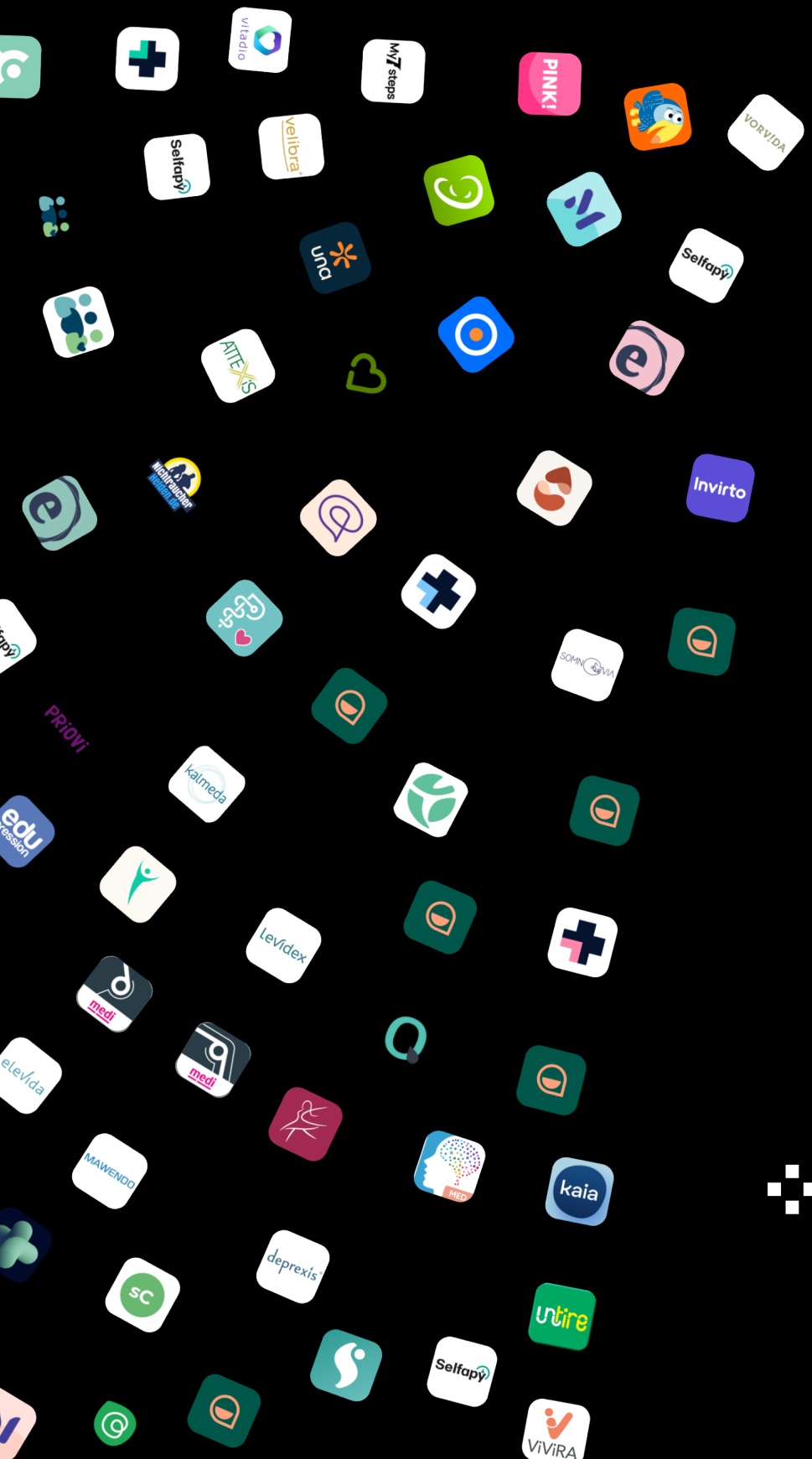
DiGA-Report 2025



Spitzenverband
Digitale
Gesundheitsversorgung

Development of the provision with digital health applications

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About the SVDGV

The German Digital Healthcare Association (SVDGV) is the leading industry representative for e-health companies in Germany. It was founded in December 2019 and brings together over 170 e-health companies. All DiGA providers listed in the BfArM directory are members of the association. Further information is available at digitalversorgt.de and on LinkedIn.

Foreword Prof. Dr. Karl Christian Broich

Digital health applications (DiGA) have become firmly established in the German healthcare system. In just a few years, a new, forward-looking area of healthcare has emerged, offering patients low-threshold access to safe and evidence-based digital therapies.

With the fast-track procedure, the BfArM has established a framework that has garnered international attention. It combines innovation with clear requirements regarding positive healthcare outcomes, data protection, data security, and quality. A recent analysis shows that manufacturers of permanently listed applications have consistently submitted randomized controlled trials. This is an important signal: DiGAs are part of science-based healthcare.

At the same time, however, it is important to acknowledge that the evidence must be considered in a differentiated manner. A systematic review from 2025 of 23 published studies on 21 digital health interventions concludes that the studies vary considerably in terms of design, endpoints and duration, and that the reported effects should be critically assessed for potential biases. This assessment does not diminish the importance of digital therapies. However, evidence quality, comparability, and long-term follow-up must be further developed.

A critical assessment must also address the question of actual use in day-to-day healthcare practice. Studies from 2025 paint an encouraging picture in some respects: in the DiGAReal rheumatology registry, 51% of users reported an improvement in symptoms; applications for back pain and weight management were particularly well received. However, another survey from the same year indicates that there is still room for improvement: whilst 39.8% of a rheumatology patient cohort were aware of DiGA, only 12.6% had actually used it.

In addition, the introduction of new regulatory requirements must be carefully balanced. If additional effort is required, it must be proportionate to the gains in security or the insights gained. Predictability is a key factor, especially for young companies and new providers.

Here, the BfArM sees itself in a dual role: as an enabler of innovation and, at the same time, as a guarantor of quality and safety. Experience from over five years of the DiGA Fast-Track program shows that, in particular, the early use of advisory services can contribute significantly to the success of a DiGA application. We therefore recommend actively utilizing these opportunities to collectively discuss approaches from a scientific perspective, clarify questions, and rapidly bring innovative applications into clinical practice.

With the DiGA system, Germany has a successful and internationally respected regulatory framework. This framework must be further developed in a targeted manner: through easier access in healthcare, compelling advancement of evidence and real-world data, regulatory reliability with a sense of proportion, and networking across Europe.

Prof. Dr. med. Karl Christian Broich

President of BfArM

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Foreword Prof. Dr. Ariel Dora Stern & Dr. med. Lars Masanneck

Dear Readers,

It is both a great honor and a great responsibility to write a foreword to this DiGA-Report – for we find ourselves at a crucial time where we are, and must be, engaged with data and evidence! Precisely because digital interventions are dynamic, context-dependent, and often closely integrated into healthcare delivery, their evaluation requires both improved access to data and methodologically appropriate evaluation approaches.

