs so far adhere closely to the established methodologies common in the pharmaceutical sector. In the analysis of clinical studies, it was noted that the type and extent of data points made available to the public vary considerably. For example, although the gender ratio of study participants must be submitted to the BfArM for assessment, only 22 (61%) out of the 36 studies have made this information available to the public. In terms of advancing methodologies specifically for DiGAs, it would be beneficial to mandate the comprehensive publication of data points to be able to report relevant trends.

The modest uptake of pSVV as a novel regulatory concept highlights a gap in the market [30]. This calls for further research into the barriers to adoption and the potential of pSVV to broaden the scope of valued outcomes in digital health, potentially enhancing the effectiveness and patient-centeredness of DiGAs [7,31,32]. The hesitancy to adopt this new concept is also a reminder for regulatory bodies that regulatory innovation also requires accompanying measures during the introduction period.

With a median duration of 17.5 months for clinical trials, it logically follows that the initially targeted timeframe of 1 year from preliminary to permanent listing is not achievable for most manufacturers. However, our data also show that the fast-track procedure and preliminary listing of DiGA are a way of mitigating some of the challenges associated with randomized controlled trials [22,24,33]. Remarkably, 75% (24/32) of the DiGAs successfully transitioned from provisional to permanent listing. Furthermore, while more DiGAs will come to the market in the following years, this provides a fertile ground for analyzing DiGA's therapeutic and economic impact together using a holistic model [34].

This paper not only sheds light on the current state of DiGA in Germany, but also signals areas for future investigation and strategic adjustment. By highlighting the need for diversified clinical study designs, a deeper exploration into regulatory innovations, such as pSVV and their adoptions, and holistic economic analysis, it offers a road map for enhancing the integration, effectiveness, and acceptance of digital health technologies within the German health care system and beyond.

Implications for DiGA Manufacturers and Health Care Professionals

While causality cannot be definitively established, our findings suggest that DiGAs available as native apps generally see higher prescription numbers. Intriguingly, DiGA manufacturers with a larger portfolio in the market often offer web applications only, which tend to be less successful than those provided by manufacturers specializing on one or a few native apps. Having

this in mind, DiGA manufacturers should consider developing native apps from the beginning. In addition, examining the implications of being first to market within specific *ICD-10* categories offers a unique lens through which to assess competitive advantage and market penetration strategies for digital health solutions. Considering that only 15 DiGAs have reached a milestone of 5000 prescriptions over their lifetime, it is crucial for DiGA manufacturers to recognize that listing in the DiGA directory does not guarantee automatic prescription success.

For health care professionals, it is essential to understand that DiGAs are subject to clinical trials akin to those required for pharmaceuticals. Moreover, the transition from preliminary to permanent listing fails for only a small number of DiGAs, highlighting the stringent evaluation process by the BfArM even at the initial listing stage. Despite public and media concerns about the potential risks associated with preliminarily listed DiGAs, our findings do not support the notion that these CE-certified, preliminarily listed DiGAs fail to deliver on their promised benefits. In addition, our findings indicate relatively positive user feedback on DiGAs, aligning with the extant research [17].

Limitations and Further Research

The insights from this study are constrained by the limited public availability of detailed prescription data beyond the top 15 DiGAs and the variability in reporting standards across DiGA clinical trials. Obviously, individuals outside the statutory health insurance system and even those outside of Germany can purchase DiGAs privately. However, due to the absence of publicly accessible data on these transactions, we were unable to incorporate this information into our analysis.

Further health economics analyses, such as correlating prescription data with the actual number of affected individuals in Germany, would be valuable as well. However, conducting these comprehensive calculations requires a larger and more robust data set with respect to prescriptions. Similarly, due to the limited number of DiGAs currently available, statistically robust calculations were not feasible at this stage. As the market continues to expand, it is anticipated that such analyses will become possible in the future. Finally, we did not assess the quality and robustness of the clinical studies in our sample [7,35] as our goal was to map rather than clinically assess the emerging DiGA ecosystem.

Furthermore, we acknowledge that the presented findings do not address all discussions and criticisms that are being debated within the German statutory health care system. For instance, it is not possible, on the basis of currently available public data, to scientifically comment on the economic impact of DiGAs on various stakeholders and doubts regarding the actual uptake and adherence to DiGAs after prescription [11-13,36-38]. We anticipate that the introduction of performance-based pricing components from 2026 onward, aimed at measuring use, patient satisfaction, and patient health outcomes, may provide usable data for future research in this area. In addition, the integration of economic aspects into the approval and pricing process of DiGAs, like the benefit assessment for pharmaceuticals [39], could be considered in this context.

Conclusions

As part of the 25th anniversary issue of the *Journal of Medical Internet Research*, this paper explores the thrilling early years of DiGAs in Germany, which marked an important stage in the digital transformation of health care. While DiGAs have not yet accelerated on a fast track to widespread adoption, their incremental positive influence on health care professionals and patients hints at a promising future. With their modest current uptake, there is a clear call for intensified efforts to boost their use in the coming years, ensuring that the best of digital health in Germany, Europe, and beyond is yet to be realized. The limited adoption of pSVV and the present monotony in clinical trial design are prominent areas for further research and potential regulatory attention.

It is encouraging to see that legislators have already adapted the DiGA fast-track procedure twice so far in 2024 (Digital Law) and in 2021 (Digital Modernization of Care and Nursing Act [German: *Digitale-Versorgung - und - Pflege - Modernisierungs - Gesetz*]) and has thus gradually adapted it

in the spirit of agile legislation. Particularly noteworthy are the extended periods for permanent listing, the permission to also approve class IIb medical devices, and the fact that a path to performance-based pricing components has been introduced [4]. It is anticipated that further changes will be forthcoming, and this is a highly respectable approach that better reflects the reality of *digital* medical devices.

Enhancing transparency in DiGA use data and promoting methodological variety in clinical trials are crucial steps toward leveraging the full potential of digital health technologies for patient care. The insights provided by this study not only enrich our understanding of the DiGA landscape, but also underscore the necessity for continuous evaluation and adaptation within this fast-evolving sector. As DiGAs slowly start to make a positive impact, it is evident that the journey toward identifying and establishing study designs for digital health applications, which are broadly accepted across the market, is far from completion. The advancement of scientific dialogue is pivotal, serving as a crucial element in securing acceptance by both market participants and regulatory bodies.

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Conflicts of Interest

MG, having previously worked as a consultant for DiGA manufacturers, declares that his past consultancy roles had no bearing on the findings of this research. SG, currently employed by a statutory health insurance company in Germany, also declares that her professional engagement with the insurance company did not influence the content or outcomes of this manuscript.

Multimedia Appendix 1

Overview of clinical trials of all permanently listed digital health applications (Digitale Gesundheitsanwendung; DiGAs) as of July 1, 2024.

[PDF File (Adobe PDF File), 36 KB-Multimedia Appendix 1]

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Abbreviations

BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)
DiGA: Digitale Gesundheitsanwendung (digital health application)
GKV-SV: National Association of Statutory Health Insurance Funds
ICD-10: International Classification of Diseases, Tenth Edition
MDD: Medical Device Directive
MDR: Medical Device Regulation
PHQ-9: Patient Health Questionnaire
pSVV: patientenrelevante Struktur- und Verfahrensverbesserung (patient-relevant improvement of structure and processes)
pVE: Positiver Versorgungseffekt (positive care effect)

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- 3.3. Publication 2 - Struktur- und Verfahrensverbesserungen auf Rezept? Eine qualitative Analyse der Potenziale und Herausforderungen des pSVV-Konzepts bei Digitalen Gesundheitsanwendungen (DiGA)



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Struktur- und Verfahrensverbesserungen auf Rezept? Eine qualitative Analyse der Potenziale und Herausforderungen des pSVV-Konzepts bei Digitalen Gesundheitsanwendungen (DiGA)



Structural benefits on prescription? Exploring potentials and challenges of the pSVV concept in the approval process of digital health applications in Germany

Sara Gehder, Moritz Goeldner*

Arbeitsgruppe Data-Driven Innovation, Technische Universität Hamburg (TUHH), Hamburg, Deutschland

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ZUSAMMENFASSUNG

Hintergrund: Mit dem Inkrafttreten des Digitale-Versorgung-Gesetzes (DVG) Ende 2019 wurden in Deutschland Digitale Gesundheitsanwendungen (DiGA) in den Leistungskatalog der gesetzlichen Krankenversicherung (GKV) aufgenommen. DiGA sind digitale Medizinprodukte, deren Hauptfunktionen wesentlich auf digitalen Technologien beruhen. Im Rahmen der Definition des Zulassungsprozesses wurde der in der Arzneimittelzulassung zur Nutzenbewertung maßgebliche Begriff des „therapeutischen Nutzens“ zum umfassenderen Konzept des „positiven Versorgungseffekts“ (pVE) erweitert. Konkret wurde ergänzend zum „medizinischen Nutzen“ das Konzept der „patientenrelevanten Struktur- und Verfahrensverbesserungen“ (pSVV) entwickelt, um den Markteintritt von Anwendungen zu ermöglichen, die die Rolle von Patient*innen in der Gesundheitsversorgung gezielt stärken. Dreieinhalb Jahre nach der Einführung von DiGA zeichnet sich jedoch ab, dass das Konzept des pSVV heute noch nicht von den Akteur*innen im Gesundheitssystem akzeptiert wurde. Lediglich eine der 56 zum 1. Juli 2024 gelisteten DiGA nutzt heute pSVV als primären Endpunkt, zehn weitere DiGA nutzen pSVV als sekundären Endpunkt.

Methode: Ein qualitativer Ansatz wurde gewählt, um die neuen und wenig erforschten Themen DiGA und insbesondere pSVV zu untersuchen. Dabei wurde die Grounded-Theory-Methode in Kombination mit der Gioia-Methode angewendet, die sich besonders für die Analyse innovativer Themengebiete eignet. Durch die induktive Herangehensweise können so neue Konzepte aus den Daten der Untersuchungsteilnehmer*innen entwickelt werden, wodurch eine flexible und dynamische Theoriebildung unterstützt wird. Es wurden Entscheidungsträger*innen aus den Gruppen DiGA-Herstellende mit und ohne pSVV, Herstellende digitaler Medizinprodukte ohne DiGA-Zulassung, Beratungen sowie am Prozess der DiGA-Zulassung beteiligte Institutionen mithilfe der Durchführung qualitativer Leitfadeninterviews in die Untersuchung einbezogen. Die Auswertung erfolgte durch eine mehrstufige Analyse, die zur Identifikation von Erstordnungskonzepten, Zweitordnungsthemen und aggregierten Dimensionen führte. Die entwickelte Datenstruktur wurde durch die Darstellung relevanter Zitate im [Anhang A](#) untermauert.

Ergebnisse: Es zeigt sich, dass eine Schärfung der Nutzendefinition der im DiGA-Leitfaden definierten pSVV-Kategorien erfolgskritisch für die Etablierung des Konzepts der pSVV ist. Auch eine weitere Analyse der möglichen Methoden zum Nachweis des pSVV und geeigneter Messinstrumente sowie die generelle Aufnahme ökonomischer Betrachtungen in die Nutzenanalyse erscheinen sinnvoll.

Diskussion: Die qualitative Analyse zeigt, dass die Schärfung des pSVV-Konzepts und die Definition geeigneter Messmethoden entscheidend für die erfolgreiche Implementierung im deutschen Gesundheitssystem sind. Eine ökonomische Bewertung könnte die Debatte um die Kosten von DiGA versachlichen und zur Transparenz im Zulassungsprozess beitragen. Weitere Forschung und die

* Korrespondenzadresse: Prof. Dr. Moritz Goeldner, Arbeitsgruppe Data-Driven Innovation, Technische Universität Hamburg (TUHH), Am Schwarzenberg-Campus 4, 21073 Hamburg, Deutschland.

E-Mail: moritz.goeldner@tuhh.de (M. Goeldner).

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Einbindung zentraler Akteure sind notwendig, um die Definition des intendierten Nutzens innerhalb der pSVV-Kategorien zu präzisieren und damit die Einführung digitaler Gesundheitsanwendungen mit besonderem Fokus auf die Stärkung der Rolle der Patient*innen in der Gesundheitsversorgung zu fördern.

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ABSTRACT

Background: With the introduction of the Digital Healthcare Act (DVG) at the end of 2019, digital health applications (DiGA) were included in the statutory health insurance in Germany. DiGA are digital medical products whose primary function is based on digital technologies. In the definition of the approval process, the term “therapeutic benefit”, which is crucial to the evaluation of pharmaceuticals, was expanded to include the broader concept of “positive healthcare effect” (“pVE”). In particular, the concept of “patient-relevant structural and procedural improvements” (pSVV) has been introduced alongside the well-known “medical benefit” to facilitate market access for applications that specifically aim to strengthen the role of the patient in healthcare. Three and a half years after the implementation of DiGA, it has become evident that the concept of pSVV has not yet been adopted in the healthcare system to the extent intended by the legislation. As of July 1st 2024, only one of the 56 listed DiGA uses pSVV as a primary endpoint, with ten others using pSVV as a secondary endpoint.

Method: A qualitative approach was chosen to explore the new and under-researched topic of DiGA and, in particular, pSVV. The Grounded Theory method was applied in combination with the Gioia method, which is particularly suitable for analyzing innovative subject areas. The inductive approach allows for new concepts to be developed from the data of the study participants, thus supporting flexible and dynamic theory building. Decision-makers from groups including DiGA manufacturers with and without pSVV, manufacturers of digital medical products without DiGA approval, consultancies, and institutions involved in the DiGA approval process were included in the study by conducting semi-structured interviews. The evaluation was conducted through a multi-step analysis leading to the identification of first-order concepts, second-order themes, and aggregated dimensions. The developed data structure was supported by the presentation of relevant quotes as part of the *Anhang A*.

Results: The analysis indicates that refining the benefit definition for the pSVV categories defined in the DiGA guidelines is critical to the successful establishment of the pSVV concept. Additionally, further analysis of potential methods for demonstrating pSVV, suitable measurement tools, and the general inclusion of economic considerations in the benefit analysis appear sensible.

Discussion: The qualitative analysis demonstrates that refining the pSVV concept and defining appropriate measurement methods are essential for a successful implementation in the German healthcare system. An economic evaluation could bring objectivity to the debate on DiGA costs and contribute to transparency in the approval process. Further research and the involvement of key stakeholders are necessary to clarify the intended benefits within the pSVV categories, thereby promoting the introduction of digital health applications with a particular focus on empowering patients in healthcare.

Einleitung

Mit dem Inkrafttreten des Digitale-Versorgung-Gesetz (DVG) Ende 2019 wurden in Deutschland Digitale Gesundheitsanwendungen (DiGA) in den Leistungskatalog der gesetzlichen Krankenversicherung (GKV) aufgenommen. Seit Oktober 2020 sind die ersten DiGA im DiGA-Verzeichnis des Bundesinstituts für Arzneimittel und Medizinprodukte (BfArM) gelistet und stehen damit allen Versicherten in der GKV zur Verfügung. DiGA sind digitale Medizinprodukte der Risikoklassen I, IIa oder IIb¹, deren Hauptfunktionen wesentlich auf digitalen Technologien beruhen.

Der Zulassungsprozess für DiGA wird durch das BfArM begleitet und dort durchgeführt. Im Vergleich zu bestehenden Zulassungsverfahren wurden im DVG mehrere regulatorische Innovationen integriert. Eine davon ist die Erweiterung des in der Arzneimittelzulassung maßgeblichen Begriffs des „therapeutischen Nutzens“ zum umfassenderen Konzept des „positiven Versorgungseffekts“ (pVE) [1]. Dieser kann entweder durch den Nachweis eines „medizinischen Nutzens“ (mN), zum Beispiel einer Verbesserung des Gesundheitszustands, oder durch eine „patientenrelevante Struktur- und Verfahrensverbesserung“ (pSVV) erbracht werden [2,3].

Die Einführung des Konzepts der pSVV soll berücksichtigen, dass DiGA im Vergleich zu traditionellen Arzneimitteln neue

Chancen bieten, um besonders die Versorgungsprozesse für Patient*innen zu verbessern. Im vom BfArM veröffentlichten DiGA-Leitfaden [4] für Herstellende, Leistungserbringende und Anwender*innen sind (nicht abschließend) neun Bereiche definiert, für die eine pSVV nachgewiesen werden kann: Die Koordination von Behandlungsabläufen, die Ausrichtung an Leitlinien und anerkannten Standards, die Verbesserung von Adhärenz, Patient*innensicherheit, Gesundheitskompetenz und Patient*innensouveränität, die Erleichterung des Zugangs zur Versorgung, die Reduktion therapiebedingter Belastungen sowie die Unterstützung bei der Bewältigung krankheitsbedingter Herausforderungen im Alltag. Per Definition des BfArM sollen DiGA, die einen pSVV als pVE nachweisen, die Rolle der Patient*innen stärken und in enger Verzahnung mit den Leistungserbringenden ihr Gesundheitshandeln unterstützen [4,5]. Die Nachweise für einen pVE in den Kategorien mN und pSVV sind gemäß gesetzlicher Regelung gleichermaßen zur Ermöglichung der Zulassung für die Erstattung innerhalb der Regelversorgung geeignet [2,4,6].

Bis zum 1. Juli 2024 wurden insgesamt 64 DiGA im nationalen DiGA-Verzeichnis aufgenommen, welches durch das BfArM gepflegt wird. 35 davon sind bereits dauerhaft aufgenommen, 21 vorläufig und acht wurden zwischenzeitlich wieder gestrichen [7]. Von den bis dahin 56 verfügbaren DiGA nutzen 11 DiGA

¹ Seit Inkrafttreten des DigiG am 26. März 2024 können auch Medizinprodukte der Klasse IIb als DiGA gelistet werden, diese müssen jedoch zwingend bereits zur Antragsstellung einen medizinischen Nutzen nachgewiesen haben. Eine Aufnahme zur Probe ist bei Medizinprodukten der Klasse IIb nicht mehr möglich.

pSVV als positiven Versorgungseffekt (Abbildung 1). Darunter befindet sich eine vorläufige gelistete DiGA mit pSVV als primärem Endpunkt, während die übrigen 10 DiGA pSVV als zusätzlichen Effekt zum mN verwenden [7,8].

Während die Zahl der Zulassungen insgesamt auf eine gelungene Einführung der DiGA in das GKV-System hindeutet [9], ist das Konzept des pSVV noch nicht in dem vom Gesetzgeber intendierten Maße im Gesundheitssystem angekommen [10–13]. Vorangegangene Studien unterstreichen die Notwendigkeit, den Schwerpunkt verstärkt auf DiGA zu legen, die diese Art des positiven Versorgungseffektes ansprechen [14], und bewerten das Konzept der pSVV als „eigentlich zentrales Wirkungsinstrument Digitaler Gesundheitsanwendungen“ [12].

Mit dem Digitale-Versorgungs- und -Pflege-Modernisierungsgesetz (DVPiMG) und dem Digital-Gesetz (DigiG) sind bereits mehrere Anpassungen im DiGA-Zulassungsprozess erfolgt. Dieser Beitrag zielt darauf ab, möglichen Anpassungsbedarf spezifisch für das Konzept der pSVV zu identifizieren. In dieser qualitativen Studie wurde anhand von Interviews mit Personen aus relevanten Interessengruppen des deutschen Gesundheitswesens ermittelt, welche hindernden und fördernden Faktoren derzeit bei der Berücksichtigung von pSVV bestehen. Die zentrale Forschungsfrage lautet daher: Welche Faktoren begünstigen oder hemmen die Implementierung von pSVV im Rahmen der Zulassung von DiGA und welche spezifischen Anforderungen und Erwartungen der relevanten Interessengruppen müssen erfüllt werden, um das Konzept der pSVV erfolgreich im Markt zu etablieren?

Methoden

Studiendesign

Da die Einführung von DiGA und das Konzept pSVV erst seit 2019 bestehen und bisher wenig erforscht wurden, wurde ein qualitativer Forschungsansatz gewählt. Diese Methode ermöglicht umfassende Einblicke in bisher wenig erforschte und komplexe Themen [15]. Zudem war die Anzahl relevanter Akteur*innen mit 35 DiGA-Herstellenden im Frühjahr 2023 begrenzt, wodurch qualitative Analysen die besten Möglichkeiten boten, tiefgehende Einblicke zu gewinnen. Die Anwendung der induktiven Grounded Theory Methode [16,17] in Kombination mit der Gioia-Methode [18,19] erlaubte eine objektive Untersuchung der Sichtweisen verschiedener Akteur*innen des Marktes auf das Konzept der pSVV. Das Studiendesign wurde nach COREQ-32 Checkliste dokumentiert [20]. Die Datenerhebung zu dieser Studie erstreckte sich über den Zeitraum von Mai bis November 2023.

Sampling und Rekrutierung

Es wurde angestrebt, Akteur*innen zu identifizieren, die einen direkten Einfluss darauf haben, welche digitalen Gesundheitsprodukte auf den Markt kommen und, falls dies im Rahmen des DiGA-Verfahrens geschieht, die damit verbundenen positiven Versorgungseffekte bestimmen. Die folgenden Einschlusskriterien wurden definiert:

- Organisationen, die direkt an der Ausgestaltung des DiGA-Verfahrens beteiligt sind, sei es durch Entwicklung, Sicherstellung oder Unterstützung der Implementierung oder durch aktive Nutzung.
- Innerhalb dieser Organisationen sollten Personen eingeschlossen werden, deren berufliche Rollen direkt die Entwicklung, Implementierung oder Nutzung des DiGA-Verfahrens umfassen.

- Zusätzlich sollten Personen einbezogen werden, die sich aktiv gegen die Nutzung des DiGA-Verfahrens entschieden haben, vorausgesetzt, sie haben sich intensiv mit dem Verfahren auseinandergesetzt und sind potenziell qualifiziert, es zu nutzen (z. B. Herstellende digitaler Gesundheitsangebote, die keine DiGA sind).

Es wurden Personen ausgeschlossen, die keinen direkten und aktiven Einfluss auf die Auswahl von Produkten, die auf den DiGA-Markt kommen, oder die Wahl des positiven Versorgungseffekts haben. Folglich führte das Ausschlusskriterium zur Ausgrenzung von Stakeholder-Gruppen im DiGA-Markt, wie DiGA-Nutzen, Verschreibenden und Forschenden im Feld, während die Einschlusskriterien zur Identifizierung der folgenden Stakeholder-Gruppen führten:

1. DiGA-Herstellende mit pSVV (DiGA mit pSVV): Diese Kategorie umfasst Entscheidungsträger*innen von Herstellenden digitaler Gesundheitsanwendungen, die im DiGA-Verzeichnis aufgeführt sind und pSVV als positiven Versorgungseffekt implementiert haben.
2. DiGA-Herstellende ohne pSVV (DiGA ohne pSVV): Beinhaltet Entscheidungsträger*innen von Herstellenden, die im DiGA-Verzeichnis aufgeführt sind, aber pSVV nicht als positiven Versorgungseffekt angewendet haben.
3. Herstellende digitaler Medizinprodukte (Nicht-DiGA): Diese Gruppe besteht aus Herstellenden, deren CE-zertifizierte digitale Gesundheitsangebote nicht oder noch nicht im DiGA-Verzeichnis gelistet sind.
4. Beratende: Bezieht sich auf Fachleute aus Beratungsfirmen, die sich auf die Unterstützung von Herstellenden beim Prozess der Aufnahme in das DiGA-Verzeichnis spezialisiert haben.
5. Prozessbeteiligte Institutionen: Diese Gruppe umfasst öffentliche Institutionen, die intensiv in die Entwicklung und Verwaltung des DiGA-Zulassungsprozesses und die Weiterentwicklung der Richtlinien (DVG, DiGAV, DiGA-Leitfaden) eingebunden sind.

Aufgrund der sehr kleinen Größe der Gruppen 1 und 5, jedoch ihrer signifikanten Relevanz für die Forschungsfragen, wurden alle Unternehmen in diesen Gruppen gemäß den Einschlusskriterien kontaktiert. Für die Gruppen 2–4 wurde aufgrund der Neuheit und der nischenhaften Natur des Themas das Schneeballverfahren [21] gewählt, um die höchstmögliche Teilnahmequote zu erreichen. Es wurden Personen ausgeschlossen, wenn bereits eine Person aus derselben Organisation an der Studie teilgenommen hatte, um Mehrfachantworten aus demselben Kontext zu vermeiden. Dieser kombinierte Ansatz führte zu einer positiven Rücklaufquote von 66% auf die Teilnahmeeinladungen.