On the one hand, it is more important than ever that we try to provide access to data for research and development. Secondary data use and the collection of data for research purposes not only enable better digital solutions but also evidence-based health policy – and thus a self-reinforcing cycle of product development and robust evidence for the entire healthcare system.

On the other hand, the tools that have been used as standard for evidence generation to date are in many cases no longer capable of answering our most important questions. For this reason, the German Society for Digital Medicine (DGDM) argues in a position paper [A] that "traditional evidence standards, evaluation concepts, and study designs should be questioned and, if necessary, realigned and redesigned." The DGDM further explicitly states: "The aim is not to 'water down' evidence standards, but to further develop existing approaches and models. The choice of methods for generating evidence should be guided by the primary function and intended treatment goals of the respective digital technology." Even though this statement was deliberately formulated broadly to encompass new digital technologies and care models, its message is particularly relevant for those who develop, test, regulate, and apply DiGA. It is necessary and time-critical that the scientific community further defines standards and priorities for high-quality evidence – and that these are recognized, accepted, and put into practice by manufacturers and regulators. Only by taking joint steps will we advance digital medicine – and thus medicine as such!

And "doing it right" with data and evidence will have further positive externalities: Once we have high and clear standards of evidence and are able to get the most out of our data, we can begin to ask crucial questions for the healthcare system and healthcare research in the broader sense: Which instruments work under what circumstances and for which patients? Answering these questions will show us how we can use digital solutions in general, and DiGA in particular, as a bridge toward value-based healthcare. Doing this – and doing it well – could position DiGA researchers as thought leaders in the German and European healthcare sectors and pave the way for a genuine digital transformation.In such a transformation, digital tools would be neither an end in themselves nor mere individual therapeutic agents, but rather a key enabler for better, patient-centered healthcare.

Prof. Dr. Ariel Dora Stern

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[A] Kilburg A, Masanneck L, Knitza J, Leber A, Ziemssen T, Betz K, Martino F. IMPULSPAPIER: EVIDENZ IN DER DIGITALEN MEDIZIN.

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DiGA are not a digital add-on; they can be a real boost to healthcare. Their value isn't measured by downloads, but by whether they provide tangible help to people with health conditions in their daily lives. That is precisely where their potential lies: bringing healthcare closer to people's lives – not once in the waiting room, but also at home, at work, and in everyday life. That is exactly why the path we have chosen is the right one: to bring innovation into healthcare more quickly.

But it is equally clear that what is paid for by the solidarity-based community must benefit many – with tangible added value, low-threshold access, and a clear contribution to better healthcare

Matthias Mieves, MdB

By 2026, digitalization is no longer an add-on, but a necessary condition for future-proof healthcare. In the future, digital, AI-based solutions will enable care that is not only more efficient but also radically tailored to the individual.

However, the fact that one in five DiGA prescriptions is still not being filled shows that while the innovations are readily available, we are too complicated when it comes to putting them into practice. We need to step up our efforts here.

Digital sovereignty remains the core element here: An interconnected, data-driven healthcare system can only function through trust. Patients must have sovereignty over their data, which in turn must, of course, be processed within a modern, stable, and secure infrastructure.

This is how we create a healthcare system that truly leverages the opportunities in the digital age – for care that is safe, equitable, and future-proof.

Dr. Thomas Pauls, MdB

Foreword

Dear Readers,

For the third time, we present to you the DiGA-Report from the German Association for Digital Health (SVDGV) and are pleased to report an impressive track record: For half a decade now, patients in Germany have been benefiting from digital health applications (DiGA).

With this, Germany has positioned itself as a pioneer in innovation: in 2020, it was the first country in the world to incorporate digital healthcare solutions into standard care. Since then, other countries have followed Germany's example. As location- and time-independent, evidence-based therapy option, DiGA can close gaps in care and empower patients. Given increasingly scarce financial and human resources and an urgent need for reform in the German healthcare system, DiGA are essential to ensuring our healthcare provision in the future. DiGA enables patients to access effective therapies early on, thereby expanding the treatment options available to healthcare providers. They can rely on certified medical devices with proven positive healthcare effects that have been thoroughly reviewed by the Federal Institute for Drugs and Medical Devices (BfArM).

Five years after the introduction of DiGA, we look back with pride on an exemplary success story. As of the publication of this DiGA-Report, patients have been able to utilize a DiGA's care offerings **over 1.7 million times**. As of December 31, 2025, they had access to a diverse range of 58 DiGA listed in the BfArM directory. Over the past five years alongside outpatient and inpatient care, DiGA care has established itself as the third pillar of healthcare, even though numerous bureaucratic and organizational hurdles make it difficult for patients to use DiGA, and the regulatory requirements for manufacturers are constantly growing and becoming increasingly complex.

With this third DiGA-Report, the SVDGV continues the success story of the previous editions. For this purpose, we have divided it into two main chapters: In the first part, we provide, among other things, a quantitative assessment of the first five DiGA years and address key regulatory changes in 2025. The second part answers the question of what is needed to ensure that DiGA remains on the path to success in the future.

1. Looking Back on Five Successful Years

The use of DiGA continues to rise. As of December 31, 2025, the number of redeemed activation codes reached a top value of 1.6 million, while the diverse range of DiGA offerings has stabilized at a high level. Last year once again confirmed the importance of the DiGA Fast Track procedure: Nearly 70 percent of the DiGA initially included on a provisional basis in the BfArM directory achieved permanent listing following a successful pilot year. Despite the growth trend, it became apparent how higher and more complex entry barriers are having a negative impact on the number of new DiGA in the directory: only a few DiGA were added.

In addition, the legislature also added further provisions to the regulatory framework. For instance, the Second Ordinance Amending the DiGAV (2. DiGAV-ÄndV) established the implementation framework for ongoing outcome measurement (AbEM). The SVDGV welcomes the Ongoing Outcome Measurement's goal of improving the quality and transparency of care, but views the current

proposal with skepticism, as it imposes a significant bureaucratic burden on all parties involved without yielding the desired insights regarding DiGA care.

Positive developments are evident when looking abroad. For example, in Switzerland, digital Health Applications from germany for the treatment of depressive disorders will be reimbursed for the first time as part of standard care starting in July 2026.

2. Future Prospects Between E-Prescriptions and European Harmonization

In the second part of the DiGA-Report 2025, we ask: What does it take to build a successful future? The SVDGV has identified four key areas that will significantly influence the future of DiGA:

- A practical concept for **e-prescriptions** as a key driver for improved access to DiGA care
- A **sensible adjustment of the Ongoing Outcome Measurement** so that it can actually contribute to the further development of DiGA care
- **Data security requirements** that ensure the protection of sensitive health data and also enable practical therapy for patients as well as innovation for DiGA manufacturers
- Europe-wide harmonized framework conditions for the reimbursement of digital therapies so that they benefit all patients in Europe

The success of the past five years is also a call to further improve the framework conditions for DiGA. With the third DiGA-Report, we provide insights into how the further development of DiGA care in Germany and Europe can succeed. Because only with digital healthcare services can we continue to rely on an efficient and functioning healthcare system in the future.