Die Rekrutierung der Teilnehmenden begann mit initialen E-Mail-Kontakten, gefolgt von Empfehlungen bestehender Teilnehmenden im Einklang mit dem Schneeballverfahren. Es wurde darauf geachtet, eine vielfältige Repräsentation der identifizierten Gruppen sicherzustellen. Insgesamt wurden 29 Personen kontaktiert, von denen 19 ihre Teilnahme zusagten. Gründe für die Nichtteilnahme waren fehlende Rückmeldungen (n=9) und Zeitbeschränkungen (n=1).

Eine detaillierte Aufstellung der Interviewteilnehmenden und ihren organisatorischen Funktionen ist im [Anhang A](#), Tabelle 1 zu finden.

Entwicklung des Leitfadens und Durchführung der Interviews

Zur Entwicklung des Interviewleitfadens orientierten wir uns an der Gioia-Methode [18]. Zunächst führten wir zwei Vorgespräche mit Expert*innen aus einschlägigen Organisationen durch und

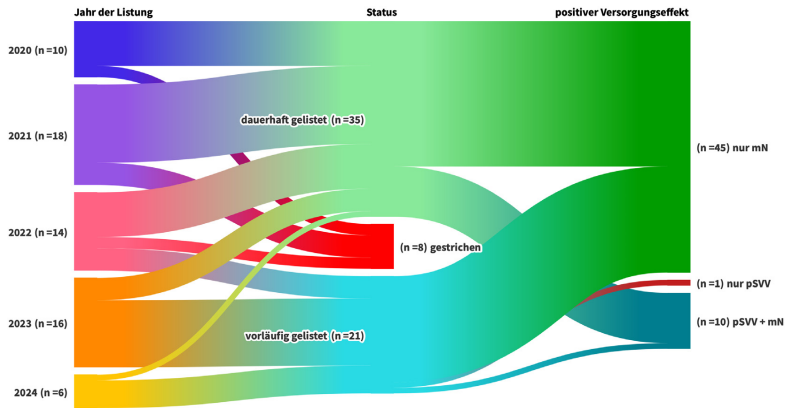


Abbildung 1. Anzahl der DiGA im Verzeichnis des BfArM, dargestellt nach Jahr der Listung, Status der Listung und Nutzung des positiven Versorgungseffektes (Stand 01.07.2024).

prüften relevante Veröffentlichungen zum Hintergrund von pSVV. Dabei kristallisierten sich zwei zentrale Themen heraus: der allgemeine Zulassungsprozess von DiGA und die Ausgestaltung des pSVV. Für jedes dieser Themen formulierten wir spezifische Fragen, die während der ersten Interviews verfeinert wurden, um Klarheit und Neutralität sicherzustellen. Eine vertiefte Literaturrecherche erfolgte in Übereinstimmung mit der Gioia-Methode erst nach Abschluss der Interviews, um eine unbeeinflusste Analyse zu gewährleisten. Die Interviews wurden nach Erhalt einer formellen Teilnahmezustimmung und Unterzeichnung einer Datenschutzvereinbarung als semi-strukturierte Gespräche geführt (Leitfäden siehe Anhang). Alle Gespräche wurden über Zoom aufgezeichnet (Audio) und ausschließlich lokal gespeichert. In der Regel waren nur die Teilnehmenden und die erste Autorin (SG) anwesend. Drei ausgewählte Interviews wurden aus Gründen der Qualitätssicherung gemeinsam von der ersten Autorin und dem zweiten Autor (MG) durchgeführt. Die Autorin (SG) weist umfassende Erfahrung in der Durchführung von Interviews im Rahmen qualitativer Nutzerbefragungen (100+ Interviews) auf, sodass die drei gemeinsam geführten Interviews, die in der ersten Hälfte der Interviewreihe stattfanden, keine Auffälligkeiten in der Qualität der Durchführung ergaben. Die Gespräche dauerten zwischen 25 und 35 Minuten, wurden aufgenommen, mit der Software „Whisper Transcription“ transkribiert, korrigiert und anschließend anonymisiert. Es wurde kein Interview wiederholt. Nach 19 Gesprächen wurde eine theoretische Sättigung erreicht, d.h. nach der Kodierung der letzten Interviews entstanden keine zusätzlichen Codes mehr.

Auswertung

Für die Datenauswertung kam die Software „MaxQDA“ zum Einsatz. SG kodierte alle Interviews, anschließend kodierte MG zusätzlich zwei zufällig ausgewählte Interviews, um eine hohe Qualität der qualitativen Analyse zu gewährleisten und ein gemeinsames Verständnis der Kodierung zu erlangen. Nach der so erfolgten Konsolidierung des Codesystems, die zur Ergänzung weniger neuer Codes und Konsolidierung einiger vorhandener Codes führte, finalisierte SG die Kodierung aller Interviews ent-

sprechend. SG erstellte das Data Model nach Gioia [18], welches nach regelmäßiger Diskussion durch beide Autor*innen in verschiedenen Stadien des Prozesses angepasst und finalisiert wurde.

Nach der Auswertung erfolgte eine Ergebnis-Triangulation mit vier Personen aus prozessbeteiligten Institutionen: Ein Interviewteilnehmer sowie drei weitere Expert*innen mit umfassender Fachkenntnis, die jedoch nicht Teil der Interviewstudie waren, nahmen an diesen Gesprächen teil. Alle vier Expert*innen aus dem regulatorischen Bereich wurden ausgewählt, da viele der abgeleiteten Implikationen regulatorische Fragestellungen betrafen.

Ergebnisse

In der folgenden Ergebnisdarstellung wird die auf Basis der Gioia-Methode entwickelte Datenstruktur zugrunde gelegt, die sich in Erstordnungs-Konzepte, Zweitordnungs-Themen und aggregierte Dimensionen gliedert. Die Ergebnisse werden systematisch entlang der aggregierten Dimensionen präsentiert und durch die entsprechenden Zweitordnungs-Themen strukturiert. Zur Verdeutlichung der Herangehensweise dient [Abbildung 2](#), die die gesamte Datenstruktur visualisiert. Ausgewählte Zitate, die zur Ableitung der Datenstruktur beigetragen haben, sind im [Anhang A](#), Tabelle 2 zu entnehmen.

Schärfung der Nutzendefinition erfolgskritisch für pSVV

Definition von pSVV unklar

Im Gespräch über die Relevanz des pSVV für DiGA-Herstellers und die Chancen der mit der Einführung des pSVV erfolgten Erweiterung des Nutzenbegriffs zeigten sich Unschärfen in der Definition. Aus Sicht einiger Interviewteilnehmenden ist die Konzeption der pSVV-Kategorien noch nicht klar:

„Was steht eigentlich genau dahinter? Es gibt so eine Definition [der pSVV-Kategorien], aber wie das in der Praxis nachher aussieht ist, glaube ich, für die meisten Hersteller unklar.“ (Beratung_4)

Befragte Personen fragen sich explizit, welche ökonomischen Ziele, die pSVV-Kategorien erzielen sollen;

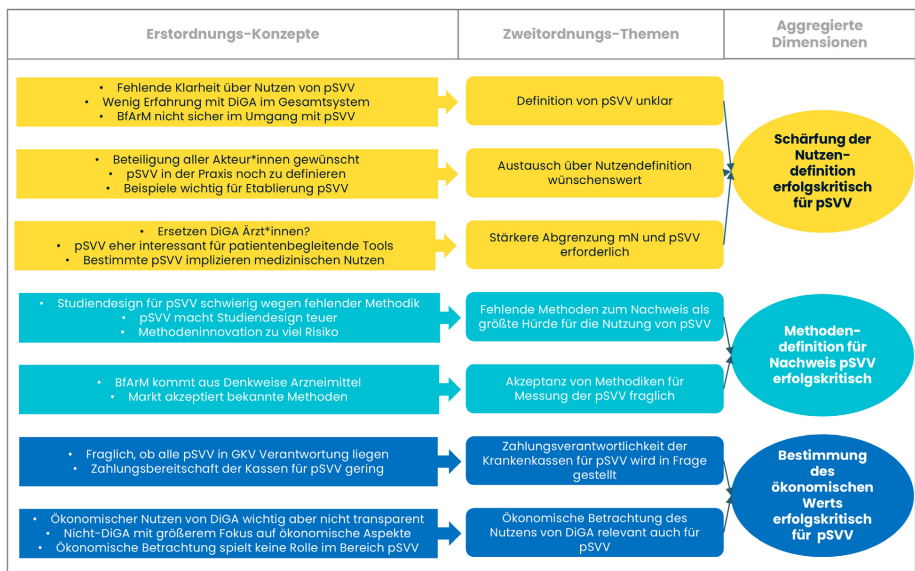


Abbildung 2. Datenstruktur-Modell entwickelt nach der Gioia-Methode [18].

„Was hat man denn [...] gedacht, welches [...] ökonomische Ziel dieser pSVV erreicht?“ (Prozessbeteiligte Institution_3)

Austausch über Nutzendefinition wünschenswert

Es wurde festgehalten, dass mehr Orientierung im Bereich pSVV gewünscht ist und dass heute im DiGA-Ökosystem kein gegenseitiges Verständnis zu diesem Thema und Unklarheit herrscht:

„[...] Wir haben schon geguckt, was haben Andere gemacht, was steht so in den Leitfäden. Es gibt ja keine ganz klaren Empfehlungen. Das wäre auch so ein Punkt glaube ich, wo man darauf hinarbeiten müsste, [...] dass man da so ein bisschen „geht, geht nicht-Listen“ hat, sich ein bisschen besser zu orientieren.“ (DiGA ohne pSVV_4)

Daher werden Beispiele eingefordert, die erläutern, wie die pSVV-Kategorien auszulegen sind. Konkret werden sowohl von Herstellenseite, als auch von Beratungen Fallstudien gewünscht, anhand derer die Nutzung eines pSVV beispielhaft dargestellt wird. Momentan wird die Einordnung des pSVV im Gesamtsystem, d.h. gegenüber den Ärzt*innen, aber auch gegenüber den beteiligten Institutionen als negativ wahrgenommen.

„Es gab viele Aussagen, die extrem negativ gegenüber den Struktur- und Verfahrensverbesserung waren. So dass wir sagen würden, wenn man denkt, man kann einen medizinischen Nutzen nachweisen, ist das vermutlich der bessere Weg Richtung Preisverhandlungen.“ (Beratung_6)

Auch von Seiten einer prozessbegleitenden Institution wurde der Wunsch nach einer offenen Diskussion unter Einbindung der regulierenden Behörden geäußert, insbesondere hinsichtlich eines offenen Umgangs mit der Innovation pSVV:

„Wenn die Anzahl derjenigen, die positiv in Richtung pSVV überlegen würden, zunehmen würde, wäre das sicherlich für die Debatte nicht schlecht.“ (Prozessbeteiligte Institution_1)

Stärkere Abgrenzung mN und pSVV erforderlich

Konkret wurde in Bezug auf den Nutzen einer DiGA die Frage in den Raum gestellt, ob diese eine ärztliche Leistung ergänzen oder ersetzen könnten:

„Inwieweit können die Anwendungen denn auch eine physische Leistungserbringung [...] ersetzen? Oder ergänzen Sie diese?“ (Prozessbeteiligte Institution_2)

Einige Teilnehmende der Interviews sehen pSVV nicht als Therapie, sondern unterstützend zu bestehenden Therapien.

„Es behandelt ja dann vielleicht die Erkrankung nicht, sondern hilft dem Patienten irgendetwas besser zu steuern [...] Eigentlich würde ich erwarten, dass wenn ich etwas verbessere in diesem Bezug, es sich gegebenenfalls auch niederschlägt im medizinischen Nutzen. [...] Ist es dann in dem Fall vielleicht keine Digital Therapy, sondern ein Patientenbegleiter, ein Hilfsinstrument?“ (DiGA mit pSVV_2)

Daher vermuten auch mehrere Interviewteilnehmende per Definition eine direkte oder indirekte Wirkung auf medizinische Parameter und damit auch einen potentiellen mN. Gerade bei Kategorien wie leitliniengerechter Behandlung oder Adhärenz erscheint es naheliegend, dass der Nachweis eines solchen pSVV auch einen mN impliziert.

„Die Herausforderung ist, dass insbesondere im Kontext der Zulassung ein pSVV immer nur dann zu tragen kommt, wenn auch ein medizinischer Nutzen nachgewiesen wurde. Ich kann klar sagen, der Blutdruck geht runter - durch Adhärenz.“ (DiGA ohne pSVV_4)

„Ich tue mich wirklich schwer mit dem Verstehen der Ausrichtung der Behandlung an anerkannten Leitlinien und Adhärenz und so. [...] Weil ich mir denke, [...] das ist ja kein Selbstzweck. Das führt auch [...] immer zu medizinischem Nutzen zurück.“ (Prozessbeteiligte Institution_3)

Als zusätzliche Schwierigkeit in der Abgrenzung von pSVV zum mN wurde genannt, dass alle DiGA im Vorfeld eine Zulassung als Medizinprodukt durchlaufen müssen und damit eine medizinische Zweckbestimmung haben. Auch wenn die Zweckbestimmung nicht direkt auf einen mN übertragen werden kann, könnte dies schon die Ausrichtung der Anwendung (beispielsweise im Vergleich zu einer nicht CE-zertifizierten Wellness-Anwendung) beeinflussen.

Um diesen Widerspruch aufzulösen, wurde von Seiten einer prozessbeteiligten Institution angeregt, die beiden Kategorien pSVV und mN zusammenzufassen, da diese beide auf das gemeinsame Ziel der Versorgungsverbesserung einzahlen würden.

„Wenn man [die Fachgemeinschaft] die Grundannahme hat, dass diese ganzen positiven Verfahren zur Strukturverbesserung auch irgendwie auf den medizinischen Nutzen einzahlen, ja, dann kann man es auch so nennen.“ (Prozessbeteiligte Institution_1)

Methodendefinition für Nachweis pSVV erfolgskritisch

Fehlende Methoden zum Nachweis als größte Hürde für die Nutzung von pSVV

Viele Befragte identifizierten das Fehlen etablierter Methoden als zusätzliche Barriere für die Anwendung von pSVV als pVE. Während Messinstrumente für den mN weitgehend aus der etablierten klinischen Forschung bekannt sind, mangelt es an entsprechendem Wissen im Bereich der pSVV. Unklar bleibt, welche Methoden und Messinstrumente möglicherweise anwendbar wären.

„Wenn ich mir die Liste der pSVV angucke [...] dann frage ich mich bei 80% wie soll ich das nachweisen? Und wie krieg' ich das eigentlich in Studien?“ (DiGA ohne pSVV_1)

Die Entwicklung geeigneter Messmethoden zur Messung von pSVV wird von den Befragten als riskant angesehen. Dies gilt sowohl bei der Verwendung der pSVV als primären, als auch als zusätzlichen Endpunkt; in beiden Fällen birgt es aus deren Sicht zusätzliche Risiken.

„Da das Risiko für den primären Endpunkt so hoch ist, dass keiner, der irgendwas medizinisch zeigen kann, pSVV zeigen wird, ist es eigentlich ein Dead End.“ (DiGA ohne pSVV_5)

Viele der Befragten arbeiten in kleinen Unternehmen, die ihre Ressourcen sehr sorgfältig einsetzen müssen, um im diesem neuen und wettbewerbsintensiven Markt bestehen zu können. Daher fällt eine Risiko-Nutzen-Abwägung oftmals zum Nachteil eines möglichen pSVV aus.

„Die Methoden sind das Problem und die fehlende Hoffnung sozusagen, dass wenn man da rein investiert, das auch klappt. Wir fokussieren uns vielleicht dann eher auf das, was wir wissen, was klappt.“ (DiGA ohne pSVV_2)

„Dass es zu wenig validierte Messinstrumente [für pSVV] gibt, da gibt es sicherlich auch einen Grund, warum es auch als sekundärer Effekt viel schwieriger ist aufzunehmen.“ (Beratung_6)

„Also wenn man jetzt unseren Chef fragt, der für die Finanzen zuständig ist, gibt es eine klare Antwort: [die Nutzung von pSVV] ist eine absolute Katastrophe. [...] Deine Studie wird halt unglaublich teuer.“ (DiGA mit pSVV_1)

Akzeptanz von Methodiken für Messung der pSVV fraglich

Die Befragten äußerten zudem Bedenken hinsichtlich der Akzeptanz neuer Messinstrumente für den Nachweis von pSVV.

Sie stellten infrage, ob diese Instrumente sowohl im Zulassungsprozess beim BfArM als auch von weiteren Akteur*innen im Gesundheitssystem anerkannt werden würden. Diese Unsicherheit könnte die Entwicklung und Implementierung solcher Messmethoden wesentlich beeinflussen.

„Wir hatten einen Kunden dessen App gibt es schon seit 12 Jahren und wird von 300.000 Personen genutzt und es sind auch entsprechende Daten da zu dieser Nutzung. Das war jetzt nichts, wo ich sagen würde, dass das das BfArM in diesem Fall wesentlich interessiert hätte im vergleichenden Studienkonzept.“ (Beratung_3)

„Wenn ich sage, ja, ich mache die Verbesserung des Gesundheitszustands mit Six-Minute Walk Test, sagt jeder: „Ja, kenne ich. Super, Du hast 30 Meter mehr, perfekt, volle Signifikanz.“ Wenn ich jetzt sage, Ich habe Behandlungen an der Leitlinie nachgewiesen. Da sagt jeder: „Hm, sehr schön.““ (DiGA ohne pSVV_1)

Bestimmung des ökonomischen Werts erfolgskritisch für DiGA

Zahlungsverantwortlichkeit der Krankenkassen für pSVV wird in Frage gestellt

Zum neuen Konzept der pSVV wird zusätzlich spezifisch das Thema der Kostenübernahme hinterfragt.

„Die Frage ist ja, was glauben wir eigentlich, sollte die Krankenkasse bezahlen? Also was wollen wir eigentlich als Gesellschaft, was im Kontext der Gesundheitsversorgung bezahlt wird? [...] Und jetzt ist natürlich die Frage bei diesen pSVV, wo stehen die denn eigentlich?“ (DiGA-Hersteller ohne pSVV_4)

Es wird überlegt, ob Kosteneinsparungen im System eine Bedingung dafür sein sollten, dass die gesetzliche Krankenversicherung die Kosten für DiGA mit pSVV übernimmt.

„Ist [pSVV] etwas, was die GKV zahlen muss? [...] Solange da kein direkter medizinischer Nutzen hinter steckt oder Einsparung der GKV [...] ist das meiner Meinung nach nichts, was die GKV zahlt.“ (Prozessbeteiligte Institution_3)

Es wird außerdem wahrgenommen, dass Mitarbeitende von Krankenkassen oder des GKV-Spitzenverbandes den finanziellen Gegenwert des pSVV nicht als gleichwertig zum mN ansehen. Mehrere Befragte äußerten die Ansicht, dass der pSVV im Zweifelsfall nur einen Bruchteil des finanziellen Wertes im Vergleich zum mN darstellt, obwohl eine solche Wertung im Rahmen der Preisverhandlungen gesetzlich nicht verankert ist.

Ökonomische Betrachtung des Nutzens von DiGA wichtig

Befragte sehen generell Chancen zur Kostenvermeidung im Gesundheitssystem durch die Nutzung von DiGA.

„Du hast eine Kostenvermeidung, die über den medizinischen Zweck erreicht wird und dann kannst du sagen „Pro Anwendung dieser DiGA spare ich einem Leistungserbringer“ X Euro auf einer Anwendungszeit von einem Jahr“. [...] Es gibt viele Chancen hier momentan, die nicht genutzt werden.“ (Beratung_1)

Aktuell lassen sich allerdings keine verlässlichen Aussagen über die ökonomischen Effekte von DiGA im Gesamtsystem treffen. Beispielsweise fehlt es an umfassenden Daten, die es ermöglichen würden, die ökonomischen Auswirkungen eines möglichen pVE auf den Gesundheitszustand einer Person mittel- und langfristig darzustellen. In diesem Zusammenhang wurde auch betont, dass eine gesundheitsökonomische Betrachtung bereits im Rahmen des Zulassungsprozesses sinnvoll wäre, um den tatsächlichen Wert eines pVE aufzuzeigen, was auch in nachfolgenden Preisverhandlungen als Argument dienen könnte.

„Das wäre natürlich auch mal ganz spannend, dann wirklich eine gesundheitsökonomische Evaluation dahinter zu legen und zu schauen, was vielleicht auch an Kosten eingespart werden kann.“ (Prozessbeteiligte Institution_2)

Es wird von mehreren Interviewteilnehmenden eingebracht, dass Anwendungen, die zum Beispiel die Verhandlung von besonderen Versorgungsverträgen mit Krankenkassen nach §140a (Selektivverträge) fokussieren, Einspareffekte ihres Produkts berechnen und im Rahmen der Vertragsverhandlungen vorlegen müssen.

„Darüber hinaus schauen wir uns vor allem auch so gesundheitsökonomische Themen an. Wenn halt gerade der Fokus ist, wir wollen auf Krankenkassen zugehen, dann ist es ja auch durchaus relevant, da die Argumentationsketten auszubauen, [...] was man an Kosten sparen kann.“ (Nicht-DiGA_1)

Zusätzlich zogen die Interviewteilnehmenden den Prozess der Arzneimittellzulassung als Vergleich heran, um zu verdeutlichen, dass eine externe Nutzenbewertung vorteilhaft sein kann.

„Bei den Arzneimitteln hat man [...] eine externe Bewertung des Nutzens durch den gemeinsamen Bundesausschuss. Und damit hat man diese Frage einigermaßen geklärt für die Preisverhandlung. [...] Und das ist, glaube ich, ein Vorteil in dem Arzneimittelnbereich gegenüber dem DiGA-Bereich.“ (Beratung_2)

Zudem wurde vorgeschlagen, die Erfassung von Ressourcenverbräuchen systematisch in die Studien zum Nachweis des pVE zu integrieren. Diese Maßnahme soll eine detaillierte Analyse der Kosten und des Ressourceneinsatzes ermöglichen, die mit der Implementierung und Nutzung der DiGA verbunden sind.

„Man kann das durchaus begleitend in der Studie machen. Man könnte das natürlich auch irgendwie machen später auf Grundlage von größeren Routinedatenanalysen [...] Aber grundsätzlich würde ich erstmal zunehmend dazu übergehen, Ressourcenverbräuche auch in den Studien mitzuerfassen.“ (Prozessbeteiligte Institution_3)

Es wird hervorgehoben, dass besonders im Bereich der Prozessverbesserung, keine ökonomischen Betrachtungen in die Bewertung der DiGA einbezogen werden.

„Dazu kommt dann halt auch noch, dass sowas wie ökonomische Studien, [...] wenn es um Prozesse geht und so ... [...], dass sowas überhaupt keine Rolle bei der Bewertung spielt.“ (Prozessbeteiligte Institution_3)

Eine umfassende Übersicht analysierter Zitate ist im [Anhang A](#), Tabelle 2 einsehbar.

Diskussion

Die Ergebnisse unserer qualitativen Analyse zeigen, dass eine Schärfung des Konzepts pSVV kritisch für die erfolgreiche Etablierung im deutschen Gesundheitssystem ist (siehe [Abbildung 3](#)). Vor allem die tiefergehende Definition des intendierten Nutzens wird gefordert. Damit einhergehend wurden zudem die Definition der Nachweismethoden sowie die Ermittlung des ökonomischen Werts als Faktoren genannt, für die Klärungsbedarf innerhalb der befragten Interessengruppen besteht.

Interviewteilnehmende wiesen darauf hin, dass der intendierte Nutzen für die im DiGA-Leitfaden des BfArM vorgeschlagenen pSVV-Kategorien noch nicht umfassend klar ist. Es besteht der

Wunsch nach weiterer Schärfung der möglichen Nutzenkategorien in einer konstruktiven Diskussion, an der alle Beteiligten im Gesundheitssystem mitwirken sollen. Innerhalb der geführten Gespräche ist eine Wahrnehmung zu erkennen, dass der Nutzen von DiGA mit einer pSVV eher als Ergänzung zu einer bestehenden (nicht zwangsläufig digitalen) Versorgung gesehen wird. Als Beispiel wurde die Unterstützung ärztlicher Leistung genannt oder die Unterstützung der Behandlung von Indikationen, für die eine Veränderung des Lebensstils erforderlich ist. Eine Abgrenzung der pSVV-Kategorien wie „Adhärenz“ oder „Ausrichtung von Behandlungen an Leitlinien und anerkannten Standards“ von der eigentlichen medizinischen Leistung sollte diskutiert werden [\[22\]](#). Gerade für DiGA, die eine Therapie unterstützen, die an sich schon einen medizinischen Nutzen hat, muss definiert sein, welcher Effekt der eigentlichen Therapie zugeordnet wird und welcher Effekt durch die Unterstützung, z.B. in Form einer gesteigerten Adhärenz oder einer verbesserten Einhaltung der entsprechenden Leitlinie, erzielt wird.