We hope you find this report insightful.

Dr. Anna Haas
Board Member SVDGV

Henrik Emmert
Board Member SVDGV

Dr. Anne Geier
Managing Director

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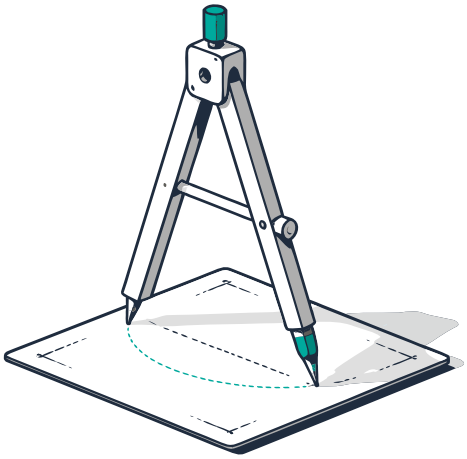


Executive Summary

Five years after the introduction of DiGA into standard care in Germany, the third DiGA-Report 2025 draws a positive conclusion: the provision of DiGA continues to grow successfully. At the same time, improvements to the framework conditions are needed so that digital therapies continue to develop sustainably as the third pillar of digital health alongside outpatient and inpatient care. This DiGA-Report builds on the data from previous editions and extends the observation period to December 31, 2025. In the fifth year, the number of redeemed activation codes nearly doubled compared to the total from the four previous years.

The year 2025 brought a new federal government and a renewed sense of urgency regarding the realization that the German healthcare system requires fundamental reforms to maintain current standards of care. Against this backdrop, digital solutions such as DiGA can help sustain an effective healthcare system in the future despite the current growing shortage of skilled workers and rising demand.

Last year, DiGA manufacturers also faced new legal and regulatory requirements – including the "Second Ordinance Amending the DiGAV" (2. DiGAV-ÄndV), which took effect on February 1, 2026. Among other things, it contains specific provisions for implementing ongoing outcome measurement (AbEM).[1] In addition, an updated version of the DiGA guideline was published in December which included a new chapter on Ongoing Outcome Measurement and new requirements for evidence assessment.

Nevertheless, the supply of DiGA continued to grow at double-digit rates in 2025. From the introduction of DiGA in October 2020 through December 31, 2025, patients redeemed a total of approximately 1.6 million activation codes – of which about 690,000 were in 2025. This means that, as of the publication date of this DiGA-Report, patients had been provided with digital therapy services over 1.7 million times.

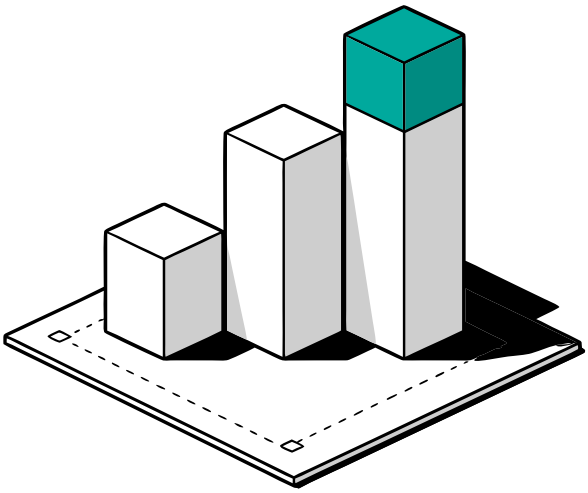
The number of DiGA included in the BfArM directory has stabilized at a high level over the past year. Of the total 58 DiGA, 48 are permanently included in the BfArM directory, while only ten remain

provisionally included. In addition, 34 of the 50 DiGA provisionally listed successfully completed their one year trial phase and were permanently included. These data underscore how important the one year trial phase is for the success of DiGA.

Like the DiGA-Report 2024, this edition also addresses international developments in digital therapies and provides an updated overview. Apart from the complexities of its regulatory implementation, the German DiGA concept serves as a model for many other countries. This year, for the first time, patients in Switzerland can use digital Health Applications (dGA) to treat depressive disorders at the expense of mandatory health insurance.

For all the successes of the past five years, the future of DiGA care depends on how the framework conditions develop. The DiGA-Report 2025 therefore addresses four key areas that will have a decisive influence on future development.

- The **e-prescription for DiGA** offers the opportunity to simplify access to digital therapies. In contrast, gematik's tried-and-tested e-prescription concept raises barriers to access for patients. This is where the SVDGV's proposal offers a practical solution that benefits both patients and healthcare providers.
- The **Ongoing Outcome Measurement** pursues the welcome goal of improving the quality and transparency of care. However, the implementation provisions of the 2nd DiGAV-ÄndV result in a high level of additional bureaucratic burden for all parties involved, which is disproportionate to the foreseeable outcomes of the Ongoing Outcome Measurement.
- Since 2025, DiGA manufacturers are required to certify their products in accordance with **Technical Guideline (TR) 03161 of the Federal Office for Information Security (BSI)**. The SVDGV supports the intended protection of sensitive health data. However, the implementation of BSI TR-03161 entails significant disadvantages for patients with statutory health insurance. The SVDGV calls for a reevaluation of the necessity of BSI TR-03161 certification for medical devices in lower risk classes and for the involvement of DiGA manufacturers and patients in defining an appropriate level of data security.
- DiGA manufacturers have demonstrated that their products meet the **high evidence requirements** in Germany for proving a positive healthcare effect. This regulatory framework can serve as the foundation for the still-missing **harmonized framework conditions** for the reimbursability of digital therapies **in Europe**. Germany and France could take a leading role here.



1. Five Years of DiGA – Where Do We Stand Today?

1.1. DiGA as a solution to urgent challenges

The German healthcare system is in urgent need of reform. The key challenges are not new: demographic change affects both patients and healthcare providers alike. On the one hand, the number of people over the age of 65 is set to rise from 17.9 million in 2018 to at least 22.7 million in 2038 – and with it, the demand for medical care. On the other hand, there will be a shortage of 2,500 outpatient physicians annually by 2040 , while the growing shortage of psychotherapists is manifesting itself in ever-longer waiting times. On average, patients must wait 20 weeks from initial contact until the start of therapy. A shortage of skilled workers is also emerging among non-medical healthcare professions – particularly in the field of physical therapy, where the annual average shortage in 2023/2024 stood at 11,584 therapists. This shortage of skilled workers will cause medical care to steadily deteriorate, especially in rural regions. At the same time, healthcare costs are rising steadily – in Germany, statutory health insurance expenditures increased by over 54 percent between 2013 and 2023 (from 181 to 279 billion euros). Other factors weighing on the German healthcare system include excessive bureaucracy and, by international standards, sluggish technological modernization and digitalisation.[ii]

Innovations in medical technology, biotechnology, and digital health solutions/e-health offer a potential solution to these pressing financial and structural challenges. According to a study by the consulting firm Prognos AG, broader use of innovations that already available today could yield savings of nearly 50 billion euros by 2045. Health Applications (DiGA) play an important role in this context. They enable efficiency gains in standardized therapies, for example for mental health conditions, metabolic disorders, and diseases of the musculoskeletal and endocrine systems.[i] DiGA can help address many of the challenges described above. As location- and time-independent solutions, they offer the opportunity to expand the range of analog care services. In addition, they can relieve the burden on healthcare professionals and help improve patient adherence and health literacy. Patients benefit from a multimodal form of therapy that they can integrate into their daily lives regardless of location or time.

What is a DiGA?

- Smartphone-App or web-based application
- To support the detection, monitoring, treatment or alleviation of diseases or the detection, treatment, alleviation or compensation of injuries or disabilities
- Cost coverage by statutory health insurers, based on a framework agreement on reimbursement negotiated with the GKV-SV (National Association of Statutory Health Insurance Funds) – also partially to fully reimbursed by private health insurers
- Evidence of positive healthcare effects demonstrated
- High standards regarding safety, functionality and quality, as well as data protection and data security
- Digital medical device of risk class I, IIa or IIb, CE certification
- Ad-free
- Interoperability: integration with the electronic health record, integration of the health ID etc.

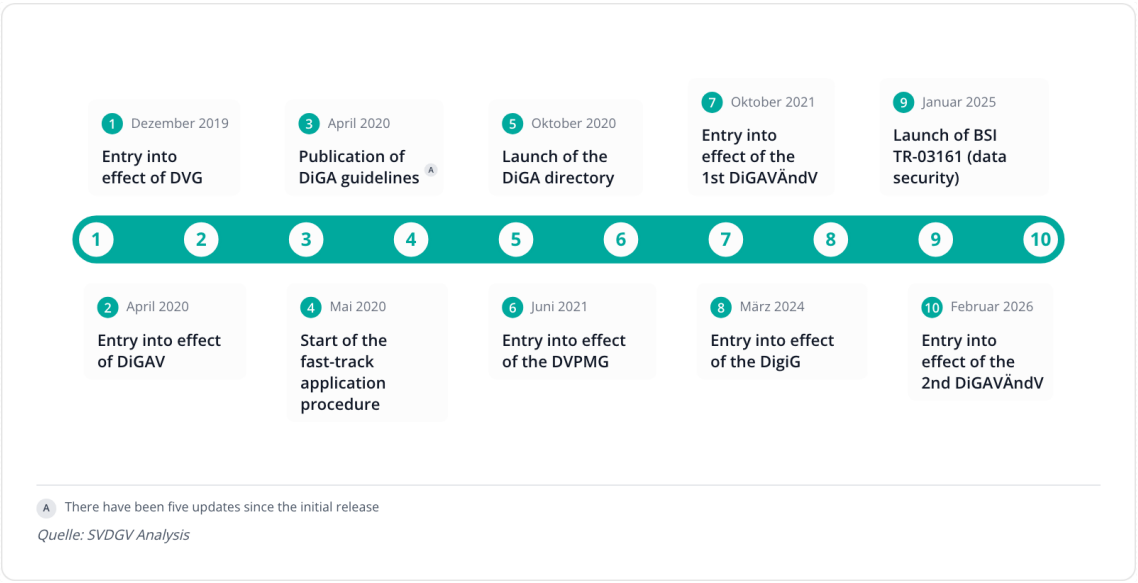
Germany is considered the global model for the use of DiGA in standard care. Since the **Digital Healthcare Act (Digitale-Versorgung-Gesetz: DVG)** came into effect in December 2019, physicians and psychotherapists have been able to prescribe DiGA. Their costs are reimbursed by statutory health insurance (Gesetzliche Krankenversicherung: GKV). (see box: What is a DiGA?). Reimbursable DiGA, as defined by the DVG, have successfully undergone a comprehensive review process with high standards set by the Federal Institute for Drugs and Medical Devices (BfArM) before being included in the DiGA directory. In this process, the BfArM assesses, among other things, the assurance of data protection and security as well as the positive healthcare effect of a DiGA. This means that DiGA must demonstrate a measurable benefit for patients and healthcare providers. The DiGA-Report 2023 describes in detail the legal and regulatory foundations of DiGA.

In addition to a prescription from a physician or psychotherapist, individuals with statutory health insurance can also apply for DiGA directly through their health insurance provider, if they can demonstrate a medical indication. For this purpose, the German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband: GKVSV) adopted the **DiGA Approval Guideline –** which is mandated by law and binding on all statutory health insurance providers – for the first time in April 2025. Among other things, it regulates the verification of medical indications by the insured individuals themselves. Accordingly, medical findings, discharge or therapy reports, or comparable medical documentation can be accepted by health insurance providers. The SVDGV generally welcomes the idea behind the new guideline, as it can provide greater clarity for insured individuals. In practice, however, it can be observed that some health insurance companies continue to interpret the provisions differently. Processing times for approvals also vary greatly among individual health insurance companies and are generally well above the 2-business-day rule stipulated in Section 67(3) of the German Social Code, Book V (SGB V) for processing DiGA prescriptions. A comparable and guideline-compliant approach across all health insurance companies would be desirable in the future.

The DiGA **framework agreement pursuant to Section 134(4) and (5) of the German Social Code, Book V (SGB V)** between the DiGA manufacturers' associations and the German National Association of Statutory Health Insurance Funds (GKVSV) is decisive for the structure of DiGA reimbursement. It was co-negotiated by the GKVSV itself. Among other things, the DiGA framework agreement specifies the calculation of the maximum amounts for DiGA, which apply to actual prices starting from the first day of prescribability (from the 2,001st prescription). Reimbursement is systematically capped and takes into account high development costs, including those for studies and certifications. An exception is made for the funding of products based on artificial intelligence. In addition, the DiGA framework agreement defines a reimbursement threshold up to which no price negotiations between DiGA manufacturers and the German National Association of Statutory Health Insurance Funds (GKVSV) are required. Overall, this therefore constitutes a clearly regulated reimbursement system within a framework agreed upon with the GKVSV.