Hier kann ein direkter Zusammenhang zu einem weiteren genannten Punkt hergestellt werden – der Bewertung des ökonomischen Nutzens. Wenn definiert ist, welcher Teil des Behandlungserfolges „der eigentlichen Therapie“ und welcher Teil der „Unterstützung der Therapie“ zugerechnet wird, ist eine ökonomische Bewertung der beiden Einzelteile und damit des Effekts der DiGA möglich.

Dies ist erstrebenswert, da die Beteiligten im Gesundheitssystem immer wieder die Höhe der Kosten für DiGA diskutieren² während über den tatsächlichen ökonomischen Effekt der Anwendungen bis dato wenig bekannt ist [\[23,24\]](#). Mehrere Interviewteilnehmende warfen die Frage auf, ob DiGA, die eine pSVV fokussieren, durch die GKV finanziert werden sollten. Ein Vergleich wurde gezogen zu Medikamenten gegen Übelkeit während der Schwangerschaft, deren Kosten nicht übernommen werden, da diese nicht medizinisch erforderlich seien (DiGA ohne pSVV_4). Wenn der Einsatz einer DiGA mit einer pSVV auf Gesamtsystemebene zu Einsparungen führe, könne die Zahlungsverantwortlichkeit bei der GKV liegen. Die unzureichende Datenlage zu ökonomischen Effekten wird darauf zurückgeführt, dass die Ermittlung des ökonomischen Nutzens einer Anwendung bisher im Rahmen der DiGA-Zulassung nicht betrachtet wird. Anders als bei der Verhandlung von direkten Verträgen mit Kostenträgern (sog. Selektivverträgen, SGB V §140a), bei der die Betrachtung ökonomischer Aspekte regelmäßig im Vordergrund steht, wird der Fokus im Bereich der DiGA-Zulassung primär auf den Nachweis des mN gelegt [\[25,26\]](#). Es konnte nicht abschließend geklärt werden, ob ökonomische Überlegungen bei den Preisverhandlungen bereits eine wichtige Rolle spielen. Die sehr vergleichbaren verhandelten Preise der dauerhaft gelisteten DiGA deuten jedoch darauf hin, dass – unabhängig von der Krankheitskategorie oder dem positiven Versorgungseffekt – diese Überlegungen bisher keine wesentliche Rolle zu spielen scheinen. Insbesondere vor dem Hintergrund der im Rahmen des Digital-Gesetzes festgelegten variablen Vergütungsanteile, die ab dem 01.01.2026 mindestens 20% des ausgehandelten Preises einer DiGA betragen, werden gesundheitsökonomische Analysen zunehmend wichtiger.

Die Einführung von ökonomischen Modellierungen des Nutzens in den Zulassungskontext von DiGA könnte auf Systemebene dazu beitragen, die Diskussion über hohe Kosten zu versachlichen und eine Abwägung von Kosten und ökonomischem Nutzen ermöglichen. Gleichzeitig erhielt die Preisverhandlung im Zuge der dauerhaften Zulassung von DiGA eine weitere Dimension, die die Transparenz innerhalb des Preisfindungsprozesses steigern kann.

² Mitteilung des Spitzenverbandes der Gesetzlichen Krankenkassen „Fokus: Digitale Gesundheitsanwendungen (DiGA)“; erreichbar unter: https://www.gkv-spitzenverband.de/gkv_spitzenverband/presse/fokus/fokus_diga.jsp; aufgerufen am 01.03.2024 oder Meldung des Deutschen Bundestages „Hohe Kosten für Digitale Gesundheitsanwendungen“; erreichbar unter: [https://www.bundestag.de/presse/hib/kurzmeldungen-985830#:~:text=lm%20Durchschnitt%20l%C3%A4gen%20die%20Herstellerepreise,digitale%20Anwendungen%20auf%C3%9ferhalb%20des%20Verzeichnisses, aufgerufen am 01.03.2024](https://www.bundestag.de/presse/hib/kurzmeldungen-985830#:~:text=lm%20Durchschnitt%20l%C3%A4gen%20die%20Herstellerepreise,digitale%20Anwendungen%20auf%C3%9ferhalb%20des%20Verzeichnisses,)



Abbildung 3. Erfolgskriterien für pSVV abgeleitet aus der Datenstruktur nach Gioia.

Nicht nur für die Messung des ökonomischen Nutzens, sondern vor allem für den Nachweis des positiven Versorgungseffektes wurde der Mangel an Methoden als ein Hindernis genannt, das DiGA-Herstellende derzeit von der Nutzung der pSVV abhält. Abgesehen von bereits etablierten Fragebögen im Bereich der Gesundheitskompetenz und der Patientensouveränität ist einem Großteil der Akteure unklar, wie die Verbesserung des adressierten Verfahrens oder Prozesses nachgewiesen werden kann. Auch die Akzeptanz von selbstentwickelten, nicht etablierten Studiendesigns seitens der Zulassungsbehörden wird in Frage gestellt. Die klassische randomisierte kontrollierte Studie wird weiterhin als Goldstandard angesehen [27,28], obwohl sie die Besonderheiten von Softwareprodukten nicht umfassend abbildet [1,29]. Auch wenn es bereits vereinzelt Studiendesigns für pSVV gibt, spiegeln diese bei weitem noch nicht die Breite der möglichen Anwendungen wider [5].

Eine Präzisierung und ggf. Co-Entwicklung der möglichen Messmethoden seitens der Zulassungsbehörden, sowie von Seiten der Wissenschaft könnte hier mittelfristig zu einer Senkung der Markteintrittsbarrieren führen [30]. Für die Definition akzeptierter Messmethoden zur Wirkungsmessung von pSVV-Kategorien ist eine Präzisierung des intendierten Nutzens und damit eine genauere Definition der zu messenden Parameter unumgänglich.

Unter Berücksichtigung der Einschränkungen dieser Studie soll eine kritische Betrachtung der methodischen Ansätze und der Stichprobe erfolgen. Die Verteilung der Geschlechter unter den Befragten ist unausgewogen, was auf die Überrepräsentation männlicher Entscheidungsträger zurückzuführen ist. Darüber hinaus wurden Patient*innen und Leistungserbringende nicht einbezogen, da die Studie auf die Gründe für die geringe Anzahl von DiGA mit Fokus auf pSVV abzielte. Dies berücksichtigt die begrenzte Vertrautheit der Endnutzer*innen mit dem Konzept der pSVV. Trotz dieser Einschränkungen bietet die Studie wertvolle Einblicke in die Herausforderungen und Potenziale der Implementierung von pSVV im Rahmen der DiGA-Zulassung. Weitere Forschung ist notwendig, um die Erkenntnisse zu vertiefen und zu erweitern.

Fazit

Die teils emotional geführte Debatte um Kosten und Nutzen von DiGA im deutschen Gesundheitswesen könnte durch eine Ergänzung um eine ökonomische Komponente verschärft werden. Nach dem Vorbild verwandter Bereiche, wie dem Zulassungsprozess für Arzneimittel oder den bestehenden Praktiken zur Bewertung von potentiellen Partnern für Selektivverträge (SGB V

§140a) durch Krankenkassen, kann eine Inklusion von ökonomischer Modellierung durch DiGA-Herstellende in den Zulassungsprozess ein erster Schritt sein. Zusätzlich können beispielhafte Modellierungen des Effekts spezifischer pSVV-Kategorien auf Gesamtsystemebene von zentraler Stelle forciert werden. Etablierte Förderstrukturen wie der Innovationsfonds³ oder gezielte Analysen von interdisziplinären Teams nach dem Beispiel des Health Innovation Hubs [1], der in Vorarbeit auf die Einführung von DiGA maßgeblich die theoretische Basis für den Zulassungsprozess erarbeitet hat, können hier unterstützend wirken.

Um die Debatte bezüglich des Nutzens auch im Bereich pSVV führen zu können, sollte die Definition des intendierten Nutzens innerhalb der pSVV-Kategorien geschärft werden. Vor allem eine Abgrenzung zum mN ist hierbei erforderlich. Eine strukturierte Analyse der bereits vorhandenen Beispiele für pSVV im Markt kann hierzu einen guten Startpunkt bilden. Diese sollte bestenfalls seitens des Bundesministeriums für Gesundheit angestoßen und begleitet werden, da hier das Konzept der pSVV initial entwickelt wurde. Eine Beteiligung von am Prozess beteiligten und bereits erfahrenen Expert*innen, wie dem BfArM [6,31,32], kann zielführend sein.

In diesem Zuge könnten nicht nur die Definition des angestrebten Nutzens konkretisiert, sondern ebenfalls dafür geeignete Messpunkte definiert werden. Dies könnte den Markteintritt der gewünschten DiGA mit einem Fokus auf pSVV zusätzlich fördern [25] und damit dazu beitragen, den Weg in Richtung einer digitalisierten Gesundheitsversorgung in Deutschland zu ebnen [33,34].

Ethik

Für diesen Beitrag wurden von der Autorin und dem Autor keine Studien an Menschen oder Tieren durchgeführt. Die analysierten Interviews wurden mit Personen geführt, die als Vertreter*innen ihrer Unternehmen und nicht als individuelle soziale Einheiten agierten. Vor der Durchführung der Interviews wurde von allen Teilnehmer*innen eine schriftliche Einverständniserklärung zur Teilnahme eingeholt. Die Aufzeichnungen (Audio) erfolgten via Zoom direkt und wurden ausschließlich lokal gespeichert. Um die Anonymität zu gewährleisten und sowohl personenbezogene als auch unternehmensbezogene Daten zu schützen, wurden die Identitäten der Teilnehmer*innen und der von ihnen vertretenen Organisationen sorgfältig anonymisiert. Das Studiendesign wurde mit dem Leiter des Instituts für Ethik in der Technologie der Technischen Universität Hamburg abgestimmt. Das Forschungsvorhaben wurde erfolgreich durch das verkürzte

³ <https://innovationsfonds.g-ba.de/projekte/versorgungsforschung/implementdiga-erforschung-des-implementierungsprozesses-von-digitalen-gesundheitsanwendungen-und-deren-wirkungen-in-der-regelversorgung.537>; Zugriff am 04.03.2024

Evaluierungsverfahren der Gesellschaft für experimentelle Wirtschaftsforschung e.V. (Nummer des Zertifikats: kNjYR7Ag) zertifiziert, welches bestätigte, dass kein spezifisches Ethikvotum erforderlich ist.

Die Studie war Teil eines Doktorandenprogramms an unserer Universität.

Verfügbarkeit der Daten

Die vollständigen Transkripte der Interviews und Audiodateien sind aus Datenschutzgründen nicht öffentlich zugänglich. Metadaten, die die Ergebnisse unterstützen (wie z. B. der Codetree), sind auf begründete Anfrage bei den Autor*innen erhältlich.

Nutzungshinweis Generative Künstliche Intelligenz

Generative Künstliche Intelligenz (ChatGPT 4 von OpenAI) wurde verwendet, um während des Schreibprozesses geringfügige Verbesserungen an Satzstruktur und Formulierungen im Text vorzunehmen – die Inhalte und Schlussfolgerungen wurden ausschließlich von der Autorin und dem Autor entwickelt.

Interessenkonflikt

Die Autorin SG ist bei einer gesetzlichen Krankenversicherung als Arbeitnehmerin beschäftigt. Sie erklärt, dass ihre Tätigkeit im Rahmen dieser Anstellung unabhängig von ihrer wissenschaftlichen Arbeit erfolgt. Der Autor MG war vor seiner Tätigkeit an der TUHH als selbstständiger Berater, u.a. für DiGA-Hersteller, tätig. Er erklärt, dass kein Interessenkonflikt zu den Inhalten der wissenschaftlichen Arbeit besteht.

Autor*innenschaft

Sara Gehder: Konzeption, Methodik, Untersuchung, Datenaufbereitung, Verfassen des Originalentwurfs, Schreiben – Überprüfung & Bearbeitung, Visualisierung, Projektadministration
Moritz Goeldner: Konzeption, Methodik, Validierung, Schreiben – Überprüfung & Bearbeitung, Visualisierung, Betreuung

Anhang A. Zusätzliche Daten

Zusätzliche Daten verbunden mit diesem Artikel finden sich in der Online-Version unter <https://doi.org/10.1016/j.zeqf.2024.11.003>.

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- 3.4. Publication 3 - Unpacking Performance Factors of Innovation Systems and Studying Germany's Attempt to Foster the Role of the Patient Through a Market Access Pathway for Digital Health Applications (DiGAs): Exploratory Mixed Methods Study

[Original Paper](#)

Unpacking Performance Factors of Innovation Systems and Studying Germany's Attempt to Foster the Role of the Patient Through a Market Access Pathway for Digital Health Applications (DiGAs): Exploratory Mixed Methods Study

Sara Gehder, MSc; Moritz Goeldner, Prof Dr

Working Group for Data-Driven Innovation, Hamburg University of Technology, Hamburg, Germany

Corresponding Author:

Moritz Goeldner, Prof Dr

Working Group for Data-Driven Innovation

Hamburg University of Technology

Am Schwarzenberg-Campus 4

Hamburg, 21073

Germany

Phone: 49 40 428784777

Email: moritz.goeldner@tuhh.de

Abstract

Background: Health care innovation faces significant challenges, including system inertia and diverse stakeholders, making regulated market access pathways essential for facilitating the adoption of new technologies. The German Digital Healthcare Act, introduced in 2019, offers a model by enabling digital health applications (DiGAs) to be reimbursed by statutory health insurance, improving market access and patient empowerment. However, the factors influencing the success of these pathways in driving innovation remain unclear.

Objective: This study aims to identify the key performance factors of the innovation system shaped by the *patient-relevant structural and procedural improvement* (pSVV) pathway within the DiGA model. By examining how this pathway supports the entry of innovative digital health technologies, we seek to uncover the systemic dynamics that influence its effectiveness in fostering patient-centered digital health solutions.

Methods: This study, conducted from May 2023 to November 2024, used a mixed methods approach. A descriptive analysis assessed how DiGA manufacturers use positive health care effects, giving a market overview of the pSVV technology. A qualitative analysis using grounded theory and Gioia methodology provided insights into stakeholder perspectives, focusing on manufacturers and regulatory bodies. A functional-structural analysis examined how components of the innovation system, such as actors, institutions, interactions, and infrastructure, interact and impact the effectiveness of the pathway.

Results: The descriptive analysis showed that only 11 (20%) of the 56 DiGAs available in Germany used the pSVV pathway, with only 1 (2%) provisionally listed DiGA using pSVV as a primary end point; 6 of 9 (67%) pSVV key areas were used. The qualitative analysis revealed that manufacturers prioritize demonstrating medical benefits over pSVV due to evidence requirements and uncertainties around pSVV acceptance. Operational barriers hindered the adoption of pSVV, despite a positive reception among stakeholders. The systemic analysis identified key issues, including a lack of entrepreneurial focus on pSVV, limited regulatory experience, inadequate measurement methods, and entrenched practices prioritizing medical benefits, that hinder market formation and legitimacy.

Conclusions: This study identifies key factors for effectively implementing innovation systems through regulated market access pathways, including content and format security, clearer framework specification, active innovation process management, and market formation stimulation. Addressing these factors can reduce uncertainties and promote wider adoption of digital health technologies. The findings highlight the need for future research on patient empowerment and the development of methodologies beyond traditional therapeutic outcomes.

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KEYWORDS

regulatory market access pathways; digital health application; DiGA; patient-relevant structural and procedural improvement; pSVV pathway analysis; qualitative and systemic analysis; policy and stakeholder insights; innovation system analysis

Introduction

Background

Innovation in health care is well known for being challenging. The complexity is driven by factors such as the involvement of diverse stakeholders in highly regulated markets [1,2], the need to address “wicked problems,” complex issues without straightforward solutions [3], and substantial “system inertia,” meaning resistance to change, which is especially pronounced in health care systems [4]. Policy approaches have been shown to act as inertial forces that can significantly shape the development of innovative technologies in health care [5], particularly digital health technologies, where patient access is greatly limited without broad and scalable market access pathways [6]. Mobile health apps are becoming increasingly available to consumers worldwide [7-9]; however, significant barriers, including regulatory complexity, insufficient evidence of clinical benefit, and data privacy concerns, still prevent their full integration into health care systems, leaving them underused in clinical practice [10-14].

To address these challenges, health policy approaches are being adopted globally to standardize regulatory processes and speed up market access, particularly in the rapidly evolving field of digital health [15-18]. Notable examples of health policy approaches include regulated market access pathways, such as the *fast-track process for digital health applications* pathway in Germany [19] and the *Prise en Charge Anticipée Numérique* (PECAN) pathway in France [20], which aim to facilitate the entry of digital health applications (DiGAs; German: Digitale Gesundheitsanwendung) into their respective markets. These new approaches are gaining significant international attention as pioneering models in the field [6,21].

To illustrate, the German Digital Healthcare Act (DVG), introduced in 2019, established the DiGA pathway to foster the integration of so-called DiGAs into the health care system. This pathway allows DiGAs to be reimbursed by statutory health insurance when prescribed by health care professionals or provided by health insurers. With approximately 90% of the German population covered by statutory health insurance [22], these “apps on prescription” are widely accessible at no cost to patients. Eligible DiGAs are included in the national DiGA Directory [23], which is managed by the Federal Institute for Drugs and Medical Devices (BfArM; German: Bundesinstitut für Arzneimittel und Medizinprodukte) to ensure transparency and oversee the approval process [24,25]. To qualify, a DiGA must be Conformité Européenne (CE)–marked (classes I and IIa or IIb), be based primarily on digital technology intended for direct patient use, and support the detection, monitoring, treatment, or alleviation of diseases, injuries, or disabilities [26]. Following a recent regulatory update in April 2024, digital medical devices classified as class IIb have been added to be eligible for recognition as a DiGA. However, this inclusion comes with specific stipulations; these devices are required to

demonstrate medical benefit only, and they are eligible solely for permanent listing, excluding the option for preliminary listing. In addition, a DiGA must meet stringent requirements for safety, quality, functionality, privacy, and data security as defined in the respective DiGA ordinance (DiGAV; German: Digitale Gesundheitsanwendungen-Verordnung) [24]. To enhance transparency around the assessment criteria and specific requirements established by BfArM, a DiGA guide [27] for manufacturers, service providers, and users was published. This guide provides a concise overview of the applicable ordinances and regulations, detailing how BfArM interprets the normative requirements set forth in the DVG and DiGAV.

Despite some emerging research examining the market dynamics following the implementation of regulated market access pathways, such as the number of products entering the market, time to market, pricing, and study designs used to demonstrate efficacy [28,29], as well as factors contributing to the success of specific DiGA products [30], broader factors influencing successful technology integration remain underexplored. This study addresses these gaps to better inform future policy and innovation strategies. To identify potential success factors, it is crucial to consider not only the regulated market access pathway itself but also the surrounding elements that influence its effectiveness. The broader network of actors, institutions, and resources involved in the creation, diffusion, and use of new technologies is defined as the technology innovation system [31]. A health policy approach, such as the creation of a regulated market access pathway that “brings about processes of change and stimulates technological innovation,” can be characterized as a systemic instrument [32]. Systemic instruments are mechanisms designed to shape the conditions under which technological innovation systems operate. Understanding the dynamics that a systemic instrument brings to a technological innovation system requires the consideration of various functional and structural components, all of which must be in place to effectively implement the targeted technological innovation [33]. These components, as outlined by Wieczorek and Hekkert [34], include the structural components, such as actors, institutions, interactions, and infrastructure, as well as the functional components, such as entrepreneurial activities (F1), knowledge development (F2), knowledge diffusion (F3), guidance of the search (F4), market formation (F5), mobilization of resources (F6), and creation of legitimacy (F7) [35].

This exploratory study aimed to identify factors contributing to the success of an innovation system shaped by a regulated market access pathway in the digital health sector. Through an exemplary case study, we sought insights to support ongoing improvements in digital health policy, focusing on optimizing market access pathways for digital health technologies. The central research question is as follows: What are the performance factors of an innovation system created by a regulated market access pathway that supports the market entry of innovative digital health technologies?

To address this question, we selected a specific case from the 2019 German policy innovation DVG, particularly the “patient-relevant structural and procedural improvements” (pSVV; German: Patientenrelevante Struktur- und Verfahrensverbesserung) pathway. The pSVV pathway is a targeted segment within the DiGA pathway, specifically modifying the element of product value assessment, 1 of the 4 “full-stack” elements (regulatory authorization, product value assessment, pricing and reimbursement, and patient access) that define a comprehensive market access pathway [6], promoting innovations aimed to specifically elevate DiGAs that enhance patient–health care provider interactions and support patient health behaviors.

Unlike traditional pharmaceuticals, which require evidence of “therapeutic efficacy” through clinical studies for coverage eligibility [36], DiGAs are allowed to demonstrate their effectiveness through “positive health care effects” defined as either “medical benefit” or pSVV. While the medical benefit criterion focuses on outcomes, such as improved health status, reduced disease duration, prolonged survival, or improved quality of life, the pSVV criterion introduces 9 additional areas to demonstrate the value that is equally eligible as defined in the DiGA guide. These areas include improving care coordination, adherence to guidelines and standards, enhancing patient adherence, facilitating access to care, increasing patient safety, and promoting health literacy and autonomy. This expansion of the traditional product value assessment beyond the traditional therapeutic benefits is further complemented in the DiGA guide by explicitly broadening the acceptable methods of evidence beyond the traditional randomized controlled trials. We selected this case due to the maturity of the evolving DiGA ecosystem [28] in Germany, which offers greater transparency and availability of data on use and uptake compared to other countries. Within this context, the pSVV pathway was chosen as a focal point because it represents a well-defined component within the DiGA pathway, involving a manageable number of stakeholders while offering sufficient accumulated experience to provide valuable insights into the factors influencing digital health innovation.

In addition, the introduction of the pSVV pathway is groundbreaking as it extends beyond traditional treatment parameters, embracing a holistic approach to health care that prioritizes patient empowerment and streamlined care processes [19,37,38]. This aligns with the global trend toward patient empowerment, emphasizing the importance of patient agency and involvement in health care processes [16,39,40].

Our research used a mixed methods approach to provide a comprehensive exploration of the factors at play. We began with a descriptive analysis of the innovation success of the targeted pSVV technology, which helps contextualize the case and assess the effectiveness of the policy intervention [41]. Following this, a qualitative analysis of the perception and use of the market access pathway was conducted to develop theoretical insights into the factors that influence the adoption of specific innovation pathways [42,43]. In addition, a functional-structural analysis of the technological innovation system was performed to uncover broader factors beyond the

pathway itself that are essential for successful technological innovation [34].

Contribution

This study contributes to the field by providing a comprehensive analysis of factors that support the successful integration of digital health innovations. Our findings will provide policy makers and stakeholders worldwide with practical insights to improve regulated market access pathways and drive innovation strategies that better meet the needs of health care systems and patient empowerment.

Methods

Setting and Study Design

This exploratory study used a mixed methods approach to investigate factors influencing the success of a regulated market access pathway for digital health technologies. We conducted a descriptive analysis to assess the adoption of pSVV technology, followed by a qualitative analysis to explore stakeholder perspectives on the pSVV pathway, using grounded theory and Gioia methodology to ensure neutrality and objectivity. Finally, we performed a functional-structural analysis to identify additional success factors within the broader technology innovation system. Each method is described in detail subsequently.

This study was carried out between May 2023 and November 2024 with interviews being conducted between May 2023 and November 2023.

First, a descriptive analysis of the use of positive health care effects by DiGA manufacturers was conducted to establish an understanding of the current developmental status of the pSVV technology in the market.

Second, a qualitative analysis was performed to explore the success factors of a regulated market access pathway by subsequently analyzing the perception and use of the pSVV pathway of key stakeholders. Since the pSVV pathway was only introduced in 2019 and has not been studied yet, a qualitative research approach was adopted. This approach allows for deep exploration of complex and less understood topics [44]. Unlike quantitative methods, which rely on larger sample sizes and predefined variables, qualitative methods provide flexibility for exploring nuanced, context-specific insights, particularly valuable given the relatively small number of relevant stakeholders (35 DiGA manufacturers as of early 2023). By using the inductive grounded theory method [45] alongside the Gioia methodology [42,43], we objectively analyzed the views of market participants on the pSVV pathway, avoiding any imposition of preconceived theories and ensuring neutrality in the analysis. For the qualitative analysis, we followed the Consolidated Criteria for Reporting Qualitative Research-32 (COREQ-32) checklist [46].