Since the DVG was enacted, the legislature has passed a total of more than half a dozen additional laws, regulations, and guidelines with implications for DiGA care over the past five years (Figure 1). These include, in particular, **the "Digital Health Act" (Digitalgesetz: DigiG)**, which came in effect in March 2024. For example, it expanded the legal framework for DiGA to include medical devices in risk class IIb. Other key elements of the Digital Health Act include regulations for improved interoperability among various digital offerings and for increased transparency regarding DiGA care. In addition, the Digital Health Act introduced a performance-based component for the reimbursement amount of DiGA, which can be based, among other things, on the results of an ongoing outcome measurement conducted during use. Further provisions of the Digital Health Act are summarized in the DiGA-Report 2024.

Figure 1: Overview of the legal regulations for DiGA from their introduction in December 2019 through December 2025



Most recently, at the end of October 2025, the Federal Ministry of Health (BMG) presented its new draft bill for **the "Second Ordinance Amending the DiGAV" (2. DiGAV-ÄndV)**, which came into effect on February 1, 2026. The draft regulation was based on a draft bill from the previous federal

government dated January 2025, which was not pursued further due to the general elections to the German Bundestag. With the 2nd DiGAV-ÄndV, the legislature aims to align the previously valid DiGAV with the requirements of the Digital Health Act and the European Union's Artificial Intelligence Regulation (AI Regulation). For example, the 2nd DiGAV contains specific provisions for implementing Ongoing Outcome Measurement, which impose a significant bureaucratic burden on DiGA manufacturers and health insurance companies without providing the desired insights into DiGA care.

In December 2025, the BfArM finally published an **updated version of the DiGA guidelines** that takes into account the changes introduced by the Digital Health Act of 2024. Among other things, a chapter on the requirements of the Ongoing Outcome Measurement (Ongoing Outcome Measurement) and on the requirements for evidence assessment (e.g., study design) was added, along with definitions of medical devices and DiGA, explanations regarding the reimbursability of hardware, and changes related to data protection, data security, and interoperability. Part II of this DiGA-Report addresses these aspects in detail, as well as the implications of the 2nd DiGAV-ÄndV.

Overall, the regulatory framework for DiGA has become significantly more extensive and complex over the past five years. Nevertheless, DiGA have successfully established themselves in healthcare, as the following chapter demonstrates with its analysis for the year 2025.

1.2. Healthcare with DiGA: Continuing on a Growth Trajectory in Its Fifth Year

1.2.1. The Data Basis of the DiGA-Report 2025

As of December 31, 2025, the BfArM directory contained 48 permanently included and 10 provisionally included DiGA. At this time, the manufacturers of all listed DiGA are members of the SVDGV. The SVDGV obtained the data contained in this report by requesting it from the respective manufacturers of the individual DiGA. Only the SVDGV office and the respective manufacturer had access to the data sheet used to collect the number of activation codes redeemed for each DiGA. This third DiGA-Report from the SVDGV builds upon the first two DiGA-Reports and their methodology.

This DiGA-Report covers the period from October 1, 2020, to December 31, 2025, with a focus on the last twelve months (January 1 to December 31, 2025). Unlike previous DiGA-Reports, this version refers to calendar years:

- DiGA year 2021: October 1, 2020, to December 31, 2021
- DiGA year 2022: January 1, 2022, to December 31, 2022
- DiGA year 2023: January 1, 2023, to December 31, 2023
- DiGA year 2024: January 1, 2024, to December 31, 2024
- DiGA year 2025: January 1, 2025, to December 31, 2025

In the first two DiGA-Reports, the reporting periods ran from October 1 of one year to September 30 of the following year. The reason for this adjustment is a legal change introduced by the Digital Health Act, under which the German National Association of Statutory Health Insurance Funds

(GKVSV)'s DiGA reporting obligation (Section 33a(6) of Book V of the Social Code) was converted to the calendar year. Due to this change, the key figures (box) in this DiGA-Report are no longer directly comparable with those of previous years:

Key figures

- Total number of redeemed DiGA activation codes
- Distribution of reedemed activation codes by months
- Distribution of reedemed activation codes by gender (female, male, diverse, gender not specified)
- Distribution of reedemed activation codes by age (18 - 29 years, 30 - 39 years, 40 - 49years, 50 - 64 years, 65 + years, age not specified)*

* The age group ‚under 18 years' was not included in the age breakdown because there were three DiGA listed for minors in the reporting period and the redeemed activation codes could therefore be traced back to them.

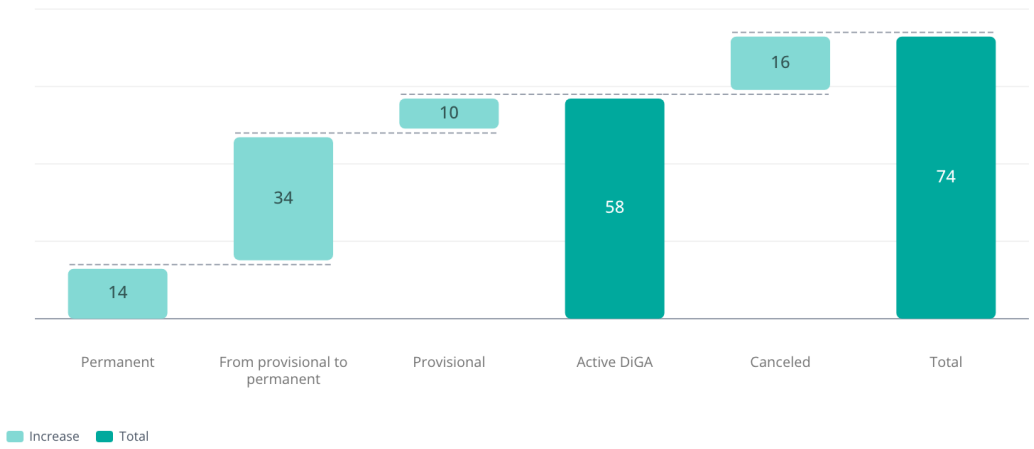
The SVDGV has received aggregated data on the number of activation codes that have been redeemed for 53 DiGA applications. This data does not allow for any conclusions to be drawn about individual patients or practitioners. DiGA manufacturers collect different metrics for their therapies and sometimes use company-specific methods to do so. Therefore, the underlying sample size (n) of the respective redeemed activation codes is specified for each metric. The information on the gender and age of users is based on self-reported data.

All 74 DiGA ever listed in the BfArM directory (including those that have been removed) were taken into account to determine the total number of redeemed activation codes. For the DiGA years 2021 through 2024, the respective total number of all redeemed activation codes was available from the German National Association of Statutory Health Insurance Funds (GKVSV)'s 2024 DiGA-Report. The total number for the most recent reporting year, 2025, was estimated using the same method as in previous DiGA-Reports: In the 2024 DiGA year, the SVDGV survey captured 97 percent of the total redeemed activation codes according to the German National Association of Statutory Health Insurance Funds (GKVSV)'s DiGA-Report. Based on this high degree of consistency, the SVDGV also calculated the total number of redeemed activation codes for the DiGA year 2025 using a coverage rate of 97 percent.