Building on the dataset from the qualitative analysis, we conducted a functional-structural analysis of the technology innovation system established by the pSVV pathway to identify additional success factors related to regulated market access pathways. This analysis followed the systemic policy framework

established by Wieczorek and Hekkert [34], enabling a comprehensive examination of the innovation system’s functional dynamics and structural components within the current policy context.

While this study provided valuable insights into potential strategies to improve the pSVV pathway in particular, the international focus of this study precluded detailed insights into Germany-specific factors. To address this, we conducted a subsequent analysis focusing specifically on the question, “What factors facilitate or hinder the implementation of pSVV within the approval process for DiGA?” and “What specific requirements and expectations of relevant stakeholders must be addressed to establish the concept of pSVV in the market?” The results of this specific analysis were published in a German-language journal to inform stakeholders in this context [47].

Sampling and Data Collection

For the execution of our descriptive analysis regarding the state of adoption of pSVV, we evaluated publicly available data on the positive health care effects of DiGA from the DiGA directory [23]. The data were retrieved via an application programming interface provided by BfArM for scientific use.

In our qualitative study, we used a hybrid approach of criterion sampling and snowball sampling for participant recruitment. We aimed to engage with stakeholders who have a direct

influence on which digital health products enter the market and, if entry occurs through the DiGA pathway, determine the associated positive health care effects. The inclusion criteria are defined subsequently.

The first inclusion criterion was organizations that are directly involved with the DiGA ordinances and regulations, whether developing it, ensuring or supporting its implementation, or actively using it.

The second criterion was individuals, within these organizations, whose professional roles directly involve the development, implementation, or use of the DiGAVs and regulations.

The third inclusion criterion was additionally individuals who have actively decided against using the DiGA pathway, provided they have extensively engaged with the ordinances and regulations and are potentially qualified to use it (eg, manufacturers of DiGAs not listed as DiGA).

Individuals without direct and active influence over the selection of products entering the DiGA market or the choice of the positive health care effect were excluded.

Consequently, the exclusion criteria led to the exclusion of stakeholder groups in the DiGA market, such as DiGA users, prescribers, and researchers in the field, while the inclusion criteria led to the identification of the stakeholder groups presented in [Textbox 1](#).

Textbox 1. Stakeholder groups included in qualitative analysis.

- Digital health application (DiGA) manufacturers with patient-relevant structural and procedural improvement (pSVV; DiGA with pSVV): This category includes decision makers from manufacturers of DiGAs that are listed in the DiGA directory and have implemented pSVV as a positive health care effect.
- DiGA manufacturers without pSVV (DiGA without pSVV): This category comprises manufacturers who are listed in the DiGA directory but have not used pSVV as a positive health care effect.
- Manufacturers of mobile health applications not listed in the DiGA directory (non-DiGA): This group consists of manufacturers whose CE–certified mobile health apps are not, or are not yet, listed in the DiGA directory.
- Consultants: This group refers to professionals from advisory firms who specialize in assisting manufacturers in the process of getting listed in the DiGA directory.
- Regulatory bodies: This group encompasses public institutions that are deeply involved in the development and management of the DiGA pathway and the evolution of the guiding ordinances and regulations (Digital Healthcare Act [DVG], DiGA ordinance [DiGAV], and DiGA guide).

Due to the very small size of stakeholder groups 1 and 5, yet their significant relevance to our research questions, we contacted all organizations in these groups in accordance with our inclusion criteria. For groups 2 to 4, given the novelty and niche nature of the topic, we opted for snowball sampling [48] to achieve the highest possible participation rate. Individuals were excluded if someone from the same organization had already participated in the study, to avoid multiple responses from the same context. This combined approach resulted in a 66% positive response rate to our participation invitations. Participant recruitment began with initial email contacts, followed by referrals from existing participants in line with snowball sampling. Efforts were focused on ensuring a diverse representation of the identified stakeholder groups.

Our outreach targeted 29 individuals, with 19 (66%) agreeing to participate. Reasons for nonparticipation included lack of response (n=9, 31%) and time constraints (n=1, 4%). The

distribution of speakers across groups and their organizational roles are detailed in Table S1 in [Multimedia Appendix 1](#).

For the interviews, a semistructured approach was used with decision makers who had consented to participate and endorsed a data protection declaration. Efforts were made to ensure neutrality, with no prior relationships between interviewers and participants. An interview guide with 7 open-ended questions was prepared to facilitate conversation while ensuring neutrality and objectivity in the analysis. The themes of the questions were developed after preliminary data gathering, which included limited literature research and initial conversations with 2 experts in the field (a managing director from a manufacturer’s association and a member of an organization that has 1 DiGA listed in the DiGA directory), adhering to the standards of the Gioia methodology [42]. These experts were not part of the subsequent interviews, ensuring that the development of the interview guide was informed yet independent of the interview

process itself ([Multimedia Appendix 1](#)). In total, 2 central themes emerged from this process: the general approval process for DiGA and the specifics of the pSVV pathway. For each of these themes, we formulated specific questions, which were refined during the initial interviews to ensure clarity and neutrality. Interviews were scheduled at the convenience of the participants and conducted via Zoom (Zoom Video Communications, Inc), with only the participant and the primary interviewer (SG) present, though 3 selected interviews had a second researcher (MG) present for quality assurance. No interviews were repeated.

Conducted in German, interviews lasted 25 to 35 minutes, audio tracks were recorded, transcribed using the software Whisper Transcription (Good Snooze), and anonymized. Data saturation was reached when no new first-order concepts or second-order themes emerged during analysis, as reflected in field notes and initial coding. This indicated that the data structure, developed through the Gioia methodology, was comprehensive, and additional data collection would not yield further insights. Following the analysis, data triangulation was enhanced through additional discussions with 4 experts from regulatory and digital health sectors to refine the results. This included a conversation with leading representatives from BfArM, which, due to confidentiality agreements, cannot be directly cited in this study. Insights from these discussions were used to cross-verify emerging themes and validate our interpretations, ensuring robustness in our conclusions.

Ethical Considerations

Informed consent was obtained from all participants who were interviewed strictly as representatives of their respective employers. Participants were selected based solely on their relevance to the research question and their experience in the field, with no consideration of personal or socially sensitive attributes. No personal data or socially relevant information were collected, and all data were fully anonymized to ensure privacy and confidentiality. No compensation was provided for participation in the study.

Furthermore, the study did not involve vulnerable populations, health care professionals, medical procedures, health-related data, or any form of deception, manipulation, or intervention that could impact participants' well-being. In addition, there was no risk of physical, psychological, social, or economic harm to participants. Following consultation with the head of the Institute for Ethics in Technology at Hamburg University of Technology and a review by the German Association for Experimental Economic Research eV (certificate number kNjYR7Ag), it was confirmed that specific ethics approval was not required. This approach fully aligns with best practices for ensuring ethical compliance in socioeconomic research.

Descriptive Analysis

For this analysis, we included all DiGA listed in the DiGA directory at BfArM as of November 8, 2024. This study specifically aimed to compare how often medical benefits are used versus pSVV, as published in the DiGA directory [23]. To further refine our understanding of the adoption levels of pSVV,

we also examined the use rates across the 9 key areas of pSVV detailed in the DiGA guide [27].

Qualitative Analysis

Transcripts were methodically analyzed in a 3-step procedure using the grounded theory and the well-established Gioia methodology [42,49] to ensure qualitative rigor in inductive research. After familiarization with the primary data, a codebook was developed by generating codes in an iterative process using the software MaxQDA (VERBI Software). SG coded all (19/19, 100%) interviews, and 2 (11%) randomly selected interviews were cocoded by MG. In addition, SG and MG regularly discussed and reflected on the data collection process and preliminary findings throughout all phases of the research. A consensus on all codes was eventually reached by the research team.

After agreeing on a coding scheme that best captured the diversity of the material, the transcripts and codes were analyzed again to identify second-order categories. First-order concepts included concepts, such as "lack of methods is the biggest hurdle for proof of pSVV" or "pSVV good ideas but difficult to operationalize." First-order concepts were combined into second-order themes, such as "study design for pSVV difficult due to lack of measurement instruments." Ultimately, second-order themes were merged hierarchically into five aggregate dimensions that best summarize the theoretical contribution in the data: (1) "key aspects for manufacturers within the regulated market access pathway," (2) "key aspects for study design," (3) "reasons for considering possibilities within new pathway," (4) "hurdles for considering possibilities within new pathway," and (5) "targeted innovative technology important for the health care system" (refer to Figure S1 and Table S3 in [Multimedia Appendix 1](#)).

Following the analysis, a triangulation of the results was conducted with 4 individuals from institutions involved in the process: 1 interview participant and 3 additional experts with extensive subject matter expertise, who had not participated in the initial interview study. All 4 experts were selected from the regulatory field, as many of the derived implications pertained to regulatory issues.

Functional-Structural Analysis

The first-order concepts, originally derived from the previous qualitative analysis as elucidated earlier, were subject to an additional analysis using the functional-structural systemic problem analyses framework [34], a methodology specifically tailored for the exploration of technology innovation systems [50,51]. Our analytical focus centered on the innovative pSVV technology, concentrating on the first-order concepts that laid the foundation for dimensions 2 to 5. Notably, the first dimension, "Key aspects for manufacturers within the regulated market access pathway," was excluded from this analysis, as it did not provide insights specific to the pSVV aspects of the DiGA pathway, but rather addressed the pathway in general.

In step 1, to facilitate a comprehensive analysis, all first-order concepts corresponding to dimensions 2 to 5 were systematically organized into a 4x7 matrix. This matrix integrates the 4 structural elements and 7 functional dimensions of an innovation

system [34,50,52]. Following the analysis framework, the objective was to elucidate overarching “systemic problems” hindering the intended innovation within the innovation system for pSVV. Refer to Table S4 in [Multimedia Appendix 1](#) for the comprehensive assignment of concepts to the functional and structural dimensions of the innovation system and the derivation of “systemic problems.” The sorting of concepts, derivation of instruments, and clustering into strategic factors were conducted by SG and subsequently agreed upon by the research team.

In step 2, to address the identified “systemic problems,” we first identified “systemic instruments” within the functional-structural framework of Wieczorek and Hekkert [34], tailored to specific systemic issues.

In step 3, we organized the “systemic instruments” identified in step 2 into 3 strategic factors to form actionable clusters. A detailed overview of the derivation process is available in Table S5 in [Multimedia Appendix 1](#).

Results

Current State of pSVV Adoption in the DiGA Market: Descriptive Analysis

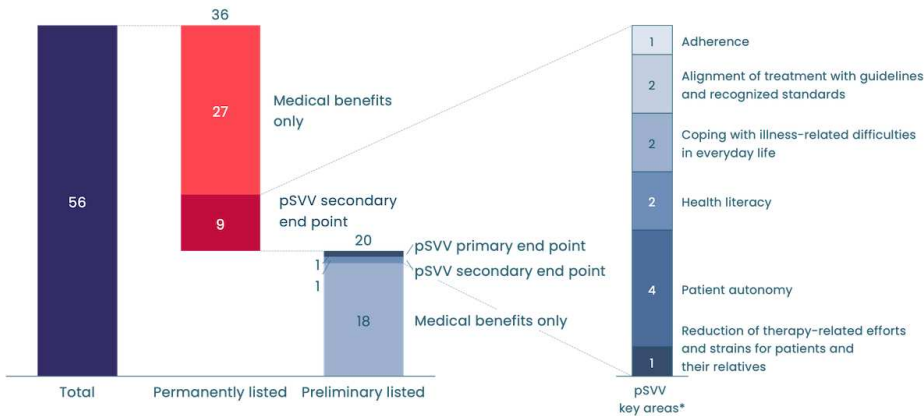
As of November 8, 2024, out of the 56 DiGAs available in Germany, only 1 (2%) provisionally listed DiGA uses pSVV

as its primary end point, with none in the permanently listed category. While 10 (19%) DiGAs incorporate pSVV as a secondary end point, the predominant focus remains on traditional medical benefits. The adoption of pSVV in comparison to medical benefits stands at 11 versus 45, meaning only 20% (11/56) of all currently listed DiGAs use pSVV. Moreover, only 1 (2%) of 56 DiGA exclusively focuses on pSVV as a primary end point [23].

The 11 (20%) of the 56 DiGA currently listed that use pSVV as a primary or secondary end point have collectively used 12 pSVV end points ([Figure 1](#)). Among these, 6 (67%) of the 9 possible key areas outlined in the DiGA guide have been used. In total, 4 (44%) of these areas have been used more than once, namely “patient autonomy,” “health literacy,” “coping with disease-related difficulties in everyday life,” and “alignment of treatment with guidelines and recognized standards.”

The 11 (20%) of the 56 DiGA currently listed that use pSVV are owned by 10 organizations, with 1 organization using pSVV end points in clinical trials to prove the positive care effect for 2 of their DiGA products. We estimated the timing of the adoption of the pSVV pathway by examining the time frame of clinical studies and found that 2 DiGA demonstrating a pSVV had already been conducting their clinical studies before the pathway was introduced in 2019 (velibra and vorvida, both developed by GAIA AG).

Figure 1. The number of digital health applications (DiGAs) listed in the DiGA directory in Germany based on positive health care effects and status of listing (as of November 8, 2024), including the breakdown of specific key areas used within patient-relevant structural and procedural improvements (pSVV). *Eleven DiGAs using pSVV use 12 pSVV end points with 1 DiGA using 2 pSVV key areas.



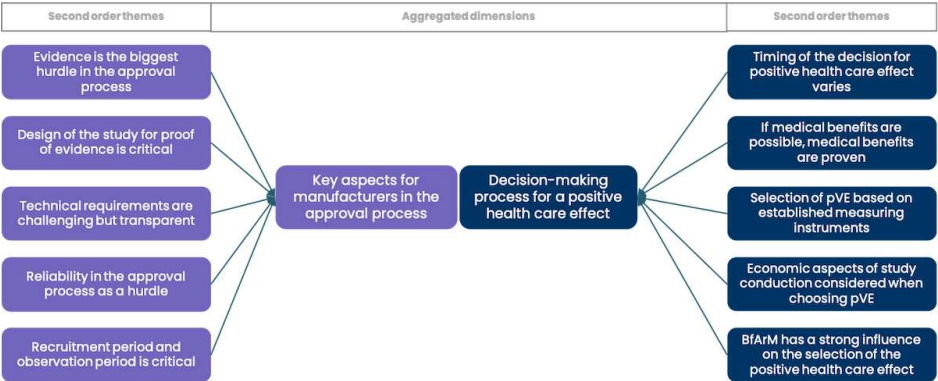
Analyzing Perception and Use of the pSVV Pathway by Key Stakeholders: Qualitative Analysis

Overview

The results are presented based on the data structure developed through the Gioia methodology ([Figure S1 in Multimedia Appendix 1](#)), which organizes findings into first-order concepts, second-order themes, and overarching dimensions. In the

subsequent sections, findings are systematically presented separating the data structure into 3 segments of aggregated dimensions and further detailed by their corresponding second-order themes. To illustrate our approach, [Figures 2-4](#) provide a visual representation of the respective parts of the data structure. In addition, [Table S3 in Multimedia Appendix 1](#) includes selected codes that were instrumental in forming the data structure.

Figure 2. Graphical illustration of selected parts of the data structure derived from Gioia methodology illustrating key aspects for manufacturers within the regulated market access pathway as well as the key aspects of choosing the health care effect. BfArM: Federal Institute for Drugs and Medical Devices; pVE: positive health care effects.



Key Considerations in the Approval Process for DiGAs: Evidence as the Key Aspect

Being asked about the key considerations a DiGA manufacturer needs to face during the approval process, most (14/16, 88%) of the surveyed manufacturers and consultants concurred on a central theme—evidence takes the forefront, serving as the primary concern for manufacturers as “...(evidence) is the crucial point, which often determines the inclusion or non-inclusion (in the DiGA Directory)” (Consultant_5). In conjunction with this, the DiGA study design for evidence generation is deemed critical. The execution of the study is recognized as one of the primary cost drivers for manufacturers and the approving authority (BfArM) has a strong influence on the final design, as described by a participant, “And one can clearly see that an evidence level is crystallizing, which, within the framework that is possible, is already on the strictest side” (DiGA without pSVV_4).

While technical requirements, such as data privacy, interoperability, and accessibility were also mentioned, discussions in these domains with the BfArM were described as negligible due to the “clear and transparent” (Consultant_2) nature of the requirements. One respondent encapsulated this sentiment by stating the following:

The key issue is undoubtedly the matter of evidence. Less so is data privacy and security, as these are issues that can be adequately addressed. [DiGA without pSVV_3]

Nevertheless, a certain level of planning uncertainty was identified in the process, stemming from updates to the DiGA guide or alterations in statements during consultations with the BfArM, as articulated by a manufacturer:

One of the most challenging aspects is the disparity between what is theoretically granted regarding research design and the actual decision practices of the BfArM. [DiGA without pSVV_2]

In addition, insights into the procedural aspects revealed that both recruitment and observation periods are critically constrained.

Key Aspects of Study Design: Strong Tendency Toward Traditional End Points

Regarding the decision on which positive health care effect a future DiGA will be evaluated for and therefore which end point is used in the study design, significant timing variations are observed. DiGA manufacturers, especially those who began developing their product after the DVG was introduced in 2019, typically determine the positive health care effect early in the development phase, often before initiating the coding process:

Ideally, I make the decision before the development begins, as the entire development process needs to be built around this choice. [DiGA with pSVV_1]

In contrast, manufacturers with established products leveraging the new DiGA approval pathway as a market entry point did not have this advantage.

In the selection of the clinical end point, manufacturers strongly lean toward medical benefits:

The medical aspects always take precedence. [DiGA with pSVV_2]

Demonstrating a positive health care effect without proof of medical benefit is perceived as challenging in 2 ways. One way is to find the appropriate instrument for evidence generation for proving pSVV, “If I look at the list of pSVV, then I wonder for 80% of the things, how am I supposed to prove that?” (DiGA without pSVV_1), while the other lies in finding an agreement with the BfArM on a study design aiming to prove pSVV, “We have to advise relying on the medical benefit...it is not fundamentally that they (BfArM) reject it (pSVV), but we also experience that they...are not so certain about it” (Consultant_5). In addition, it is perceived that other stakeholders in the system are better equipped to evaluate medical benefits compared to pSVV, which could be relevant for price negotiations:

If you believe you can demonstrate medical benefits, that is probably the better path towards price negotiations because it's something the system understands and can perhaps evaluate better. [Consultant_6]

The perceived challenges conclude in a perception of a stronger acceptance of evidence that substantiates a medical benefit, highlighting a potential current bias toward well-known, medically oriented outcomes.

Manufacturers and consultants choose the end points, if possible, based on the example of other DiGA that are already listed and where validated measurement instruments are available:

[The selection criteria are] essentially hard facts in the sense that it has worked before, and there are validated measurement instruments. [Consultant_3]

In addition, both listed DiGA and unlisted health applications prioritize economic considerations:

Ultimately, we paid attention to...economic aspects, like the speed at which the study is conducted. [DiGA without pSVV_2]

At present, pivotal guidance in the process emanates from consultations with the BfArM. The influence of the conversations is underscored by the following statement:

So as a manufacturer, you would never do anything where the BfArM advice said otherwise. [DiGA without pSVV_5]

Reasons for Considering a New Pathway: Additional Evidence

Both, consultants and DiGA manufacturers, currently view the use of pSVV primarily as an opportunity for generating additional evidence alongside medical benefits. This perspective was succinctly expressed by one participant, who mentioned the following:

pSVV is included as a secondary endpoint in such a study. If possible, you confirm it, but you would always prefer to demonstrate medical benefits. [Consultant_3]

DiGA manufacturers and consultants have pinpointed 3 substantial benefits associated with the implementation of the possibilities given within the new pSVV pathway. Potential differentiation from providers of similar DiGA was mentioned:

But in the case of [indication X], it could well be that with our DiGA, other DiGA are also approved or provisionally approved. In such instances, I could envision that a pSVV might serve as a consideration for or against a DiGA. [DiGA without pSVV_4]

Overall positive impacts on sales were also mentioned:

Distribution is also a crucial task we undertake when engaging with physicians, ensuring a clear delineation of what is effective beyond standard practices. Particularly with DiGA, the argument hinges on the fact that the pSVV dimension precisely provides the benefit. [DiGA without pSVV_3]

Moreover, there is an expectation of a positive impact on the official price negotiations occurring later in the process between manufacturers and payers. It is highlighted that “The more evidence you have, the greater the likelihood of maintaining certain price points” (DiGA with pSVV_1) and “Possibly, pSVV can indeed be an enhancing criterion (during the price negotiation process) for the respective product” (Regulatory body_2).

Hurdles for Considering a New Pathway: Operational Insecurities

When asked about the reasons why manufacturers tend to not use the new possibilities within the pSVV pathway, many (5/7, 71%) manufacturers and consultants referred to a lack of clarity on operationalizing pSVV as outlined in the DiGA guide, particularly concerning the methods applicable for assessing the impact:

But when I look at them [the pSVV key areas], I wonder with about 80% of them, how am I supposed to prove that? And yes, how do I actually incorporate that into studies? [DiGA without pSVV_1]

In addition, there is skepticism among DiGA manufacturers and consultants regarding the economic impact of demonstrating pSVV. One participant succinctly expressed this viewpoint by stating the following:

Purely from the procedural and financial perspective—if you were to ask our boss, who is responsible for finances—there is a clear answer: this is an absolute disaster. [DiGA with pSVV_1]

At the same time, introducing and establishing new measurement tools like the use of real-world data is deemed too expensive and risky for DiGA manufacturers:

If you had to essentially innovate methods and also deal with the uncertainty...in the worst-case scenario, you would end up with three studies.... That alone costs you a million, just for these studies. No one is willing to foot that bill. And then, if it goes wrong... [Consultant_3]

In addition, manufacturers and consultants observed a general uncertainty within the system regarding the concept of pSVV:

Not that they (BfArM) fundamentally reject it, but we experience that they, how should I say, are not so certain about it. [Consultant_5]

Moreover, they observed a general lack of knowledge about pSVV that leads to the need for explanation:

There is a significant need for explanation, actually, among the different stakeholders. Both with patients and with doctors. What is it exactly? Why is it good? What is in it for me? [DiGA with pSVV_1]

Consultancies sometimes actively discourage the choice of pSVV in the clinical trial:

If you believe you can demonstrate medical benefits, that is probably the better path towards price negotiations because it's something the system

understands and can perhaps evaluate better.
[Consultant_6]

Relevance Perception: Targeted Innovative Technology Is Important for the Health Care System

Looking at the general perception of pSVV as a concept, stakeholders highlighted the systemic benefits, emphasizing the impact on the overall health care system efficiency and supply effects:

It...makes sense from the overall health care system perspective. [Non-DiGA_2]

Patient-centric advantages emerged, revealing the influence of DiGA beyond conventional medical outcomes. A consultant illustrated this by pointing out the positive impact of patient empowerment on intervention success:

Individuals with higher health literacy typically respond more effectively to interventions, as they have a better understanding and feel a greater sense of control. [Consultant_1]

DiGA might also address practical challenges like long waiting times, presenting substantial value beyond traditional medical considerations:

But if we now say we would compare ourselves to a traditional intervention...then the pSVV...plays an even greater role. Because when I say, I have something here with a positive effect, and it is more accessible than the therapy, that is already a value where I say, it makes a difference. [DiGA with pSVV_2]

However, the unique benefits of DiGA, such as the improvement of patient adherence and reduction of therapy-related efforts, often eluded recognition in conventional benefit assessments:

pSVV is crucial for the system, but the evidence must focus on it. Thus, the usability of the product must be ensured and tailored to that. The evidence must reflect the particular added value of these applications.
[DiGA without pSVV_5]

Regulatory bodies acknowledged this oversight, emphasizing the need to broaden evaluation criteria to encompass these critical aspects:

DiGA can have medical benefits, but they are not solely limited to medical utility.... And these are points that get lost in traditional benefit assessments.
[Regulatory body_1]

In addition, the political and collaborative nature of the development process that led to the pSVV concept was highlighted: "We had many stakeholders involved there. On the one hand, we had colleagues from self-administration, but we also had the manufacturers [stretching the collective effort] in understanding potential, addressing challenges, and bridging the gap between traditional assessment methods and innovative logics" (Regulatory body_1).

Analyzing the pSVV Technology Innovation System: 5 Systemic Problems Identified

Actors' Presence Problem in "Entrepreneurial Activities" and "Market Formation"

Examining the participants presently engaged in the pSVV innovation system reveals a discernible pattern. Only one of the DiGA entrepreneurs within this emergent system has developed a product with a primary emphasis on pSVV. Notably, some manufacturers have established market longevity before the introduction of the DVG and thus pSVV; therefore, orienting their product toward medical benefits. Moreover, some actors are concurrently navigating evidence-generation endeavors while exploring alternative pathways for market access in Germany, such as individual "selective contracts" with statutory health insurance under §140a SGB V (Sozialgesetzbuch 5; a German law that covers all regulation concerning statutory health insurance and therefore also covers DiGA and selective contracts), which lacks the concept of pSVV. The absence of *entrepreneurial activities* singularly centered on pSVV emerges as a contributory factor hindering the *formation of a distinct market* for dedicated pSVV-related regulated digital medical devices.