1.2.2. Stabilization with a broad DiGA offering

Following a sharp increase in the early years, the number of DiGA stabilizes at a high level: As of December 31, 2025, the BfArM directory contains 74 DiGA (including those that have been removed) across twelve categories. Of these, 48 DiGA are now permanently listed in the directory and ten are provisionally listed (Figure 2). Just under 70 percent of the DiGA initially provisionally included have successfully completed their one year trial phase and achieved permanent listing (34 out of 50). This development confirms that the studies for provisional listing are a very robust indicator for demonstrating a positive healthcare effect of a DiGA. At the same time, it confirms that the legislature's decision to allow for a one year trial phase is sensible and promotes innovation.

Figure 2: DiGA Overview as of December 31, 2025



Looking at the twelve available DiGA categories, as of December 31, 2025, the “Mental Health” category led with 30 DiGA, followed by the “Muscles, Bones, and Joints” category with seven DiGA and the “Hormones and Metabolism” category (including obesity and diabetes mellitus) with six DiGA. This means that potentially suitable digital therapies are available for many patients and their physicians and psychotherapists (Table 1).

Table 1: Overview of DiGA listed and removed from the BfArM directory as of December 31, 2025

DiGA	Category	Initial inclusion	Status as of 31.12.2025
Kalmeda	Ears	25.09.2020	Permanently included
velibra	Psyche	01.10.2020	Permanently included
somnio	Nervous system; Psyche	22.10.2020	Permanently included
Vivira	Muscles, bones, and joints	22.10.2020	Permanently included
zanadio	Hormones and Metabolism	22.10.2020	Permanently included
Invirto - Die Therapie gegen Angst	Psyche	03.12.2020	Permanently included
elevida	Nervous System	15.12.2020	Permanently included
Selfapys Online-Kurs bei Depression	Psyche	16.12.2020	Permanently included
deprexis	Psyche	20.02.2021	Permanently included
Mindable: Panik & Agoraphobie	Psyche	29.04.2021	Permanently included
vorvida	Psyche	06.05.2021	Permanently included
Selfapys Online-Kurs bei Generalisier-ter Angststörung	Psyche	19.06.2021	Permanently included
NichtraucherHelden-App	Psyche	03.07.2021	Permanently included
Mawendo	Muscles, Bones, and Joints	09.08.2021	Permanently included
Oviva Direkt für Adipositas	Hormones and Metabolism	03.10.2021	Permanently included
companion patella powered by medi - proved by Dt. Kniegesellschaft	Muscles, bones, and joints; injuries	04.10.2021	Permanently included
Novego: Depressionen bewältigen	Psyche	10.10.2021	Permanently included

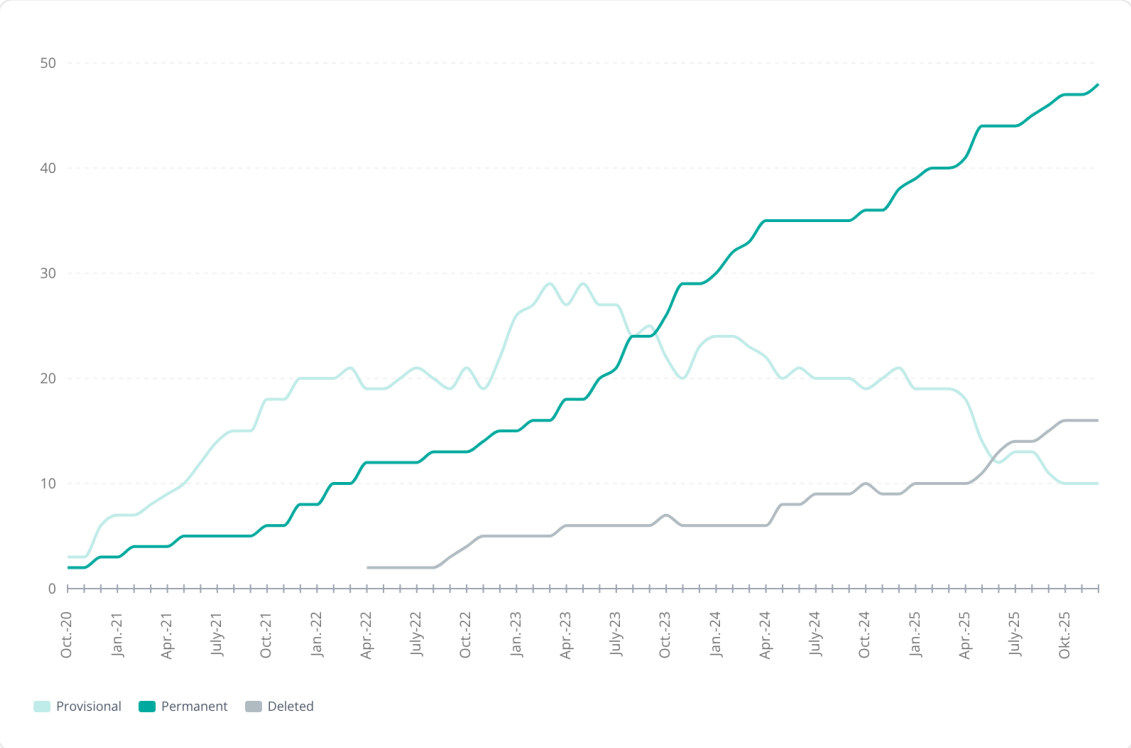
DiGA	Category	Initial inclusion	Status as of 31.12.2025
HelloBetter Stress und Burnout	Other	18.10.2021	Permanently included
HelloBetter Diabetes	Hormones and Metabolism	11.12.2021	Permanently included
HelloBetter Chronische Schmerzen	Muscles, Bones, and Joints; Psyche	18.12.2021	Permanently included
Kranus Edera	Genitals, kidneys and urinary tract	18.12.2021	Permanently included
Cara Care für Reizdarm	Digestion	26.12.2021	Permanently included
HelloBetter Vaginismus Plus	Psyche	04.02.2022	Permanently included
neolexon Aphasie	Other	06.02.2022	Permanently included
Meine Tinnitus App - Das digitale Tinnitus Counseling	Ears	06.03.2022	Permanently included
HelloBetter Panik	Psyche	03.04.2022	Permanently included
Vitadio	Hormones and Metabolism	15.04.2022	Permanently included
PINK! Coach	Cancer	27.06.2022	Permanently included
Endo-App	Genitals, kidneys and urinary tract	09.10.2022	Permanently included
HelloBetter Schlafen	Nervous system; Psyche	18.12.2022	Permanently included
edupression.com®	Psyche	26.12.2022	Permanently included
elona therapy Depression	Psyche	26.12.2022	Permanently included
Selfapys Online-Kurs bei Binge-Eating-Störung	Psyche	05.01.2023	Permanently included
Selfapys Online-Kurs bei Bulimia Nervosa	Psyche	05.01.2023	Permanently included
levidex	Nervous System	07.01.2023	Permanently included
Smoke Free - Rauchen aufhören	Psyche	29.01.2023	Permanently included
Kaia Rückenschmerzen - Rückentraining für Zuhause	Muscles, Bones, and Joints	03.02.2023	Permanently included
My7steps App	Psyche	17.02.2023	Permanently included
priovi - digitale Unterstützung der Borderline-Behandlung	Psyche	05.03.2023	Permanently included
Novego: Ängste überwinden	Psyche	24.03.2023	Permanently included
NeuroNation MED	Psyche	13.05.2023	Permanently included
ProHerz	Heart and Circulation	15.05.2023	Permanently included
Mindable: Soziale Phobie	Psyche	11.12.2023	Permanently included
Untire®	Cancer	25.12.2023	Permanently included
Kranus Lutera	Genitals, kidneys and urinary tract	15.04.2024	Permanently included
somnovia	Psyche	28.10.2024	Permanently included
attexis - die digitale Therapie bei ADHS im Erwachsenenalter	Psyche	06.08.2025	Permanently included
Kranus Mictera	Genitals, kidneys and urinary tract	27.10.2025	Permanently included
sinCephalea - Migräneprophylaxe	Nervous system	10.10.2022	Provisionally included
glucura Diabetestherapie	Hormones and Metabolism	11.01.2024	Provisionally included