Actors' Capability Problem in "Knowledge Dissemination"

The supervising governmental institution, in its role as advisor for manufacturers before and during the admission process, has limited experience with pSVV but rather a strong focus on medical benefits. This emphasis can be attributed to its dual role, as the BfArM in Germany oversees admissions not only for DiGAs but also for traditional pharmaceuticals. The lack of experience with pSVV in this key role as a knowledge multiplier and also in this specific innovation system hampers *knowledge dissemination*. In addition, practitioners prescribing DiGA as well as end users of the products have limited experience with products focusing on pSVV, which leads to a need for significant efforts to explain the concept while the demand from potential users is unclear.

Infrastructure Presence Problem in "Knowledge Development" and "Guidance of Search"

The suitability of existing measurement methods designed for therapeutic effects in assessing pSVV is often limited, contributing to its restricted adoption. Simultaneously, the lack of positive examples for products in the pSVV category hampers *knowledge development*. In addition, the absence of positive price examples not only further constrains manufacturers' support for pSVV but also contradicts the *guidance of search*.

Institution Intensity Problem in "Knowledge Development" and "Resources Mobilization"

In the *institutional* dimension, it was noted in particular that the existing *instructions* (DiGA guide) pose challenges to the operationalization of pSVV. The *established practices* and formed *expectations* regarding pSVV are perceived as counterproductive, particularly for cost-sensitive manufacturers who cannot afford to allocate their limited resources toward pSVV despite existing barriers. The limitations of the DiGA

guide concerning pSVV, namely lack of examples or standards and possible end points for evidence demonstration, are identified as a challenge in *knowledge development*, while the *established practices*, inclined toward medical benefits, hinder *resource allocation* for the advancement of pSVV.

Institution Intensity and Interaction Intensity Problem in “Guidance of the Search,” “Market Formation,” and “Creation of Legitimacy”

Established practices in the approval process that make it difficult to enter the market without proven medical benefits diverge from the introduced laws and regulations, creating a misalignment. Interactions within the approval process, especially with the official advisory body, tend to emphasize medical benefits. Notably, consultancies actively guide manufacturers toward prioritizing medical benefits over pSVV, thus steering the guidance of the search away from pSVV and hindering market formation.

Positive expectations on the value of using pSVV that would support the *creation of legitimacy* remain mainly hypothetical. The economic effect, specifically, was formulated in the subjunctive by interviewees. Coupled with the pervasive *established practices*, this poses a significant obstacle to *creating legitimacy* for pSVV.

Discussion

Principal Findings

Our research explored the factors that need to be considered when bringing a specific digital health technology innovation to market through the implementation of a regulated market access pathway as a health policy approach.

For this example case study, the pSVV pathway, the descriptive analysis revealed that only a few DiGAs currently in the market have demonstrated a pSVV. Of the 11 currently listed DiGAs that have entered the market with a pSVV as one element of a positive health care effect since the introduction of the pathway in 2019, only 1 DiGA has a primary focus on pSVV (ie, pSVV as the primary end point of the positive health care effect). Notably, 2 of the products (developed by the same DiGA manufacturer) that demonstrate pSVV as a secondary end point conducted their clinical studies before 2019. This indicates that few manufacturers have taken the initiative to develop a product with a special focus on improving structures and procedures for patients, even though the introduction of the pSVV pathway was intended to encourage this. To date, pSVV is mostly used as an additional end point to medical benefits. To provide a basis for interpreting the results in further analyses on the performance factors of innovation systems shaped by regulated market access pathways, our initial conclusion is that the innovation in DiGAs targeting pSVV, which the pSVV pathway

was designed to foster, has not yet been fully realized within the system. This is particularly daunting, as previous studies emphasize the need to focus more on products that address structural and procedural improvements for patients [53-55] and consider the concept of pSVV to be a “fundamental mechanism of action for DiGAs” [56].

Our qualitative analysis of stakeholders’ perspectives during market access reveals that evidence generation is the most critical component of the DiGA approval process. While multiple factors are considered in determining a positive health care effect, our findings suggest that, at the operational level, manufacturers of DiGAs primarily focus on demonstrating medical benefits as evidence for positive health care outcomes (Figure 2). Economic considerations, in light of the lack of established methodologies for measuring the defined key areas and uncertainty about the acceptability of the proposed study design, including pSVV, lead to more cautious use. Bearing the cost for methodological innovation is not considered attractive among manufacturers, particularly as DiGAs with pSVV so far do not negotiate substantially higher prices than DiGAs without pSVV [28]. Consistent with the findings of the descriptive analysis, the use of pSVV is often considered “incidentally” as an addition to medical benefit, only when a methodology for demonstrating one of the pSVV key areas exists for a specific product (Figure 3). It can be concluded that the specific challenges associated with proving the efficacy of pSVV, particularly the lack of established methodologies, currently outweigh its potential benefits. Previous studies have highlighted content and format security [57] as a critical factor, particularly for pioneers in medical technology, which also appears to hold true for the market entry of innovative products in DiGAs. The fact that only one company has attempted to pioneer a product specifically targeting benefits under pSVV may be attributed to the innovators’ need for content and format security, in this case specifically the lack of standards to generate evidence for the targeted technology innovation. Without such security, the costs for pioneers become prohibitively high.

However, the implementation of the pSVV concept is recognized as vital for the health care system’s evolution itself (Figure 4).

Our qualitative analysis highlights a common gap in health care innovation between the perceived importance of new technologies and their actual implementation. This gap is often influenced by systemic factors, such as regulatory conditions and inherent system inertia, alongside a general openness to innovation among stakeholders [58]. For the pSVV pathway, while there is strong stakeholder support for introducing products that demonstrate pSVV, significant operational hurdles, particularly concerning content and format security, have delayed its adoption. These barriers suggest that, despite a willingness to embrace this innovation, the pathway’s practical challenges currently limit its broader impact (Figure 5).

Figure 3. Graphical illustration of selected parts of the data structure derived from Gioia methodology illustrating hurdles of DiGA manufacturers for considering possibilities within the new pathway as well as reasons for doing so. DiGA: digital health application; pSVV: patient-relevant structural and procedural improvement.

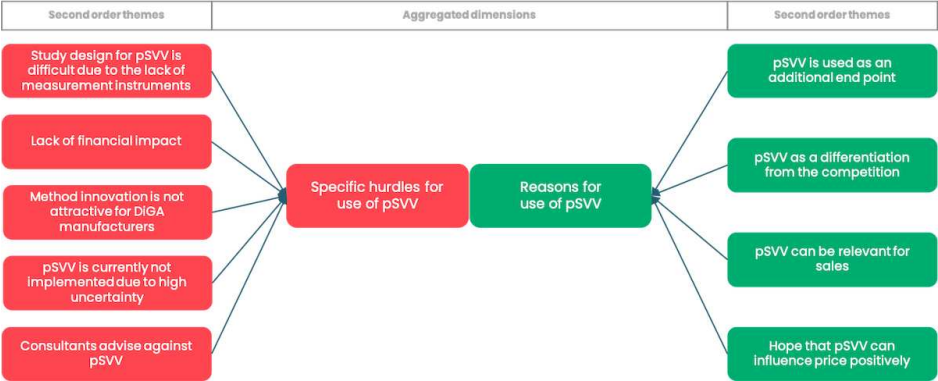
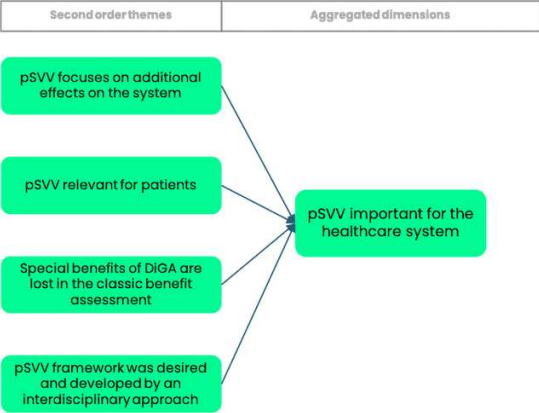


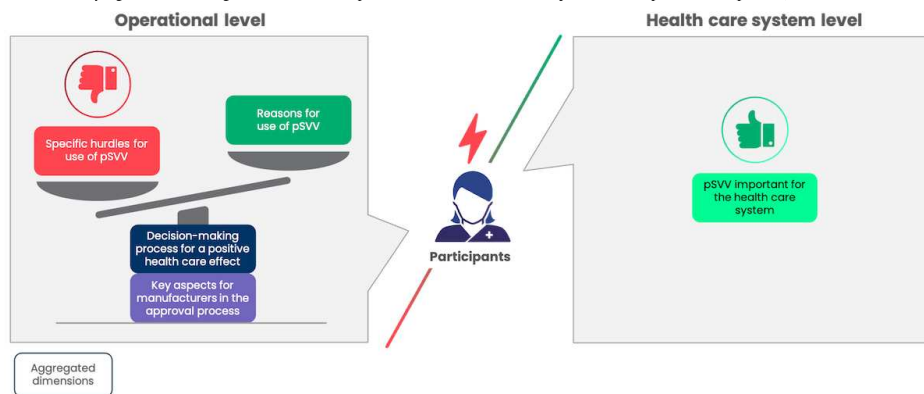
Figure 4. Graphical illustration of a selected part of the data structure derived from Gioia methodology illustrating the perception of the importance of patient-relevant structural and procedural improvements (pSVVs) in the health care system. DiGA: digital health application.



To further explore performance factors in the innovation system shaped by the pSVV pathway, we conducted an analysis of the innovation system’s maturity level in relation to pSVV. Our findings indicate 3 central strategic factors of an innovation system in which we can expedite the adoption of innovative technology: *framework specification*, *active innovation processmanagement*, and *market formation stimulation*

While previous work has highlighted the general need for frameworks [16,59], our emphasis is on the degree of specificity required for the successful implementation of a market access pathway for DiGAs. In our example, the specification of the pSVV pathway, defined in the DiGA guide, requires 2D

adjustments. First, the creation of a knowledge infrastructure would enable entrepreneurs to navigate the DiGA market, including pSVV, better if the development of exemplary models for pSVV products and especially congruent methodologies for demonstrating the evidence base of pSVV would exist. In addition, a multitude of studies highlight the ongoing challenges associated with identifying appropriate study designs that are capable of measuring effects solely attributable to the use of digital products [60-62]. We conclude that the presence of a specific level of knowledge infrastructure, which underpins the innovation driven by the introduction of a regulated market access pathway, can affect how widely it is adopted [6,63].

Figure 5. Underlying conflict leading to the underuse of patient-relevant structural and procedural improvements (pSVVs).

Second, studies in the field of regulated medical products have indicated that the uncertainty about the accepted content and format during the approval of new products can make the pathway into the market unattractive for first movers [57]. Our analysis has shown that the DiGA guide, which serves as the most relevant instruction at the operational level in this system, requires timely updates to keep pace with advancing knowledge development and ensuring up-to-date format and content security. Simultaneously, for the successful implementation of a pathway, *active innovation process management* is crucial. Providing training to key actors in the defined process, such as the BfArM or consultants, has been shown to be essential for empowering stakeholders to support and advance pSVV as an innovation. In addition, as previous work has highlighted the importance of education and awareness as well as patient and health care provider support while training for physicians on digital health solutions is limited [25,64], the inclusion of user groups and prescribing physicians can be focused to sharpen the objectives of pSVV. Conversely, it is crucial to ensure that involved actors are not overly familiar with traditional processes, as this can lead to inflexible adherence to these methods. The involvement of key actors with an excess of experience in medical benefits (ie, experienced regulatory assessor previously involved in assessing pharmaceuticals) could potentially impede innovation speed if their participation is overly predominant.

Furthermore, targeted *market formation stimulation* can aim to introduce manufacturers into the DiGA market, focusing primarily on addressing pSVV key areas [65]. Creating positive examples can accelerate innovation at multiple levels. In addition, stimulating constructive exchange regarding the pSVV concept can expedite knowledge generation and distribution, contributing to faster market formation.

In summary, our study revealed that the lack of established methodologies for proving pSVV has led to significant uncertainty for manufacturers regarding the acceptable formats and evidence required, contributing to slower adoption. To complement these findings on the specific pathway level, the functional-structural analysis identified 3 key factors critical to enhancing the total innovation system: clearer framework

specification to provide precise guidelines, active innovation process management to support stakeholders in navigating the regulatory process, and market formation stimulation to foster positive examples and increase engagement with the pSVV pathway. These factors are essential for overcoming both the operational and systemic barriers to successfully introducing innovative digital health technologies into a market.

As initiators of the systemic innovation of pSVV, the regulatory body can implement additional measures to promote its further establishment. This includes stimulating the development of a knowledge infrastructure by involving all stakeholders in the innovation system. Academia can actively contribute to advancing the definition of the pSVV and particularly developing suitable methodologies for evidence generation [66-68]. Existing mechanisms to promote scientific progress, such as dedicated research funds (eg, in Germany by the Federal Ministry of Education and Research or the Innovation Fund of the Federal Joint Committee), could be set up for this objective [69].

Initiating a public debate on pSVV can engage relevant stakeholders, such as professional societies and associations in a discourse to further develop the pSVV framework [13,66]. Economic measures, such as granting financial support for conducting clinical trials assessing pSVV or even tax incentives for implementation, can provide additional incentives for manufacturers driving innovation and initiating the pSVV market until these products are established in the standard of care. Furthermore, spaces can be created for key stakeholders in the system to educate themselves about pSVV. This could include offering policy laboratories or training programs for knowledge multipliers.

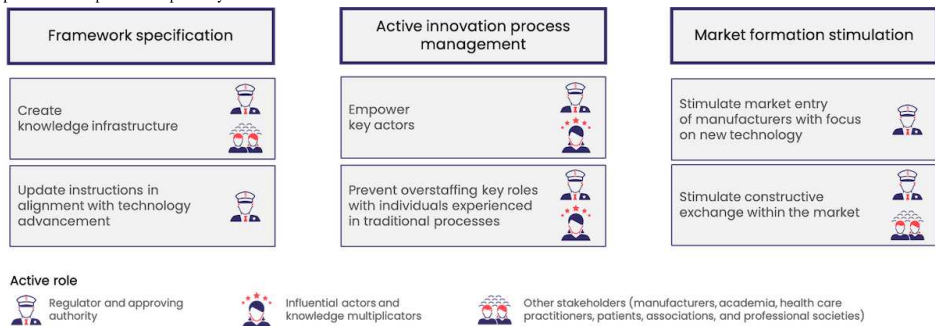
Consultancies and the BfArM, as influential players in the system, can provide room for their employees to further educate themselves about the possibilities of pSVV, to prevent disproportionately biased inclinations toward medical benefits. Ensuring a balanced wealth of experience regarding the use of medical benefits within the workforce can promote openness to innovative processes. It is critical to ensure that the experience of the staff responsible for evaluating the proof of benefit of

DiGAs is balanced in assessing medical quality [70]. Previous work has shown that the Food and Drug Administration might actively aid in similar innovation processes [71]. This assistance is rendered through the administration's in-depth knowledge to improve study designs and by championing innovative methods. Although the breadth of authority and scope of the regulated processes vary, BfArM or other regulatory agencies involved in the approval process and specifically in evaluating coverage eligibility can also contribute their expertise. For manufacturers seeking to use the potential of pSVV in their DiGAs, it is important to prioritize evidence of positive health care effects early in the development process. Identifying the "active

ingredient" and its mechanism is crucial for crafting studies effectively assessing DiGA [60].

Besides proposing solutions for individual stakeholder groups within the health care system (Figure 6), the collaboration and coordination among all involved parties should be underscored as crucial for success. As highlighted on an international scale, effective collaboration between regulatory agencies, academia, app developers, payers, and health care providers is essential to truly leverage advances in science and technology and to translate the vision into reality, guided by the right incentives and guidelines [69,71,72].

Figure 6. Central strategic factors for progress exploration in the innovation system derived from an exemplary analysis of the patient-relevant structural and procedural improvement pathway.



Our analysis suggests that the strategic factors identified are valuable considerations for the establishment of a regulatory market access pathway, to ensure its widespread and successful adoption. Drawing on previous research, the strategic factor of content and format security [57] is highlighted, alongside the adoption of recognized and accepted methods for measuring proposed parameters [59,61,68,73-76]. This is particularly relevant in digital health technology aimed at patient empowerment, where significant progress is still needed [68,74]. Furthermore, it is advantageous to strike an optimal balance between leveraging established processes and frameworks allowing room for innovation [77]. As indicated by the strategic factor of innovation process management, it is crucial to carefully select and train key players and individuals in pivotal roles, equipping them with the specific skills and mindset needed to drive innovation. Finally, the strategic factor of market formation stimulation points to the critical need to consider the practicality of a framework in enabling a viable business model, particularly within the context of systemic innovation [21,60,78].

Limitations

Acknowledging the limitations of this study, a conclusive assessment of the economic value of pSVV is precluded, as no product with pSVV as a primary end point has undergone final price negotiation yet (Table S2 in Multimedia Appendix 1). In addition, it could be questioned whether pSVV can ever be the primary end point of a DiGA, as all DiGAs must also be CE-certified medical devices with the corresponding intended purpose. We have not explored this discussion in detail, as it can certainly be conducted more effectively with selected

examples of products focusing on pSVV, once these are available in the market. Furthermore, our qualitative analysis, conducted through semistructured interviews, did not encompass all functional-structural dimensions of innovation systems. Entities, such as academia or associations were not mentioned by any interviewees and were thus not part of the evaluation. In addition, our sampling strategy did not include patients or physicians, as the study concentrated on identifying reasons for the scarce number of products targeting the pSVV key focus areas. This decision acknowledges the limited familiarity of end users and prescribers with the pSVV concept at this point and their marginal impact on market entry decisions shortly after the introduction of a new framework designed to facilitate market access.

Conclusions

This exploratory study examined critical factors for bringing digital health technology innovation to market through a regulated market access pathway, with a focus on the pSVV pathway as an example case. Key success factors identified included content and format security, the need for precise framework specification, active innovation process management, and market formation stimulation. These elements collectively help reduce uncertainties for manufacturers and promote broader adoption of digital health innovations. Our findings revealed that although the pSVV pathway was intended to encourage a focus on pSVVs, the current use remains limited, with most manufacturers prioritizing medical benefits as evidence of positive health care outcomes.

The mixed methods approach enriched the analysis by allowing a deep exploration of stakeholder perspectives through qualitative analysis, complemented by the functional-structural analysis of the technology innovation system. The combination of grounded theory and Gioia methodology enabled an objective and detailed examination of how market participants view and use the pSVV pathway, while the systemic analysis highlighted additional success factors in the broader innovation system context.

Our findings contribute valuable insights for stakeholders in the digital health sector, providing recommendations for policy adjustments that can strengthen innovation pathways. With this work, we contribute by identifying critical areas for improvement, including the need for clearer guidelines, the development of a knowledge infrastructure, and enhanced training for stakeholders to help overcome operational barriers. In addition, fostering public discourse on pSVV and introducing economic incentives, such as financial support for clinical trials, may further drive innovation. These recommendations are valuable for health care systems and regulatory bodies seeking to support similar pathways and advance patient-centered digital health solutions.

Furthermore, the impartial perspectives gathered from stakeholders, combined with a holistic analysis of the innovation system, contribute to identifying clear fields for action and proposing solutions relevant beyond this specific case. Our findings provide transferable insights for health care systems embarking on similar systemic innovations, as seen in countries like France, Belgium, and Austria, where comparable concepts to pSVV are being introduced. The implications of our research extend to other systemic innovation initiatives in health care systems facing significant adoption challenges that could otherwise lead to initiative failure. Ongoing efforts from national and international scholars are critical in supporting the success of these initiatives. In Germany, for example, a reimbursement pathway for digital nursing care applications (DiPA), a “regulatory sibling” to DiGA, has been established. While speculative, similar challenges may emerge for DiPA manufacturers, particularly concerning the nursing benefit that aligns with both medical benefit and pSVV, possibly contributing to the current absence of DiPA in the marketplace and highlighting gaps in this systemic innovation approach.

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The authors used generative artificial intelligence (ChatGPT, version 4o; OpenAI) to incorporate minor improvements in sentence structure and wording throughout the publication; the contents and conclusions have purely been developed by the authors [79].

Data Availability

The datasets generated and analyzed during this study are not publicly available due to data protection reasons but are available from the corresponding author on reasonable request.

Authors' Contributions

SG conceived and designed the study, interviewed the participants coded the interviews, analyzed the data, and drafted the manuscript. MG transcribed the interviews using Whisper Transcription (Good Snooze). MG cocoded on randomly selected interviews and took part in reflexive discussion and consensus building together with SG. MG supervised the project. SG and MG interpreted the results and finalized the manuscript. All authors approved the final manuscript.

Conflicts of Interest

SG is employed at a statutory health insurance company in Germany. She declares that her work at the statutory health insurance is unrelated to this topic. MG has previously worked as a consultant for digital health application (DiGA) manufacturers. He declares that his previous work is unrelated to the results of the conducted work.

Multimedia Appendix 1

Semistructured interview questionnaires, overview of interview participants, full data structure based on Gioia methodology, negotiated digital health application prices and health care effects, selected interview codes generated using grounded theory, functional-structural analysis of patient-relevant structural and procedural improvement as a systemic innovation, and derivation of strategic fields using the functional-structural framework by Wieczorek and Hekkert [34].

[DOCX File, 651 KB-Multimedia Appendix 1]

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Abbreviations

BfArM: Federal Institute for Drugs and Medical Devices (German: Bundesinstitut für Arzneimittel und Medizinprodukte)

CE: Conformité Européenne

COREQ-32: Consolidated Criteria for Reporting Qualitative Research-32

DiGA: digital health application (German: Digitale Gesundheitsanwendung)

DiGAV: digital health application ordinance (German: Digitale Gesundheitsanwendungen-Verordnung)

DiPA: digital nursing care application

DVG: Digital Healthcare Act

PECAN: Prise en Charge Anticipée Numérique

pSVV: patient-relevant structural and procedural improvement (German: Patientenrelevante Struktur- und Verfahrensverbesserung)

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- 3.5. Publication 4 - A Scoping Review on Using Real-World Data to Evaluate the Effectiveness of mHealth Applications

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A scoping review on using real-world data to evaluate the effectiveness of mHealth applications

Sara Gehder^{1,4}✉, Stefanie Brückner^{2,4}, Stephen Gilbert^{2,3} & Moritz Goeldner¹

Mobile health (mHealth) applications are increasingly integral to healthcare delivery, yet traditional randomized trials face practical challenges in evaluating these dynamic tools. Real-world data (RWD), collected during routine app use, offers a complementary pathway to real-world evidence (RWE) that may reflect how mHealth applications are used in everyday settings. We conducted a scoping review to map how naturally emerging RWD are currently used in peer-reviewed studies to evaluate patient-facing mHealth applications. We systematically searched PubMed, Scopus, and Web of Science (January 2007–November 2024) and extracted data on application type, RWD characteristics and study design aspects. Study-level, design-centred evidence levels for RWD-based effectiveness evaluations were assigned using a combined Oxford Centre for Evidence-Based Medicine and FDA RWE framework. Seventy-two studies evaluating 61 unique mHealth applications were included. Most studies focused on mental health or metabolic conditions and relied predominantly on data actively reported by users, often via in-app surveys, with comparatively limited use of device-generated data or integration with system-generated data such as clinical or claims data. Single-group pre–post approaches were most frequently observed, while only a minority employed comparative observational, quasi-experimental, or randomized designs. These findings illustrate current patterns in the use of RWD for mHealth evaluation and highlight both opportunities and constraints in longitudinal and comparative assessments of mHealth applications in real-world contexts.

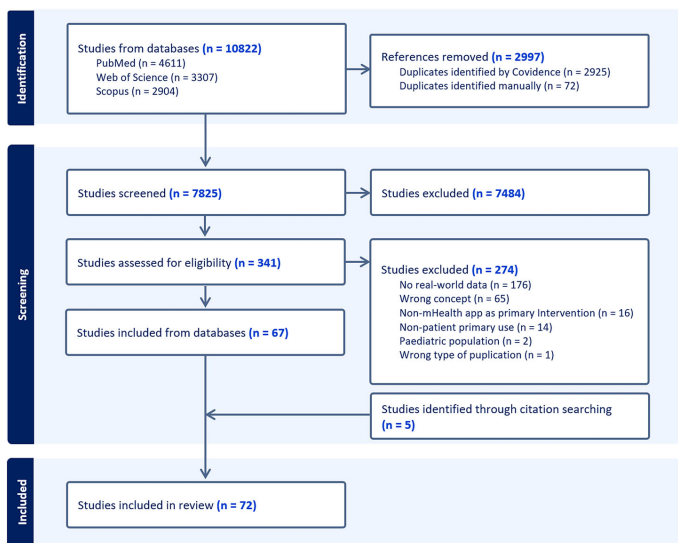
The integration of mobile and wireless technologies into healthcare (mHealth) is transforming health service delivery globally, particularly in resource-limited and remote settings, contributing to Sustainable Development Goal 3 on universal health and well-being^{1,2}. Central to this transformation are mobile health applications, now widely adopted, with over 337,000 health apps listed in Apple App Store and Google Play Store³, and an estimated 200 new digital health apps released daily across app stores⁴. Patients value their accessibility and personalization⁴, and many apps now support chronic disease self-management and behavior change.

To support the safe and effective use of digital health technologies, regulatory and reimbursement pathways, such as Germany's DiGA pathway⁵ (app on prescription) and the UK's NICE Evidence Standards Framework⁶, alongside similar initiatives internationally^{7–10}, have introduced structured evidence expectations^{11,12}. In parallel, real-world data (RWD) is playing an increasingly important role in regulatory decision-making, market access, and post-market performance monitoring for mHealth interventions^{13–16}.

Robust evidence is critical for enabling these pathways. Clinicians and payers alike emphasize the need for stronger evidence bases to inform decisions about the use of mobile health applications in practice⁷. However, evaluating the effectiveness of software-based health interventions presents methodological challenges. Traditional randomized controlled trials (RCTs), while considered the gold standard for establishing causal effectiveness of interventions, face practical challenges for digital tools due to rapid product iteration cycles, personalized delivery and the integration into care pathways^{18–21}. Another methodological challenge is the proper blinding of patients and providers. Digital placebos, so-called sham apps, that mimic the digital intervention without the active therapeutic component, have been introduced but require further investigation for widespread application²². RWD, defined as routinely collected, longitudinal health data from everyday clinical or user interactions²³, is increasingly recognized as an important complementary data source to generate real-world evidence (RWE) and regulatory guidance for its implementation is evolving^{24,25}.

¹Data-Driven Innovation, Hamburg University of Technology, Hamburg, Germany. ²Else Kröner Fresenius Center for Digital Health, TUD Dresden University of Technology, Dresden, Germany. ³Faculty of Business and Economics, TUD Dresden University of Technology, Dresden, Germany. ⁴These authors contributed equally: Sara Gehder, Stefanie Brückner. ✉e-mail: sara.gehder@tuhh.de

Fig. 1 | PRISMA Flow Diagram Illustrating the Study Selection Process.



However, the quality and validity of RWE, defined as “the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD”²³, depends on the quality of the RWD source, how it is generated and how it is evaluated to yield meaningful insights into the performance of mHealth applications. Key considerations include whether data are captured as part of routine product use or introduced solely for research purposes, and whether collection is passive (e.g., through sensors or usage logs) or active (e.g., user-entered symptom tracking). Structured, nonobtrusive in-app data capture is generally considered to better reflect real-world use compared to study-specific instruments administered externally, which may introduce bias or alter user behavior^{26–28}. Moreover, the strength of the resulting RWE is determined by study design, including the presence of comparators and the use of causal inference methods, in alignment with guidance from frameworks such as the Oxford Centre for Evidence-Based Medicine (OCEBM)²⁹ and the FDA’s RWE guidance²³.

Despite the potential of mHealth applications to generate valuable RWD, it remains unclear how extensively such data are used in the peer-reviewed literature to evaluate real-world effectiveness. In some cases, apps may lack the infrastructure to support data generation; in others, available data may remain underused due to technical, methodological, or regulatory barriers. To better understand this landscape, we examined published studies as a proxy for current practice. Published evaluations provide insight into how RWD are currently used and reported in the peer-reviewed literature and therefore serve as a practical lens for understanding the current state of evidence generation. At the same time, existing evaluations span highly heterogeneous application types, clinical domains, data sources, outcome constructs, and study designs, and no standardized framework yet exists to structure RWD-based evaluation of mHealth interventions. Against this backdrop, a scoping review allows a structured mapping of how RWD are currently being used across these dimensions.

To this end, we conducted a scoping review to systematically map the landscape of published studies evaluating mHealth applications using RWD. Our analysis focused on patient-facing applications that collect “naturally emerging” RWD from routine app use, without the use of study-

specific data collection instruments. We considered three categories of RWD: user input, device-generated, and system-generated data.

Our review addressed the following questions: To what extent is RWD generated through the routine use of mHealth applications used to (continuously) demonstrate their effectiveness in improving care, as reflected in peer-reviewed studies?

1. Which types of patient-focused mHealth applications currently incorporate naturally emerging RWD in studies for effectiveness evaluation?
2. What categories and types of naturally emerging RWD from routine app use are being reported in these studies?
3. Which study designs are used to assess the effectiveness of specific mHealth applications using naturally emerging RWD, and how do they align with regulatory and scientific recommendations?

By synthesizing the current state of scientific practice, this scoping review aims to identify emerging patterns, gaps, and methodological challenges in leveraging RWD to evaluate how effectiveness is assessed in mHealth. In doing so, we seek to inform future research, guide regulatory development, and support more targeted validation frameworks for digital health technologies.

Results

Screening results

Our search identified 10,822 records across three databases (Fig. 1). After removing duplicates, 7,825 records underwent title and abstract screening, yielding 341 studies for full-text review. 67 studies met the eligibility criteria. Citation tracking of included studies identified 5 additional studies. In total, 72 studies were included.

Characteristics of identified studies

The 72 included studies were published between 2016 and 2024, with an increase in yearly publications from 2021 onward. The studies spanned 16 countries, with the United States ($n = 28$) most represented, followed by Germany ($n = 6$), China ($n = 5$), the United Kingdom ($n = 5$), and France ($n = 4$). Seven studies were multinational, while the country of origin was

Table 1 | Number of apps and studies across potential regulatory status and mHealth category

Potential Regulatory Status	mHealth Category	# of apps	# of studies
Potentially General Health & Wellness Tool		13	17
	Health & Care Diaries	3	3
	Promoting good health	10	14
Potentially Medical Device		48	55
	Inform Clinical Management	16	17
	Drive Clinical Management	6	8
	Treat Specific Condition	26	30
	Diagnose Specific Condition	0	0
Total		61	72

unclear in three studies. Among the 72 included studies, 61 distinct mHealth applications were evaluated. Three applications were assessed in three studies each, and five additional applications appeared in two studies each. Full study-level characteristics with citations are provided in Supplementary Table 2.

Characteristics of mHealth applications

To assess the medical device (MD) status of the 61 patient-facing mHealth applications included in the studies, we reviewed whether each app met the criteria for classification under the EU Medical Device Regulation (MDR)³⁰ and the accompanying guidance MDCG 2021-24³¹. None of the included studies explicitly reported device classification. However, for 16 applications, regulatory status was confirmed via developer websites or the EUDAMED database. For the remaining tools, MD classification was inferred based on publicly available product descriptions of their intended medical use. This was combined with an assignment of their respective mHealth category, drawing on a hybrid framework adapted from Olla & Shimskey³² and the NICE Evidence Standards Framework³³. Based on this assessment, 48 applications met the criteria for medical devices (Treatment, Diagnosis, guiding medical choices), while 13 fell into the general health and wellness category. While this does not constitute a formal regulatory designation, it provides a consistent overview of risk classification.

Twenty-six applications were designed to treat specific conditions, 16 to inform clinical management, and six to drive clinical decision-making. No application was classified under diagnostic use. Table 1 summarizes the number of applications and associated studies per potential regulatory status and mHealth category.

The 61 applications addressed a variety of clinical areas, with the most common being mental health (*n* = 19), endocrine and metabolic disorders (*n* = 18), cardiovascular conditions (*n* = 7), and musculoskeletal disorders (*n* = 6). Additional applications focused on reproductive health (*n* = 4), nervous system disorders (*n* = 3), and genitourinary conditions (*n* = 1). Three applications addressed less common or cross-cutting clinical areas not listed above and are detailed in Table 2, which also presents the mapping between medical specialties and mHealth categories.

Characteristics of real-world data

RWD characteristics were categorized according to a predefined taxonomy (Supplementary Note 2). App-collected user input data was the most frequently used category of RWD, appearing in 71% (51/72) of studies, followed by device-generated data in 26% (19/72) and system-generated data in 7% (5/72) (Table 3). Because three studies used more than one RWD category (e.g., user input combined with device-generated data), these proportions sum to more than 100%. These three studies are further labeled as hybrid. Fewer studies used system-generated data (7%, 5/72). As shown in Fig. 2, the first publications found using RWD focused mainly on user input data. Over the next few years, device-generated data or a combination of both will be increasingly used.

Among the studies using user input data, either alone (*n* = 48) or in combination with device-generated data (*n* = 3), the total number was 51. The most common data type in these studies was in-app surveys (68%, 35/51), capturing symptoms, disease severity, and pain scores. Within this group of studies, 63% (22/35) used validated instruments, such as Patient Health Questionnaire-9 (PHQ-9) or Insomnia Severity Index (ISI), while 37% (13/35) used surveys that were not described as established, previously validated Patient Reported Outcome Measures (PROMs) in the respective publications. Other studies collecting vital stats (24%, 12/51), such as body weight or blood pressure measurements, were also frequent, while event tags (8%, 4/51), including entries like smoking or unprotected sexual activity, were less common.

In total, 19 studies used device-generated data - 16 exclusively, and three in combination with user input data. The most frequently used data type in this group was connected devices (79%, 15/19), such as Bluetooth-enabled scales, Continuous Glucose Monitoring (CGM) devices, or activity trackers. User device-generated activity data (11%, 2/19) included passively recorded step counts, task performance data (5%, 1/19) assessed cognitive or motor function, and app engagement metrics (5%, 1/19) tracked user interaction frequency.

Studies using system-generated data equally relied on admission/discharge reports (20%, 1/5), procedures (20%, 1/5), and vital statistics from electronic health records (20%, 1/5). Medication data from claims were used in 20% of studies (1/5), and one study (20%, 1/5) used both medication data and admission/discharge reports.

Among all studies, continuous data collection (44%, 32/72) was most common (Fig. 3). Continuous data collection in this review includes both truly continuous (e.g., passive sensor data) and continual (e.g., daily symptom trackers) modes with a high frequency of data collection (e.g., daily or at every app use). Intermittent collection (24%, 17/72) allowed participants to self-report data at chosen time points. Periodic collection (22%, 16/72) followed predefined intervals (other than daily), while one-off collection (10%, 7/72) involved a single data entry. In user input data studies (*n* = 51), continuous collection (38%, 19/51) and intermittent collection (33%, 17/51) were the most frequent, while periodic (27%, 14/51) and one-off (2%, 1/51) were less common. In device-generated data studies (*n* = 19), continuous collection (74%, 14/19) was predominant, while periodic (11%, 2/19) and one-off collection (11%, 2/19) were less frequent. In system-generated data studies, one-off data collection was the most frequent (80%, 4/5) while continuous data collection was less common (20%, 1/5).

Use of RWD categories per medical specialty and mHealth application category

Among studies centered on mental health applications (*n* = 24), user input data dominated (92%, 22/24), while device-generated and system-generated data were each used in 4% (1/24). In studies on endocrine and metabolic applications (*n* = 21), device-generated data were most frequent (52%, 11/21), followed by user input (38%, 8/21) and system-generated data (10%, 2/

Table 2 | Number of apps and studies across medical specialty and mHealth category

Medical Specialty	mHealth Category	# of apps	# of studies
Mental Health		19	24
	Treat Specific Condition	13	16
	Promoting good health	4	6
	Inform Clinical Management	1	1
	Drive Clinical Management	1	1
Endocrine and Metabolic System		18	21
	Treat Specific Condition	2	2
	Promoting Good Health	5	7
	Inform Clinical Management	9	10
	Drive Clinical Management	1	1
	Health & Care Diaries	1	1
Cardiovascular System		7	7
	Treat Specific Condition	2	2
	Inform Clinical Management	4	4
	Drive Clinical Management	1	1
General Wellbeing		3	3
	Health & Care Diaries	2	2
	Promoting Good Health	1	1
Nervous System		3	3
	Treat Specific Condition	2	2
	Inform Clinical Management	1	1
Musculoskeletal System		6	7
	Treat Specific Condition		
Reproductive health	Drive Clinical Management	2	4
Respiratory System	Drive Clinical Management	1	1
Cancer	Inform Clinical Management	1	1
Genitourinary System	Treat Specific Condition	1	1
Total		61	72

Table 3 | Number of studies across data categories and data types. Studies may contribute data to more than one category or type; counts are therefore not mutually exclusive

RWD Categories	RWD Types	# studies
User Input Data		51
	In-App-Survey	35
	Vital Stats	12
	Event tags	4
Device-Generated Data		19
	Connected Device	15
	Activity Data	2
	Task Performance	1
	App Engagement	1
System-Generated Data		5
	Procedures (EHR)	1
	Admission/Discharge and Progress Reports (EHR)	1
	Vital Stats (EHR)	1
	Medication Use (claims data)	1
	Medication Use (claims), Admission/Discharge and Progress Reports (claims)	1

21). Studies on musculoskeletal applications ($n = 7$) relied mostly on user input data (86%, 6/7), with one study (14%) using system-generated data. Among studies on cardiovascular applications ($n = 7$), device-generated data (43%, 3/7) and user input data (29%, 2/7) were most frequent, with combined user input and device-generated (14%, 1/7) and system-generated data (14%, 1/7) also used. Information for additional specialties and data types are summarized in Fig. 4.

For studies on applications treating specific conditions ($n = 30$), user input data was most used (83%, 25/30), followed by device-generated data (11%, 3/30), while system-generated data was used at 6% (2/30). For studies on applications informing clinical management ($n = 17$), device-generated data (59%, 10/17) was the most common RWD category, followed by user input data (24%, 4/17), while user input and device-generated data were combined in 12% (2/17), and system-generated data was used in 5% (1/17). Among studies on applications promoting good health ($n = 14$), user input data was dominant (79%, 11/14), with device-generated data used in 14% (2/14) and system-generated data in 6% (1/14). For studies on applications driving clinical management ($n = 8$), user input data was used in 75% (6/8), with user input and device-generated data combined in 13% (1/8), and system-generated data in 13% (1/8). In studies on health and care diary applications ($n = 3$), user input data was most common (67%, 2/3), while device-generated data was used in 33% (1/3).

Study design characteristics and levels of evidence in effectiveness evaluation

Evidence levels were assigned using a hybrid classification based on the Oxford Centre for Evidence-Based Medicine (OCEBM) hierarchy²⁹ and the

Fig. 2 | Number of Studies published per year per Data Category.

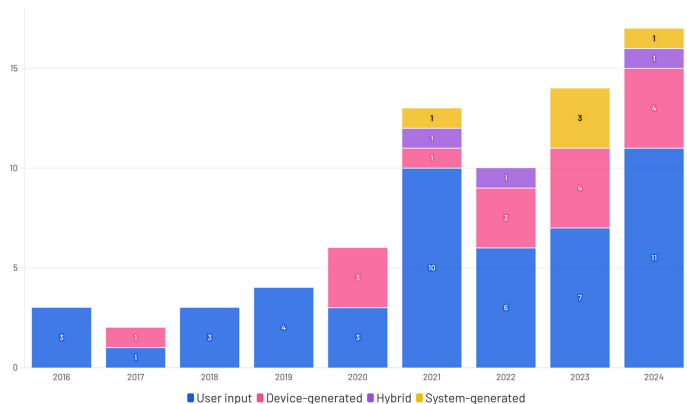
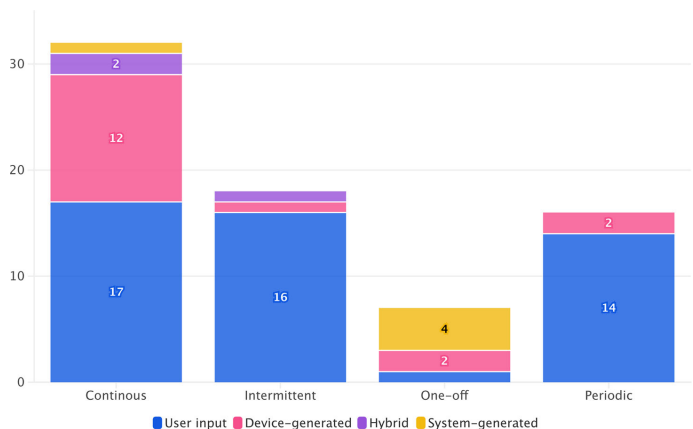


Fig. 3 | Distribution of Data Collection Frequency Across Data Categories in Identified Studies.



FDA RWE framework²³ (see Methods and Supplementary Note 3). Among the 72 included studies, the majority (57%, 41/72) were classified as level 4 evidence, using pre-post single-group designs with individual comparisons. Twenty-one studies (29%, 21/72) fell into level 3b, consisting of observational cohort studies that used intergroup comparisons without matched external comparators. Seven studies (10%, 7/72) were categorized as level 3a, employing quasi-experimental real-world evidence (RWE) designs with comparators. Finally, three studies (4%, 3/72) met criteria for level 2 evidence: one randomized controlled trial (RCT), one pragmatic randomized controlled trial (PCT), and one prospective cohort study with a concurrent control group.

Of the 72 studies, only 10 (14%, 10/72) included a real comparator such as a propensity score-matched or self-selected usual-care comparator. Two retrospective studies using system-generated data employed propensity score-matched usual-care comparators. In this group, the other three studies, using clinical data, were prospective and used either a randomized or self-selected usual-care comparator. Studies using device-generated data included one prospective study with a propensity score-matched comparator derived from clinical data and one retrospective study with a self-selected usual-care comparator using data from the products platform.

Among the three studies relying on user input data, one prospective study used self-selected limited app feature usage as a comparator, and two retrospective studies used either propensity score-matched usual care from registry data or propensity-adjusted comparisons across therapeutic modules. Detailed descriptions of study design, evidence levels, and comparator types are provided in Supplementary Table 3.

Study sample sizes varied considerably (Fig. 5), with a median of 1529 participants (mean: 10,666). Retrospective studies generally had larger sample sizes (median: 2027; mean: 12,888) compared to prospective studies (median: 633; mean: 3999). Study durations ranged broadly from 14 days to 5 years, with a median duration of 180 days (mean: 300 days). Short-term studies (≤ 90 days) comprised approximately 33% (24/72), and studies of intermediate duration (6 months–1 year) accounted for 44% (32/72). Long-term studies exceeding 1 year were less common, representing 22% (16/72) of the total.

Discussion

This scoping review examined how RWD generated during routine use of patient-facing mHealth applications is being used to support effectiveness evaluation in peer-reviewed studies. Using published research as a proxy for

Fig. 4 | Distribution of real-world data categories across medical specialties in identified studies (Bubble sizes relate to the number of studies).

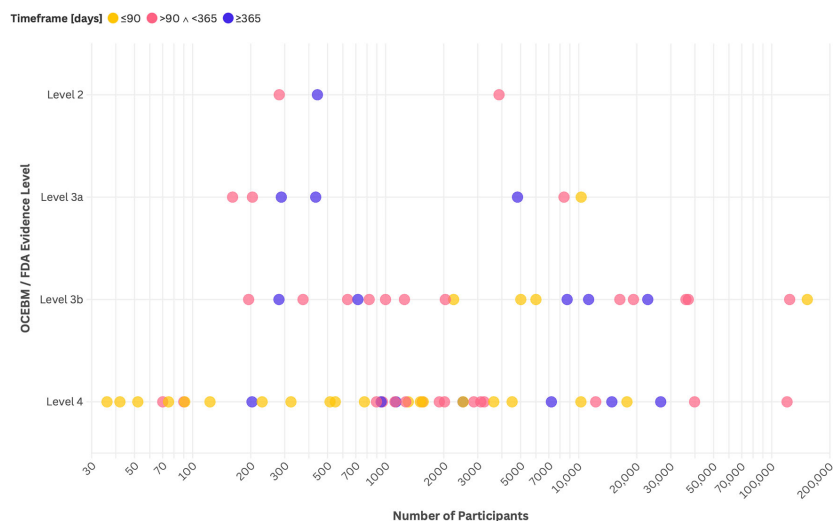
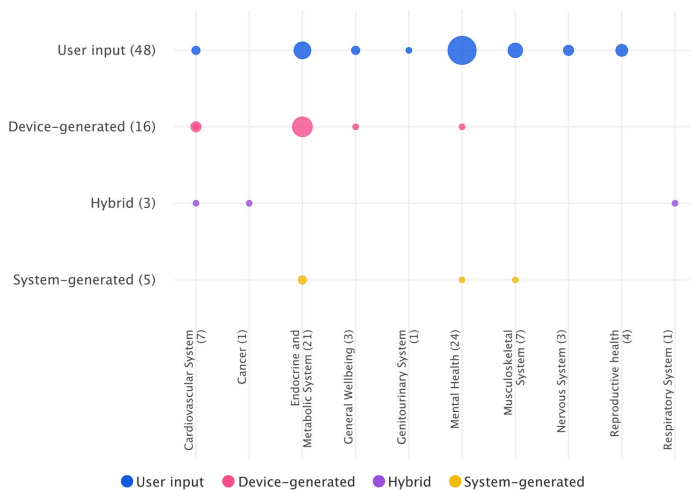


Fig. 5 | Distribution of evidence level and study size (number of participants) in identified studies (Bubble color represents the duration (in days) over which application usage was monitored).

current evidence-generation practices, we mapped types of mHealth applications assessed with RWD, the data categories and types employed, and the range of the study designs and respective evidence levels used. We observed substantial variation in RWD characteristics and study designs, highlighting current patterns and gaps in the integration of RWD into effectiveness assessments across the field.

In 72 included studies, we identified 61 unique mHealth applications using naturally emerging RWD. These were unevenly distributed across medical specialties and application types. The observed concentration of applications in mental health ($n = 19$) and endocrine/metabolic disorders

($n = 18$) suggests that these domains may be more amenable to current RWD collection and evaluation practices. In mental health, 89% of applications (17/19) used data actively entered by the user, most commonly via in-app symptom surveys (e.g., PHQ-9, ISI), aligning with the clinical need to capture subjective patient perceptions such as mood, anxiety, or sleep quality³⁴. In metabolic disorders, 50% (9/18) employed device-generated data, e.g., from connected sensors such as continuous glucose monitors and Bluetooth-enabled scales, supporting the collection of objective physiological data³⁰. Interestingly, musculoskeletal and mental health apps rarely use wearable sensor data despite demonstrated potential to enhance objective

outcome assessments³¹. Notably, no diagnostic application using RWD was identified, which may reflect broader challenges in generating the type of high-quality RWD, such as structured clinical observations or confirmatory testing, needed to evaluate diagnostic performance^{23,35}.

The characteristics of RWD employed also reflect opportunities and constraints. User input data was the most common data category, used in 71% of studies (51/72), reflecting how easily such data can be embedded into app interfaces. When only considering studies using in-app surveys (35/72), we found that more than a third (37%, 13/35) relied on non-validated instruments, which may limit comparability across interventions and complicate interpretation across studies. While PROMs offer valuable insights into subjective health states, their evidentiary value depends heavily on standardization and methodological rigor. In contrast, device-generated data from connected devices appeared in only 26% of studies (19/72), despite their potential to provide objective, high-frequency, and passive monitoring. Although especially useful in conditions with clear physiological markers, such as glucose levels in diabetes, wearable and sensor data are currently less frequently represented in domains like mental health, where emerging evidence suggests they could serve as proxies for clinical symptoms such as depressive episodes³¹. Only three hybrid studies (3/72) combined multiple RWD categories. However, integrating data from various categories can enhance the comprehensiveness and robustness of evaluations^{36,37}. For instance, combining subjective PROMs with continuous glucose data has been shown to improve the precision and timeliness of diabetes management⁴⁸. The rare use of system-generated data (5/72) underscores the lack of integration between health apps and healthcare systems. At the same time, the current fragmentation of data use reinforces the broader need to tailor evidence strategies to the capabilities and constraints of specific mHealth application types, rather than relying on uniform evaluation models³⁹.