DiGA	Category	Initial inclusion	Status as of 31.12.2025
Una Health für Diabetes	Hormones and Metabolism	09.02.2024	Provisionally included
Uroletics	Cancer	14.12.2024	Provisionally included
companion® shoulder	Muscles, bones, and joints	27.12.2024	Provisionally included
eCovery - Therapie bei Schmerzen im unteren Rücken	Muscles, bones, and joints	27.12.2024	Provisionally included
elona explore – für die mentale Gesundheit	Psyche	18.02.2025	Provisionally included
ORIKO ADHS-Therapie	Psyche	09.07.2025	Provisionally included
hiToco®: ADHS Elterntraining	Psyche	16.07.2025	Provisionally included
memodio	Psyche	29.12.2025	Provisionally included
M-sense Migräne	Nervous system	16.12.2020	Deleted
Rehappy	Heart and Circulation; Nervous System	29.12.2020	Deleted
Mika	Cancer	25.03.2021	Deleted
CANKADO PRO-React Onco	Cancer	03.05.2021	Deleted
Selfapys Online-Kurs bei Panikstörung	Psyche	19.06.2021	Deleted
ESYSTA App & Portal – Digitales Diabetesmanagement	Hormones and Metabolism	04.07.2021	Deleted
optimune	Cancer	14.07.2022	Deleted
re.flex	Muscles, bones, and joints	29.09.2022	Deleted
Kaia COPD: Meine aktive COPD Therapie	Respiratory system	26.12.2022	Deleted
Selfapys Online-Kurs bei chronischen Schmerzen	Muscles, bones, and joints; Psyche	21.04.2023	Deleted
mebix	Hormones and Metabolism	14.07.2023	Deleted
Orthopy bei Knieverletzungen	Muscles, bones, and joints; injuries	09.09.2023	Deleted
actensio	Heart and Circulation	30.12.2023	Deleted
Vantis | KHK und Herzinfarkt	Heart and Circulation	19.01.2024	Deleted
MindDoc Auf Rezept	Psyche	08.02.2024	Deleted
My Dose Coach	Hormones and Metabolism	16.06.2024	Deleted

Figure 3 shows the number of DiGA over time, from the beginning in fall 2020 until December 31, 2025. This illustration highlights that the one year trial phase contributes significantly to the success of DiGA. Many DiGA manufacturers are utilising the tried-and-tested option of a trial year with provisional approval to provide definitive evidence of the positive clinical benefit during this period. Only 14 DiGA have been directly and permanently included in the BfArM directory so far.

The timeline also makes it clear that in 2024 and 2025, compared to the first three years, only a few new DiGA were added to the directory. In 2025, there were six new DiGA. It can be assumed that the increased regulatory requirements are making the introduction of further DiGA increasingly difficult and are even forcing existing providers to withdraw.

Figure 3: Number of DiGA over time



1.2.3. More and more patients are using digital therapies

The strong growth trend in redeemed activation codes continued for the fifth consecutive year. From October 2020 through December 31, 2025, a total of approximately 1.6 million activation codes were redeemed – of which approximately 690,000 were redeemed in 2025 alone. This means that, as of the publication date of this report, patients had already been provided with digital therapy services over 1.7 million times.

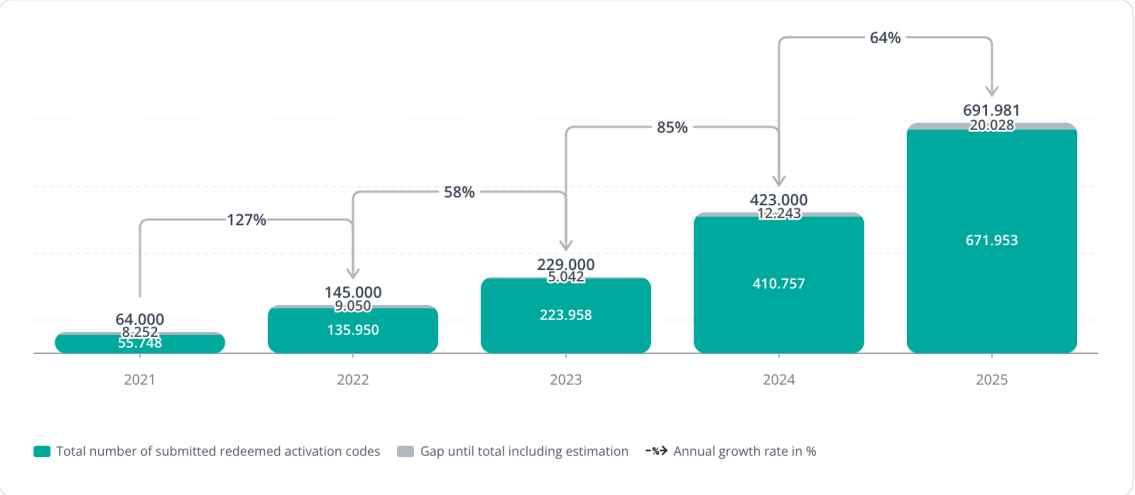
Figure 4 highlights the growth momentum for DiGA over the past five years. Most recently, the percentage growth in 2025 compared to 2024 was a remarkable 64 percent. Compared to the four previous DiGA years, which saw a total of 861,000 activation codes redeemed, the number of redeemed activation codes nearly doubled in the fifth year.

Alongside outpatient and inpatient care, DiGA have thus established themselves as the third pillar of the German healthcare system.