The distribution of study designs illustrates the range of methodological approaches currently used in published RWD-based mHealth evaluations. Evidence levels in this review reflect study design characteristics and should not be interpreted as supporting effectiveness inference. In practice, most studies relied on pre-post single-group designs without comparators, which correspond to lower evidence levels within our classification framework adapted for the scope of this review from the OCEBM²⁹ and FDA RWE framework²³ (Supplementary Note 3). Only a minority employed quasi-experimental approaches or included real-world comparator groups, despite clear regulatory guidance encouraging the use of external or synthetic controls for RWE generation^{40–42}. Notably, the few studies integrating clinical or claims data as comparators achieved higher levels of evidence. For example, one prospective cohort study evaluating an app designed to reduce emergency department admissions used routine EHR data to construct a concurrent usual-care comparator, raising its evidence level from 3b to 2a³⁹. Importantly, among studies using system-generated health data, a small number employed randomized or pragmatic randomized designs, suggesting compatibility between controlled trial methodologies and real-world data. This underscores the value of linked, longitudinal data in improving study quality. Even among studies that collect substantial volumes of RWD, design features such as the absence of predefined outcomes, short study durations, or passive observational designs constrain the types of inferences these studies are able to support. While retrospective designs are cost-efficient and often feature large samples, they typically lack the planning necessary to control for bias. To advance evidentiary standards, future research should incorporate more rigorous comparator strategies, including pragmatic randomized controlled trials⁴³ or advanced quasi-experimental methods like interrupted time series or difference-in-differences analyses²⁴.

mHealth applications' inherent capability to continuously collect RWD uniquely positions them for dynamic, ongoing effectiveness monitoring on-market, aligning well with evolving health technology assessment frameworks^{24,44}. However, this potential is not yet widely reflected in current evaluation designs. Although 44% of studies (32/72) employed continuous or continual data collection, the majority (56%, 40/72) relied on

intermittent, periodic, or one-off approaches and only 22% of studies (16/72) featured a long-term follow-up. This indicates that most evaluations still treat app data as static snapshots rather than sources of real-time, evolving insight, highlighting a broader gap in the sustained assessment of effectiveness over time.

A key strength of this review is its transparent approach to mapping how naturally emerging RWD is currently used to evaluate patient-facing mHealth applications. We applied predefined, literature-based frameworks to classify application types (NICE Digital Health Technology evidence standards³³), RWD categories (adapted from Swift et al.⁴⁵), and study design characteristics (based on the Oxford Centre for Evidence-Based Medicine²⁹ and FDA RWE guidance²³). This structured methodology, combined with a piloted and expert-informed data extraction process, enabled a detailed cross-sectional overview of current evaluative practices. The synthesis highlights methodological gaps and provides a foundation for aligning future evidence generation with evolving regulatory expectations. All extracted data is available in Supplementary Tables 2 and 3 to support transparency and reproducibility.

This review has several limitations. Only peer-reviewed, English-language publications were included, which may have introduced language bias and excluded gray literature. Despite iterative refinement of search strings, the absence of standardized terminology in digital health may have led to missed studies. Our focus on effectiveness outcomes reflects regulatory priorities but excludes other important aspects such as safety, cost-effectiveness, or user experience, which warrant further investigation. Although we searched three major medical and multidisciplinary databases, we did not include engineering-focused databases such as IEEE Xplore or the ACM Digital Library. As a result, some technically oriented studies without a primary clinical effectiveness focus may not have been captured. Study selection involved initial calibration by two reviewers on a random sample, followed by independent screening with regular consensus checks; although inter-rater reliability was not formally calculated, this consensus-based approach aligns with best practice in scoping reviews. Data extraction and study classification were conducted by a single reviewer. While this approach is acceptable for scoping reviews, it may increase the risk of misclassification, particularly given the multi-dimensional nature of our framework (mHealth application category, RWD source, study design, and evidence level). To mitigate this risk, data extraction was piloted by two reviewers with 10 studies, classification rules were predefined, and regular consensus discussions were held within the review team to resolve ambiguities. Nevertheless, some degree of subjective interpretation cannot be fully excluded. In addition, some included studies evaluated mHealth applications delivered under trial-like/highly structured care settings. Although these outcomes were generated via routine in-app functionality and classified as RWD in this review, these hybrid contexts are not fully naturalistic and may limit generalisability. Finally, because traditional frameworks like OCEBM do not fully capture how digital health tools generate and use RWD, we combined it with the FDA's RWE framework. The combination of OCEBM and FDA RWE frameworks was necessary to address the unique features of digital health data, but further tailored evaluation standards are needed. Our evidence-level classification is applied at the level of the individual RWD-based effectiveness study and is design-centred; it does not constitute a comprehensive reassessment of the overall clinical effectiveness or regulatory evidence base for the underlying technologies. The absence of widely accepted evaluation standards reinforces the need for baseline mapping of current practices, which this review provides.

Although support for RWE in policy is growing, its adoption in digital health research remains limited. While study volume has increased since 2021, the overall number of evaluations using RWD to generate evidence remains modest and highlights a gap between regulatory ambition and implementation. This reflects ongoing challenges in translating policy ambitions into research practice⁴⁶. Most studies relied on limited data types, short follow-up periods, and non-comparator designs, with only a few integrating external data sources or using designs aligned with higher evidence levels. These patterns may reflect a combination of factors, including,

Box 1 | Practical implications for advancing RWE-based evaluation of mHealth

Evidence generation

- Future studies could increasingly move from predominantly single-group pre-post designs toward comparator-based and quasi-experimental approaches, including pragmatic randomized designs where feasible.
- Greater use of validated PROMs may help with subjective outcomes to support reliability and comparability across studies.
- The longitudinal nature of mHealth data offers opportunities for sustained effectiveness monitoring rather than short-term snapshot evaluations.

Technology design and data infrastructure

- Expand the use of device-generated and passive sensor data, particularly beyond metabolic indications and into domains such as mental health.
- Design applications with interoperability and future linkage to clinical and administrative data as a core requirement.

Health system and regulatory context

- Strengthen technical and governance frameworks for secure app-EHR/claims data linkage to enable higher-quality real-world evidence generation.
- Support fit-for-purpose RWE standards that reflect the iterative and data-rich nature of mHealth and incentivize longitudinal, comparator-based post-market evaluation.

but not limited to, the continued predominance of trial-centered evaluation practices in some regulatory contexts⁷ and the substantial heterogeneity of existing digital health evaluation frameworks⁴⁸. To advance the field, adaptable but clear regulatory frameworks and improved access to clinical and claims data will be essential^{49,50}. In this context, the forthcoming European Health Data Space may play a pivotal role by facilitating secure access to high-quality clinical data from routine care, thus enabling more rigorous and integrated real-world evidence generation⁵¹. Importantly, future mHealth evidence-generation strategies may benefit from stronger integration of comparator designs, continuous data capture, and multi-source RWD linkage. These steps will enhance the credibility and impact of mHealth applications in real-world care. To translate these system-level challenges into practical next steps for evidence generation, technology design, and policy, we summarize key implications in Box 1.

Methods

We conducted a scoping review following the framework by Tricco et al.⁵². to map how RWD are used in peer-reviewed studies evaluating the effectiveness of mHealth applications and to identify key themes and research gaps. This format was chosen to characterise current evaluation practices focusing on RWD characteristics, study designs and applied evidence frameworks, rather than to estimate the intervention effectiveness or establish causal effects. The PRISMA-ScR checklist⁵³ guided reporting (Supplementary Table 1), and the protocol was registered prospectively on the Open Science Framework (<https://osf.io/3f5ur/>).

Search strategy

A three-step search strategy, based on Joanna Briggs Institute (JBI) guidelines^{54–56}, was implemented. A preliminary search in PubMed identified key articles related to mHealth, RWD use, and effectiveness assessment. Using 11 key studies as a starting point, a search strategy was developed, refined with an expert librarian, and adapted for PubMed, Scopus, and Web of Science. These databases were selected to provide comprehensive coverage of biomedical, clinical, and applied digital health research. The search strings combined three core concept blocks: (1) mHealth and digital health applications (e.g., “mHealth app”, “digital health application”), (2) effectiveness and performance outcomes (e.g., “effectiveness”, “clinical outcome”, MeSH terms for outcome assessment), and (3) real-world data concepts (e.g., “real-world data”, “real-world evidence”, “electronic health records”, “claims data”, “registry”). The final searches for all databases were executed on November 29, 2024. Backward and forward citation tracking supplemented database searches. No direct contact with study authors was undertaken to identify additional sources. The complete electronic search strings with all Boolean operators and database-specific search string adaptations are provided in Supplementary Note 1.

Eligibility criteria

We defined eligibility criteria using the PCC (Population, Concept, Context)⁵⁴ framework. The population included studies evaluating mHealth applications designed for independent use by patients to improve health or clinical outcomes. Applications intended for use primarily by healthcare professionals or caregivers were excluded.

The context focused on the use of naturally emerging RWD to support the effectiveness-related evaluation of these applications. Naturally emerging RWD were defined as data produced during routine app use through standard in-app functionality, whether actively entered by users, passively captured by sensors or integrated from health-system sources, without study-specific instruments.

The context was real-world care settings, for example, home or routine clinical practice. Study-specific recruitment and participant onboarding were permitted. Inclusion was based on outcome data captured through standard app functions during routine use, as well as routinely collected healthcare system data generated in the context of real-world application use, and excluded outcome data collected via external, study-specific research instruments. We focused on patient-facing mHealth applications that support health improvement or clinical outcomes, specifically those used independently by adults for self-management and health information tracking. To maintain this focus, we excluded apps developed primarily for productivity or efficiency enhancement, as well as those intended solely for educational purposes or for patient-provider communication.

The publication timeframe (January 2007 to November 2024) was selected to align with the introduction of modern touchscreen smartphones and the resulting emergence of mHealth applications as a distinct category of digital health technologies. Restriction to peer-reviewed literature was applied to ensure a minimum level of methodological reporting quality and scientific scrutiny. Studies published in English were included due to resource constraints for high-quality translation. A minimum sample size threshold of 30 participants was applied to exclude pilot-level feasibility studies and to ensure inclusion of studies with a basic level of empirical stability for mapping evaluation practices.

Additional application characteristics were specified to guide consistent inclusion and exclusion decisions, particularly regarding intended use and functionality. Full criteria are detailed in Table 4.

Study selection

Search results were imported into Covidence (Veritas Health Innovation) for automated duplication removal, title, abstract, and full-text screening. Two reviewers (S.B. and S.Ge.) independently screened a random sample of 20 studies to calibrate inclusion decisions. Following calibration, both reviewers independently screened all titles, abstracts, and full texts at each stage against the predefined eligibility criteria. Disagreements were resolved through consensus meetings. If consensus could not be reached, a third

Table 4 | Eligibility criteria based on the PCC framework (Population, Concept, Context)

Criteria	Inclusion	Exclusion
Population	Studies with a focus on mHealth applications designed for independent use by patients in real-world settings Study participants 18 years or older	Studies focusing on mHealth applications intended to be used by HCPs or caregivers Studies focusing on mHealth applications designed to collect data for HCPs without an interface for patients or without an active role for the patient in data collection and usage Study participants under 18 years
Concept	Studies evaluating the effectiveness of mHealth applications in achieving their intended health outcomes using RWD Preliminary efficacy studies were included, provided they were conducted with diagnosed patients	Studies evaluating user experience, usability, or acceptance of mHealth applications Studies on economic value/cost savings Preliminary efficacy, validation or feasibility studies with fewer than 30 participants
Context	Studies conducted in real-world care settings (e.g., at home, in the community or clinical practice) Studies acquiring data within routine use of the application using standard in-app functionalities (e.g., sensor tracking, app usage logs, in-app symptom tracking, in-app surveys), without modification of the core application functionality for research purposes. Study-specific recruitment was permitted Studies using routinely collected healthcare system data generated in the context of real-world application use (e.g., claims data, electronic health records, pharmacy dispensing data, or hospital utilization)	Study settings not reflecting real-world use of the device (e.g., simulated or laboratory-based settings) Studies using applications modified specifically for research Studies in which outcome data were collected primarily through external, study-specific instruments or platforms explicitly described as separate from the routine app environment, including separate survey tools, email questionnaires, or non-app-based assessments. Studies where data is generated primarily through professional-grade equipment in structured clinical environments (e.g., hospital at home), even if supplemented by consumer wearables
Application Characteristics/Scope	mHealth applications, defined as smartphone or web-based health applications on mobile devices (e.g., smartphones and tablets) mHealth applications may operate standalone or in combination with (external) sensors mHealth applications must be intended to improve health outcomes, support behavior change, or assist with chronic disease self-management	mHealth applications designed solely for passive information delivery (e.g., educational apps without tracking, personalization, or intervention components) mHealth applications limited to patient–provider communication (e.g., secure messaging platforms, SMS-based triage, or remote consultation tools) that do not generate patient-entered or device-captured data during routine use and do not provide a patient-facing data interface
Other Criteria	Peer-reviewed empirical studies using quantitative, qualitative, or mixed methods Studies published between January 2007 and November 2024 Language of publication: English	Reviews, books or non-empirical research (e.g., systematic reviews, letters, opinion pieces, theoretical papers) Study protocols and non-peer-reviewed articles (e.g., preprints, unpublished trial data, conference proceedings) Studies published before 2007 Studies published in languages other than English

author was consulted to make a final determination. The study selection process is summarized in the PRISMA flow diagram (Fig. 1).

Data extraction and analysis

Two reviewers (S.B. and S.Ge.) developed a standardized data extraction form (Google Sheets), piloted it with 10 studies, and iteratively refined it based on included studies and an expert interview with an mHealth scientific director. In line with JBI guidelines⁵⁴, final data extraction was conducted by one reviewer (S.Ge.), due to resource constraints. To ensure consistency and accuracy, regular discussions were held with the review team to resolve uncertainties and verify data interpretation. Data synthesis was performed in Microsoft Excel (Microsoft Office, 2019).

The following variables were extracted:

- Study details, including study title, authorship, DOI, year of publication, journal, country of participants, recruitment context (routine users vs. research-recruited), number of participants, and timeframe of data analysis (in days).
- Application details, including application name, medical specialty, primary intended app purpose, mHealth category, and potential medical device status, including whether formal regulatory information was publicly available.
- Data Details, including measured health outcome (study endpoint), mode of data collection (active vs. passive), RWD category (user input, device-generated, system-generated), data type (e.g. in-app surveys, connected devices, app engagement, EHR/claims data), use of validated in-app instruments, data collection frequency and frequency specifications, as well as up to two primary parameters and their associated measurement tools.

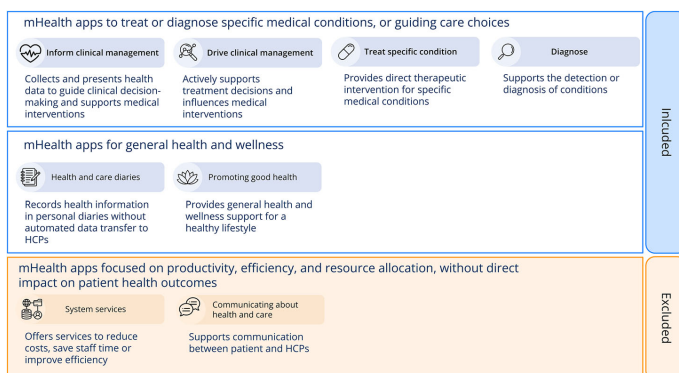
- Study Design Details, including study design classification based on the adapted OCEBM/FDA RWE framework, interventional versus observational intent, presence of randomization, temporal orientation (prospective vs. retrospective), mechanisms of outcome comparison (e.g., intra-individual, intergroup), type and nature of comparator or control condition, and assigned evidence level.
- Interpretive Study Design Summary, consisting of a structured free-text description of how real-world data were used in each study to evaluate the intended application purpose.

To classify the mHealth applications in categories, we used a combined framework based on the mHealth taxonomy by Olla & Shimskey⁷³ and the NICE evidence standards framework³³ (see Fig. 6), which stratifies tools based on their intended medical function. Applications were categorized according to their primary intended function, even when they featured multiple functionalities.

RWD were categorized using a refined version of the framework proposed by Swift et al.⁴⁵, tailored to mobile app–based interventions. The final taxonomy comprises three categories: User Input Data, Device-Generated Data, and System-Generated Data. User input data included in-app surveys capturing patient-reported outcomes, manually entered vital stats and event tags; device-generated data included connected devices, app engagement, task performance, and mobile device data like activity metrics; and system-generated data included admission/discharge reports, procedures, vital stats or medication variables derived from electronic health records and claims data. Details on the taxonomy adaptation process and category definitions are provided in Supplementary Note 2.

To assess study design, we applied the Oxford Centre for Evidence-Based Medicine (OCEBM) 2011 framework²⁹ in combination with the FDA Real-World Evidence framework²³, which together informed our classification of

Fig. 6 | Classification of patient-used mHealth applications to improve health outcomes based on the mHealth taxonomy by Olla & Shimskey, as well as the NICE evidence standard framework. MHealth applications included in the review are marked in blue. *System services and communicating about health and care* marked in orange are outside the scope of this review. HCPs = Healthcare professionals.



levels of evidence for the specific scope of this review. The combined evidence grading approach is described in Supplementary Note 3. Although mHealth applications constitute the unit of analysis in this review, the evidence grading is applied at the level of the individual effectiveness study and is specific to our research scope. Classification was based on structural study design characteristics, including interventional versus observational intent, presence or absence of randomization, temporal orientation (prospective versus retrospective), mechanisms of outcome comparison (intra-individual versus intergroup), and the presence and type of external comparator. No formal risk-of-bias appraisal was conducted, and the assigned evidence levels do not represent a comprehensive appraisal of the overall clinical effectiveness or regulatory evidence base of the respective technologies.

All analytical categories were operationalized during piloting of the data extraction form and assigned directly at the point of data extraction. When methodological reporting was ambiguous (e.g., whether an in-app survey was pre-existing or study-specific), conservative coding decisions were applied strictly based on explicit descriptions in the original publications. For in-app survey instruments, validation status was classified as validated when the study explicitly reported use of an established, previously validated PROM. Instruments developed specifically for the application or study without reference to prior validation were classified as not validated. No independent reassessment of psychometric properties or digital-format validation was performed. No imputation of missing variables was performed. The extracted study-level variables were then used as grouping variables for quantitative aggregation in Tables 1–3 and Figs. 2–5, and the narrative synthesis was structured iteratively around the predefined research questions and the resulting distributions.

Descriptive statistics and narrative synthesis identified key patterns and trends in the extracted data. Data are presented in tables and graphical formats where appropriate. Percentages are rounded to one decimal place where applicable, and continuous variables are summarized using medians (with means reported for descriptive reference). Unless otherwise stated, all proportions reported in the Results refer to the total number of studies included ($N=72$). Studies using hybrid data sources (e.g., user input combined with device-generated data) are counted in all applicable RWD categories; therefore, percentages across categories may exceed 100%.

This structured approach enabled comparability across studies. The full list of included studies and extracted data is provided in Supplementary Tables 2 and 3. No additional data were sought from the original study authors.

Critical appraisal of included sources

Consistent with the objectives of this scoping review and with PRISMA-ScR and JBI guidance, no formal critical appraisal or risk-of-bias assessment of

individual studies was conducted. The aim of this review was to map the extent, nature, and methodological characteristics of published evaluations using real-world data in mHealth, rather than to assess intervention effects or to compare the internal validity of individual studies. Moreover, the included evidence base comprised highly heterogeneous study designs (ranging from single-group pre-post studies to pragmatic randomized trials), app types, and data sources, which would have required multiple, design-specific appraisal tools and would not have supported a unified quality scoring approach. Accordingly, critical appraisal results were not used to inform study inclusion or data synthesis. Instead, methodological heterogeneity was addressed descriptively through explicit classification of study design features and evidence levels using the adapted OCEBM–FDA real-world evidence framework.

Data synthesis and summarization

Charted data were synthesized using descriptive quantitative methods and structured narrative synthesis. Study-level variables were aggregated using absolute counts and proportions to summarize distributions across application types, real-world data categories, and study design features. No statistical pooling or meta-analysis was undertaken, as the objectives of the review were descriptive and the included studies were highly heterogeneous with respect to interventions, outcomes, and data generation modalities. Findings were summarized across predefined analytical groupings aligned with the review questions and are presented in tabular and graphical form. The narrative synthesis was developed iteratively from the quantitative distributions to contextualize observed patterns, gaps, and methodological tendencies in the use of real-world data for mHealth evaluation.

Data availability

All data generated and analyzed during this study are included in the article and its Supplementary Information.

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Author contributions

S.Ge. and S.B. conceptualized and designed the study. S.Ge. and S.B. developed the search strategy and conducted title and abstract screening, with full-text review performed independently. S.Ge. extracted the data, with S.B. reviewing and discussing the extracted data for accuracy. S.Ge. drafted the manuscript, and M.G. and S.Gi. supervised the study. All authors had

access to the data and critically revised and edited the manuscript for important intellectual content. All authors read and approved the final version of the manuscript.

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Competing interests

S.B. declares no competing interests. S.Ge. is employed by a statutory health insurance company in Germany, with no relation to this work. M.G. has previously consulted DiGA manufacturers, unrelated to this study. S.Gi. is an Advisory Group member for the EY-coordinated “Study on Regulatory Governance and Innovation in Medical Devices” for the European Commission (DG SANTE). He has or has had consulting relationships with Una Health GmbH, Lindus Health Ltd., Flo Health UK Limited, Thymia Ltd., FORUM Institut für Management GmbH, High-Tech Gründerfonds Management GmbH, haeon plc and Ada Health GmbH and holds share options in Ada Health GmbH. S.Gi. is a News and Views Editor for npj Digital Medicine. S.Gi. played no role in the editorial handling of this article.

Additional information

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Correspondence and requests for materials should be addressed to Sara Gehder.

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4. Discussion

This cumulative dissertation set out to examine to what extent, and under which conditions, regulation can act as a driver of innovation in digital health, using the German DiGA Fast-Track as a case example and situating it within broader debates on evidence generation and real-world evidence (RWE). Across the four included publications, three overarching findings emerge.

First, addressing RQ1 on market development and drawing primarily on Paper 1 of this dissertation, the DiGA Fast-Track has enabled structured market formation and scaled access over time. The establishment of a reimbursable category and a defined procedural pathway lowered entry barriers and led to measurable expansion in listed applications, utilization, and negotiated pricing dynamics, alongside consolidation effects among leading products. Similar developments have also been noted in recent analyses of the DiGA ecosystem (e.g., GKV-Spitzenverband 2025; Schmidt et al. 2024). Figure 2A further indicates that the early expansion phase of the DiGA pathway between 2020 and 2023 was followed by comparatively fewer new entries in subsequent years. While this dissertation does not analyze the drivers of this development, it may indicate that the market is moving from an initial exploratory phase toward a more stabilized stage.

However, while the regulatory architecture successfully fostered market growth and procedural stabilization, its innovation effects remained concentrated at the level of access. The broadened value framework and formal openness to alternative evidence strategies did not translate into substantive shifts in value articulation or study design. Evaluation practices continued to align predominantly with established clinical paradigms, including a strong preference for endpoints framed as medical benefit and randomized controlled trials. Similar patterns of methodological conservatism in digital health evaluation have also been observed in recent analyses of digital therapeutics and DiGA evidence practices (Mahadik et al., 2025; Sippli et al., 2025).

Second, addressing RQ2 on value interpretation and institutional conditions, the pSVV pathway is conceptually compelling but operationally under-institutionalized. Papers 2 and 3 converge in showing that pSVV is rarely used as a primary endpoint and is predominantly treated as an auxiliary value category appended to demonstrations of medical benefit. Only a small subset of DiGA use pSVV at all, and today, no application employs it as a primary endpoint.

Beyond descriptive uptake, the qualitative analyses illuminate how pSVV is interpreted and negotiated within the ecosystem. While stakeholders generally acknowledge its conceptual relevance for digital health, it is perceived as methodologically ambiguous, lacking established measurement conventions, and subject to uncertain acceptance in

assessment practice. Combined with economic risk considerations, these conditions systematically favor medical benefit demonstrations. pSVV thus remains discursively supported but strategically deprioritized under prevailing institutional conditions (Paper 2).

From an innovation-system perspective (Paper 3), this limited uptake is further associated with underperformance in key system functions, particularly guidance of search, knowledge development and diffusion, market formation, and legitimacy creation, which remain insufficiently activated for pSVV and thereby constrain its stabilization as a distinct and credible value pathway within the DiGA ecosystem.

Third, addressing RQ3 on the role of real-world data in effectiveness evaluation, the broader mHealth field demonstrates that the empirical use of naturally emerging real-world data (RWD) remains methodologically limited and only partially aligned with the ambitions articulated in policy and regulatory discourse. As shown in Paper 4, RWD is predominantly operationalized through user-input data (especially in-app symptom surveys) and embedded in single-group pre–post designs, while comparator-based, quasi-experimental, or pragmatic randomized approaches remain comparatively limited.

Moreover, system-generated data (e.g., claims or electronic health record linkages) are rarely integrated into effectiveness evaluations. Even where RWD is available, it does not automatically translate into higher levels of evidence, as study designs often do not leverage comparators, longitudinal linkage, or causal inference strategies. These observations align with broader discussions in the real-world evidence literature emphasizing that the evidentiary strength of RWD depends less on data availability than on the methodological frameworks through which such data are analyzed and interpreted (Zou and Berger 2024). At the same time, the presence of routinely generated application data indicates unrealized potential for more robust lifecycle-oriented evaluation strategies, provided that appropriate methodological and system-level conditions are established. Recent work on digital measurement and endpoint development similarly highlights that translating continuously generated digital data into regulatorily credible evidence requires validated constructs, standardized measurement approaches, and appropriate analytical strategies rather than merely large volumes of data (Boers et al., 2025).

Although Paper 4 examines the broader mHealth literature rather than DiGA specifically, its findings are directly relevant to the DiGA context. The Fast-Track pathway explicitly anticipates flexible evidence strategies, including the potential use of real-world data and alternative evaluation approaches, as part of the lifecycle assessment of digital health applications (Stern et al., 2022). At the same time, the persistence of conventional study

designs observed in Paper 4 reflects a broader pattern described in recent digital health evaluation research, where methodological practices tend to remain anchored in established clinical paradigms despite formal regulatory openness to alternative approaches (Mahadik et al., 2025). Understanding how such evidence is currently generated and analyzed in the wider mHealth field therefore provides important context for interpreting the evidentiary trajectory of DiGA within this regulatory framework (Schmidt et al., 2024; Sippli et al., 2025).

Taken together, this dissertation's primary results support a differentiated answer to the overarching thesis question. Regulation can clearly act as a market-enabling driver of digital health innovation (by creating a reimbursable category and predictable access framework). But the evidence across the included publications also suggests that regulation's capacity to act as a driver of epistemic and evaluative innovation, i.e., transforming what counts as value and how evidence is credibly generated, depends on additional conditions that have not yet fully materialized in the DiGA system or in the broader mHealth evidence landscape.

The remainder of this discussion deepens the interpretation along two axes that directly follow from the dissertation's framing and publications: (i) value construction and legitimacy with pSVV as the central case, and (ii) methodological adaptation and RWE with RWD-based effectiveness evaluation as the central case.

4.1. Value Construction and Institutional Stabilization in the DiGA Pathway

A central innovation claim of the DiGA Fast-Track is that it extends the conventional "therapeutic benefit" concept toward "positive healthcare effects," allowing proof via either medical benefit or pSVV. The pSVV construct is explicitly designed to capture value dimensions that are highly plausible for software-based interventions: improved care coordination, adherence support, access facilitation, health literacy, and patient autonomy, among others (Bundesministerium für Gesundheit - Federal Ministry of Health, 2020). The policy logic is coherent, many digital interventions plausibly act through process and behavior mechanisms rather than direct medical change, and therefore evaluation frameworks should not be restricted to traditional clinical endpoints alone (Murray et al., 2016; Stern et al., 2022). Recent conceptual work similarly identifies health information management, self-management, and social-emotional support as core empowerment capabilities enabled by digital health technologies, closely mirroring several pSVV domains (Fomo et al., 2025).

However, the empirical reality across the included DiGA studies is that this broadened value definition has not become equally "usable" in practice. Papers 1, 2 and 3 emphasize

that pSVV has not yet been adopted to the extent intended, and that the pathway's intended innovation focus is only partially realized.

This gap between formal equivalence in law/guidance and practical equivalence in market behavior is one of this dissertation's most important integrative findings. It indicates that introducing a new value category is not sufficient; it must also become institutionalized through shared interpretation, feasible evidence strategies, and credible legitimacy signals. This insight is particularly valuable because it is likely not limited to value expansion within the DiGA context but may have broader applicability. For example, similar dynamics may help explain why other digital care initiatives, such as the digital care applications (DiPA) introduced in Germany, have so far faced difficulties in achieving comparable levels of implementation.

4.1.1. Interpretive Flexibility and Operational Uncertainty of pSVV

To further interpret the trajectory of pSVV, it may be helpful to draw on the concept of "boundary objects" (Caccamo et al., 2023) from innovation and science and technology studies. Boundary objects are constructs that are sufficiently flexible to accommodate different stakeholder perspectives while remaining structured enough to enable coordination across heterogeneous actors.

From this perspective, pSVV can be understood as a regulatory construction designed to bridge regulators, manufacturers, payers, and clinicians by allowing multiple interpretations of what constitutes patient-relevant improvement. However, while pSVV exhibits conceptual flexibility, it has not yet achieved the degree of institutional stabilization required for routine operationalization. In contrast, medical benefit remains more deeply institutionalized and therefore carries higher epistemic legitimacy (Hekkert et al., 2007; Suddaby and Greenwood, 2005). Under conditions of uncertainty, actors tend to default to such established categories rather than invest in less stabilized value constructs (Stern, 2017).

In the DiGA context, pSVV is broad: it includes multiple domains and invites context-specific operationalization. That breadth is attractive, but it also shifts the burden to manufacturers to specify what "counts," how it is measured, and how causality is demonstrated. pSVV is often perceived as "a good idea" but difficult to operationalize because of missing standards, missing examples, and missing measurement conventions, combined with uncertainty about what will be accepted in assessment practice. One possible avenue for reducing this uncertainty would be the systematic mapping of potential pSVV domains and measurement approaches. For example, scoping reviews of digital health interventions could help identify recurring categories of structural and procedural improvements and corresponding outcome measures, thereby providing a

clearer empirical basis for operationalizing pSVV in future evaluations. Paper 2 shows that refining benefit definitions within pSVV categories and developing appropriate measurement methods are decisive for successful implementation.

This creates a paradox: pSVV was introduced to make room for digital-health-typical value, yet its practical use requires the kind of stabilized endpoint and measurement infrastructure that tends to accumulate only after repeated successful implementations. In early phases of a pathway, that infrastructure is often absent by definition.

4.1.1.2. Economic Incentives and Methodological Risk Allocation

A recurring finding in Papers 2 and 3 is that manufacturers operate under a portfolio of interrelated risks, including development costs, regulatory uncertainty, evidence-generation expenses, and reimbursement unpredictability. Under such conditions, strategic decision-making tends to prioritize approaches that maximize predictability, particularly in a capital-constrained environment characterized by substantial upfront trial investments (Hekkert et al., 2007; Stern, 2017).

The empirical analyses demonstrate that cost-sensitive manufacturers are disincentivized from allocating limited resources to pSVV-based strategies. Established evaluative conventions and advisory practices remain predominantly oriented toward medical benefit, and consultative interactions frequently reinforce this orientation. Moreover, legitimacy expectations for pSVV are perceived as aspirational rather than empirically validated through established precedents.

The findings further indicate that assuming the costs of methodological innovation is strategically unattractive in the absence of clear economic advantages, such as differentiated pricing outcomes or accelerated regulatory procedures for pSVV-oriented products. This aligns with broader innovation policy research showing that firms' willingness to engage in costly innovation activities is influenced by the availability of economic incentives and predictable returns, including public support and investment conditions that reduce risk and enhance strategic attractiveness (Rosário et al., 2024).

Formal regulatory equivalence between medical benefit and pSVV does not translate into strategic equivalence if the effective incentive structure favors established medical endpoints. Where evidence expectations for pSVV are perceived as less predictable, market legitimacy is assumed to be stronger for medical outcomes, and no compensatory advantages are present, manufacturers rationally gravitate toward medical benefit. Accordingly, the limited uptake of pSVV reflects not resistance to patient-centered value, but strategic adaptation to the prevailing institutional and economic configuration of the DiGA pathway.

4.1.3. Innovation System Functions and the Stabilization of pSVV

The findings of this dissertation indicate that, despite the formal recognition pSVV within the DiGA Fast-Track, this pathway has not yet stabilized as a distinct innovation trajectory. Manufacturers continue to rely predominantly on traditional medical benefit endpoints, suggesting that the introduction of new value categories alone does not automatically alter practices within an innovation system.

From a Technological Innovation Systems perspective, the diffusion of new innovation pathways depends on the coordinated activation of several system functions, including knowledge development, knowledge diffusion, guidance of the search, market formation, and legitimacy creation (Bergek et al., 2008; Wieczorek and Hekkert, 2012). The empirical findings suggest that several of these functions remain oriented toward established clinical paradigms in the DiGA ecosystem, which constrains the stabilization of pSVV-based value propositions (Figure 6).



Figure 6 - Innovation system functions constraining the stabilization of pSVV in the DiGA ecosystem. The figure illustrates how several Technological Innovation System functions (Wieczorek and Hekkert, 2012) influence the emergence of pSVV as an innovation pathway within the DiGA Fast-Track.

Guidance of the search within the system continues to favor clinical endpoints as the dominant evidentiary pathway. Even though regulatory frameworks formally recognize pSVV, advisory practices and evaluation expectations remain strongly aligned with traditional biomedical outcome measures. At the same time, knowledge development related to the measurement of structural and procedural improvements remains limited. Compared with clinical outcomes, fewer validated instruments and methodological standards exist for operationalizing pSVV domains, which complicates their systematic evaluation (Murray et al., 2016; Silberman et al., 2023).

The creation of legitimacy for pSVV as a value pathway remains incomplete. Institutional theory suggests that new evaluative categories require sustained legitimacy-building processes within the organizational field before they become widely accepted (Clegg et al., 2006; Greenwood et al., 2002). In the DiGA context, the absence of established precedents and widely recognized success cases limits the credibility of pSVV-based strategies. Similarly, market formation for process-oriented value propositions remains weak, as the small number of pSVV-centered applications prevents the emergence of a distinct innovation niche.

These dynamics are consistent with broader observations in healthcare innovation research, which emphasize the strong institutional inertia of healthcare systems. Professional norms, regulatory routines, and established evaluation standards tend to stabilize existing practices and slow the adoption of alternative approaches (Coiera, 2011; Haring et al., 2022). As a result, even where regulatory frameworks formally expand the definition of healthcare value, innovation trajectories may remain anchored in established evidence paradigms.

Taken together, the limited stabilization of pSVV reflects the interaction between regulatory innovation and innovation system dynamics. While the DiGA framework introduces a broader concept of healthcare value, several key system functions remain aligned with traditional clinical evaluation practices. The stabilization of new value pathways therefore depends not only on regulatory recognition but also on the gradual development of methodological infrastructures, legitimacy, and market expectations within the broader innovation ecosystem.

4.2. Evidence Generation and Methodological Adaptation in Digital Health

Building on the RQ3 findings, the central issue is not whether real-world data (RWD) are generated in mHealth contexts, but how they are translated into evaluative claims. Paper 4 demonstrates that the methodological embedding of RWD rather than its availability shapes evidentiary strength. The predominance of single-group pre–post designs and the comparatively limited use of comparator-based or quasi-experimental approaches suggest that current evaluation practices often prioritize feasibility and internal monitoring over stronger causal inference.

This pattern indicates that the evidentiary role of RWD is mediated by design conventions, measurement practices, and institutional expectations. In many cases, intra-individual comparisons are conducted without external benchmarks, which constrains interpretability even where substantial data volume exists. The resulting dynamic reflects not an absence of data generation, but a cautious operationalization of RWD within established evaluative frameworks.

4.2.1. From Data Availability to Evidentiary Strength

A key interpretive contribution of this dissertation is the clarification that the quality of RWD-based evidence is not primarily determined by data volume, but by construct validity, comparability, and causal interpretability.

The review indicates that, although in-app survey data are widely used, reporting of validated measurement instruments is inconsistent. Moreover, many studies rely on intra-individual comparisons without external comparators. While such designs are valuable for feasibility testing and early signal detection, their causal strength is limited (Murray et al., 2016; Pham et al., 2016). Secular trends, regression to the mean, selection effects, and engagement-related confounding are difficult to disentangle without comparator groups or more robust quasi-experimental designs (Franklin et al., 2021; Hernán and Robins, 2016).

Advancing the methodological maturity of mHealth evaluation therefore requires greater integration of comparator logic, longer-term follow-up, and linkage to additional data sources to support more credible real-world assessments. This observation parallels the DiGA evidence pattern identified in Paper 1. Even within a regulatory framework that conceptually anticipates lifecycle evidence and acknowledges RWD, evidentiary strategies tend to remain anchored in established paradigms (Mahadik et al., 2025; Schmidt et al., 2024; Sippli et al., 2025).

At the same time, the design of the DiGA Fast-Track theoretically permits methodological experimentation of this kind. The provisional listing phase and the broader lifecycle evidence logic create conditions under which different forms of evidence generation could be combined. Future research could therefore explore hybrid evaluation strategies that for example collect intra-individual longitudinal data in parallel with comparator-based or randomized study designs. Systematic comparisons of these approaches could help clarify under which conditions RWD-based monitoring can complement or extend conventional clinical evaluation in digital health technologies.

4.2.2. Infrastructural Conditions and Data Linkage Constraints

The relatively limited integration of system-generated data, such as claims or electronic health record linkages, provides further insight into the contextual conditions shaping RWE. This pattern may reflect constraints related to data access, interoperability, governance arrangements, or transaction costs associated with data linkage. Analyses of real-world data frameworks similarly emphasize that credible RWE depends on data quality dimensions such as interoperability, discoverability, and linkability across sources, which in turn presuppose supportive technical and governance infrastructures for the

secure integration of application-level and routine-care data (Sherman et al., 2016; Zou and Berger, 2024). The European Health Data Space (European Union, 2025), that was established as an EU regulatory framework to harmonize electronic health data exchange and support secondary use for research and innovation in 2025, exemplifies how system-level infrastructure and governance reforms could progressively address these structural constraints by enabling secure cross-border linkage and standardized access to health data for research and regulatory purposes, including RWE generation (Kypmpouropoulos, 2023).

From this perspective, the development of RWE capabilities appears at least partly infrastructure dependent. Where conditions for secure linkage and sustained longitudinal monitoring are limited, the range of feasible evaluation designs may also be constrained. The methodological pattern observed in Paper 4 should therefore be interpreted within a broader systemic context rather than solely as a matter of analytic choice.

4.2.3. Regulatory Flexibility and Methodological Conservatism

The findings from the DiGA case in paper 1 reinforce this interpretation. Despite formal regulatory openness to alternative evidence strategies, permanently listed DiGA predominantly rely on randomized controlled trials. The anticipated diversification of evidentiary approaches has not yet materialized to a substantial degree.

Across both the regulated DiGA pathway and the broader mHealth literature, a consistent pattern emerges - formal flexibility does not automatically translate into methodological diversification. Evidentiary practices appear to evolve incrementally and remain anchored in established paradigms that provide predictability and legitimacy (Mahadik et al., 2025; Torous et al., 2022). This dynamic mirrors the trajectory observed for pSVV. In both domains, regulatory innovation expands the formal space of value and evidence, while practical implementation remains comparatively conservative.

4.2.4. Lifecycle Evidence and Continuous Evaluation

From the perspective of the findings in Paper 4, a central issue concerns the relatively limited use of continuous data collection in published effectiveness evaluations. Although patient-facing mHealth applications routinely generate longitudinal data streams during routine use, many studies rely on defined assessment intervals rather than leveraging continuous monitoring as an evaluative strategy. This suggests that the lifecycle character of digital interventions is not yet systematically reflected in evaluation practice.

Work on digital biomarkers and continuous monitoring in neurodegenerative diseases illustrates that the challenge lies not merely in generating high-frequency data, but in translating such data into validated and regulatorily credible endpoints (Brzenczek et al.,

2024). Similarly, initiatives such as the Digital Medicine Society (DiMe) (Silberman et al., 2023; Stern et al., 2022) emphasize the need for structured validation and standardization frameworks for digital measures. These examples reinforce that the evidentiary value of longitudinal data depends on endpoint validation and methodological integration rather than on data volume alone (Boers et al., 2025).

In this context, the recently introduced Continuous Effectiveness Evaluation during Application (Anwendungsbegleitende Erfolgsmessung, Short AbEM) in the revised DiGA regulation (Bundesministerium für Gesundheit - Federal Ministry of Health, 2026) provides a relevant practical illustration. AbEM establishes a formal framework for application-accompanying outcome measurement during routine use. It requires a predefined evaluation concept, explicit endpoint specification, documentation of data collection procedures, and transparency regarding analytic methods. In doing so, it institutionalizes the possibility of structured longitudinal data collection beyond the initial study phase.

With respect to the findings of Paper 4, AbEM is partly aligned with the identified gap. The scoping review showed that continuous data streams generated during routine use are comparatively underutilized in published effectiveness evaluations. By explicitly formalizing ongoing outcome measurement during real-world use, AbEM creates a regulatory basis for leveraging such longitudinal data more systematically. At the same time, AbEM does not prescribe specific longitudinal analytic strategies, comparator integration, or particular approaches to modeling temporal trajectories. Its contribution therefore lies primarily in enabling structured continuous data collection rather than in redefining methodological standards for causal inference. From the perspective of RQ3, AbEM can be interpreted as a step toward lifecycle-oriented evidence generation, but its impact on the strength of RWE will depend on how longitudinal data are analytically operationalized within the required evaluation concepts.

4.3. Implications for Innovation System Stakeholders

The findings of this dissertation suggest that the DiGA pathway has succeeded in enabling market formation but has not yet fully translated regulatory innovation into epistemic and evaluative transformation. Strengthening this second dimension requires coordinated action across stakeholders, particularly with respect to value definition, evidence generation, and the economic incentives embedded in reimbursement structures.

4.3.1. For regulators

One implication for regulators concerns the reduction of interpretive and methodological uncertainty around pSVV and lifecycle evidence, as regulatory clarity has been shown to

play a central role in shaping innovation trajectories and guiding search processes within emerging technological fields (Arcà et al., 2025). The limited uptake of pSVV reflects ambiguity in operationalization and legitimacy rather than conceptual rejection. Regulators should therefore continue to refine endpoint definitions, publish illustrative precedents, and ensure consistent assessment practice. Clearer guidance on acceptable measurement approaches and illustrative examples of successful pSVV operationalizations could reduce uncertainty for manufacturers and contribute to strengthening legitimacy within the innovation system.

With regard to lifecycle mechanisms such as AbEM, the focus should lie on transparent expectations for longitudinal evaluation concepts rather than on data collection alone. As discussed in Section 4.2, the challenge in digital health evaluation lies less in generating data than in translating such data into credible evidentiary claims. Regulatory guidance could therefore place greater emphasis on methodological aspects such as comparator logic, longitudinal modeling strategies, and the integration of routine-care data sources. Clarifying how lifecycle evidence generated under mechanisms such as AbEM is assessed and weighted in regulatory decision-making is central to activating guidance of search and legitimacy within the innovation system.

4.3.2. For payers and price negotiators

Ensure coherence between evidentiary expectations and economic incentives (Stern, 2017). Where no differentiated economic signal accompanies pSVV-based value articulation or structured longitudinal evidence generation, firms will rationally prioritize established medical-benefit strategies. Greater transparency regarding how alternative value claims and lifecycle evidence affect reimbursement logic could mitigate strategic conservatism.

The pricing dynamics observed in Paper 1 further suggest that the current negotiation outcomes produce relatively limited differentiation across DiGA products. Despite heterogeneity in development costs, therapeutic scope, and evidentiary investments, negotiated reimbursement prices tend to converge within a relatively narrow range. While this contributes to predictability for payers, it may weaken incentives for methodological innovation and may also limit the economic viability of applications targeting small patient populations. In particular, DiGA addressing niche or rare conditions may face structural disadvantages if development costs cannot be recovered within a largely uniform pricing environment.

Future pricing frameworks could therefore consider mechanisms that better reflect differences in evidentiary investment, therapeutic scope, or patient population size. Such differentiation could strengthen incentives for manufacturers to explore alternative value

pathways, including pSVV-based value propositions or more sophisticated lifecycle evidence strategies.

4.3.3. For manufacturers

Strengthen internal capabilities in endpoint specification and longitudinal evaluation design (Stern et al., 2022). The findings show that the constraint lies less in data generation than in methodological embedding. Firms that systematically integrate comparator logic, validated measurement concepts, and structured longitudinal monitoring into their development strategies may reduce assessment uncertainty and enhance credibility.

At the same time, the results of Papers 2 and 3 indicate that manufacturers currently operate under incentive structures that favor established medical-benefit endpoints. Under conditions of regulatory ambiguity and economic risk, firms rationally prioritize evidence strategies that provide predictable assessment outcomes. Strategic evidence planning therefore becomes a central capability, allowing firms to align product functionality, endpoint selection, and evaluation design with the expectations of the DiGA pathway early in the development process.

If regulatory guidance, precedents, or economic incentives for alternative value pathways such as pSVV become clearer in the future, manufacturers may also be better positioned to explore these approaches. Until such conditions stabilize, however, methodological credibility and regulatory predictability are likely to remain dominant drivers of evidence strategy.

4.3.4. For research and intermediary actors (consultancies, academic partners)

Contribute to knowledge development and diffusion. The innovation-system analysis highlights weaknesses in knowledge infrastructure and legitimacy creation for pSVV and alternative evidence designs. Shared methodological standards, transparent reporting practices, and critical reflection on advisory routines can support gradual institutional stabilization.

Academic and intermediary actors can play a key role in advancing methodological work on endpoint operationalization and measurement strategies for digital health interventions. Developing validated instruments for process-oriented outcomes and establishing methodological guidance for the evaluation of structural and procedural improvements could help reduce the interpretive uncertainty currently associated with pSVV.

In addition, systematic evidence syntheses may help clarify the empirical basis of digital-health-specific value dimensions. For example, scoping reviews or conceptual mapping exercises could identify recurring categories of patient-relevant structural and procedural improvements across digital health interventions and link these domains to measurable outcomes and evaluation approaches.

Finally, researchers and consultants can contribute to bridging the gap between regulatory expectations and industry practice. By translating methodological advances into practical guidance, evaluation frameworks, and shared reporting standards, intermediary actors can support the diffusion of credible evidence-generation strategies and strengthen legitimacy for alternative value pathways within the DiGA ecosystem.

In sum, advancing regulation as a driver of innovation requires more than formal rule expansion. It requires coordinated strengthening of guidance, methodological clarity, legitimacy-building, knowledge infrastructures, and incentive alignment across the DiGA innovation system.

5. Conclusion

This dissertation examined whether and under which conditions regulation can act as a driver of innovation in digital health, using the German DiGA Fast-Track as an empirical case. The findings show that regulation can play a powerful enabling role by creating structured market access pathways and reducing uncertainty for innovators. By establishing a reimbursable category and a defined evaluation framework, the DiGA Fast-Track enabled the emergence and consolidation of a digital health application market within routine healthcare.

At the same time, the analysis demonstrates that regulatory innovation in itself is not sufficient to transform how value is defined or how evidence is generated. Although the DiGA framework formally broadened the concept of positive healthcare effects and opened the door to alternative evidence strategies, evaluation practices remain largely anchored in established clinical paradigms. Similarly, while digital health technologies generate extensive real-world data, its integration into robust effectiveness evaluations remains methodologically limited.

Taken together, the results suggest that regulation can effectively drive innovation at the level of market formation, but its ability to transform value frameworks and evidence practices depends on broader institutional conditions. Methodological standards, knowledge infrastructures, economic incentives, and shared legitimacy within the

innovation ecosystem all shape whether regulatory innovations translate into practical change.

The German DiGA Fast-Track therefore illustrates both the potential and the limits of regulation for innovation. It shows that regulation can enable the development of new digital health markets, but that the long-term transformation of evaluation and value frameworks requires continued institutional learning and coordination across the digital health ecosystem.

Looking ahead, digital health regulation will continue to evolve in response to growing pressures on healthcare systems and the rapid development of data-driven technologies. Emerging policy initiatives, including lifecycle evidence mechanisms such as AbEM, new European data infrastructures such as the EHDS (Kypourouopoulos, 2023; Raab et al., 2023), and expanding digital care frameworks such as DiPA, are likely to further reshape how digital health technologies are evaluated, integrated, and reimbursed. At the same time, digital interventions increasingly aim to support patient empowerment through improved self-management, health literacy, and care coordination (Fomo et al., 2025). Recent research also emphasizes the growing importance of robust real-world evidence infrastructures and methodological standards for evaluating digital therapeutics and other patient-facing digital health technologies (Boers et al., 2025; Mahadik et al., 2025). Understanding how regulatory frameworks interact with these developments, and how they influence evidence generation, value definition, and innovation incentives, therefore remains an important agenda for future research on digital health governance.

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