This conclusion is also supported by the initial results of the "ImplementDiGA" Innovation Fund project, which show that DiGA have also proven their worth from the patients' perspective. According to the findings, the majority of DiGA users see a benefit in this digital therapy: In addition to improved health (56 percent), they cite improvements in quality of life (62 percent), better management of illness-related difficulties in daily life (60 percent), and greater knowledge about the disease and therapy (69 percent). As part of the "ImplementDiGA" project, the use of DiGA is being scientifically researched from the perspective of various healthcare stakeholders.[11]

DiGA usage itself has also improved over the past two years. According to a survey by the auditing and consulting firm Deloitte, the proportion of patients who used their DiGA until the end of the prescription period grew from 58 percent in 2023 to 75 percent in 2025.

Figure 4: Total redeemed activation codes: 1.6 million



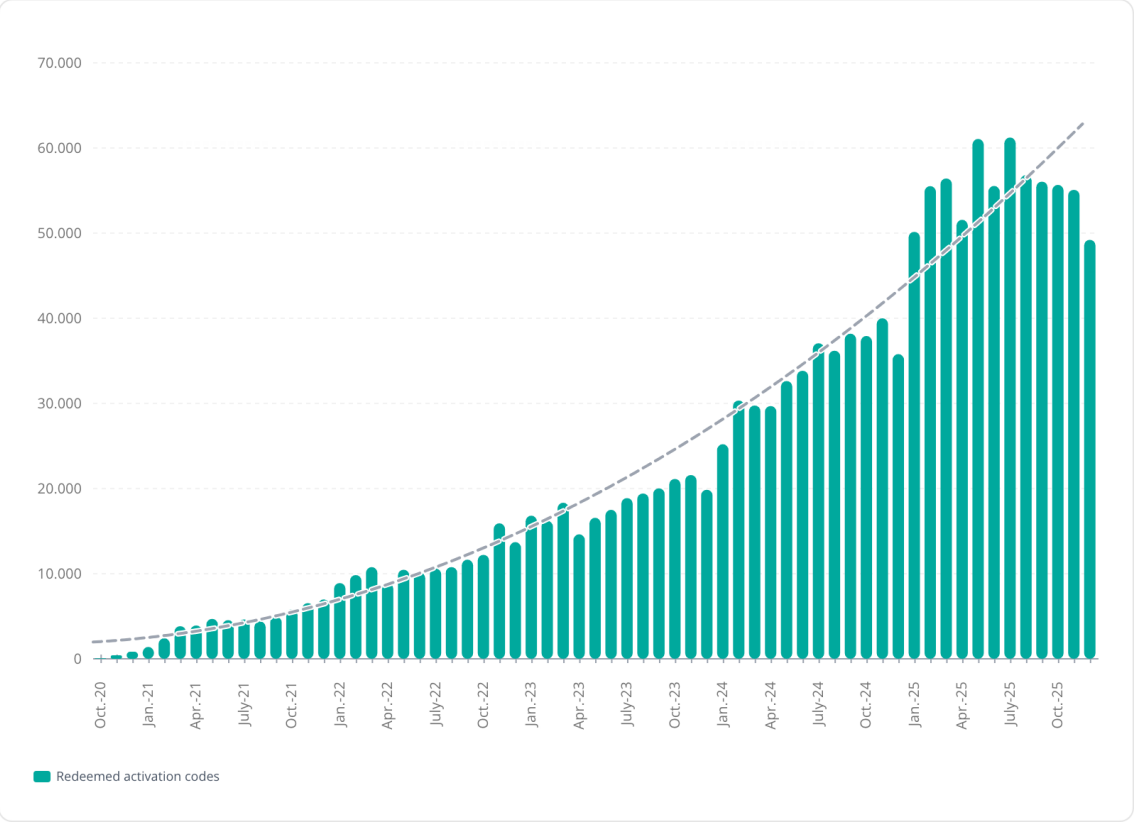
The monthly analysis of the number of redeemed activation codes shows a steady upward trend with a compound monthly growth rate of approximately 11 percent over the total period of 63 months (Figure 5).

Fluctuations during the year, such as those in June 2025, are partly attributable to technical difficulties – such as server outages at the health insurance companies' IT service providers – which lasted anywhere from a few hours to several days or even weeks. As a result, the affected health insurance companies were unable to generate or validate DiGA activation codes. In the past, a serious cyberattack on a major health insurance provider had also disrupted DiGA care (details in the DiGA-Report 2023).

In addition to these technical glitches, many other sources of error are affecting the prescription and authorization process for DiGA, which remains manual. A direct reimbursement pathway that does not require authorization generation by health insurance companies – as the SVDGV has long advocated – would significantly improve patient care.

Furthermore, the data reveals a seasonal pattern related to holidays (such as Christmas) – Medical offices are closed during these periods, and consequently fewer treatments are performed.

Figure 5: Redeemed activation codes per month

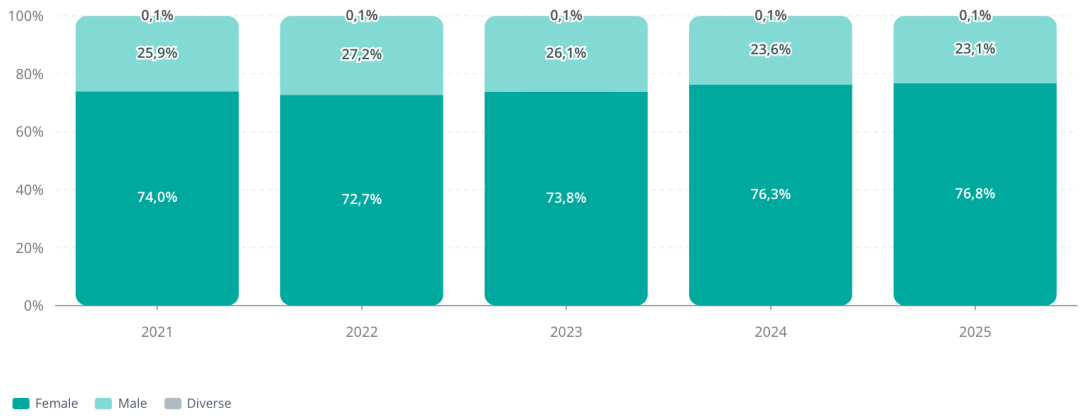


1.2.4. DiGA care for all – regardless of age and gender

As in previous years, the current DiGA-Report shows that DiGA users can be found in all (adult) age groups and across all gender identities.

In the DiGA year 2025, the proportion of female users was 77 percent, consistent with the range of the previous four years, which saw a female share of 73 to 76 percent (Figure 6). The reasons for this gender distribution were explained in the two previous DiGA-Reports. For instance, some DiGA are aimed exclusively at women, and some of the conditions addressed – such as depression (currently seven listed DiGA) – occur with a higher prevalence in women than in men or are diagnosed more frequently in women.[11]

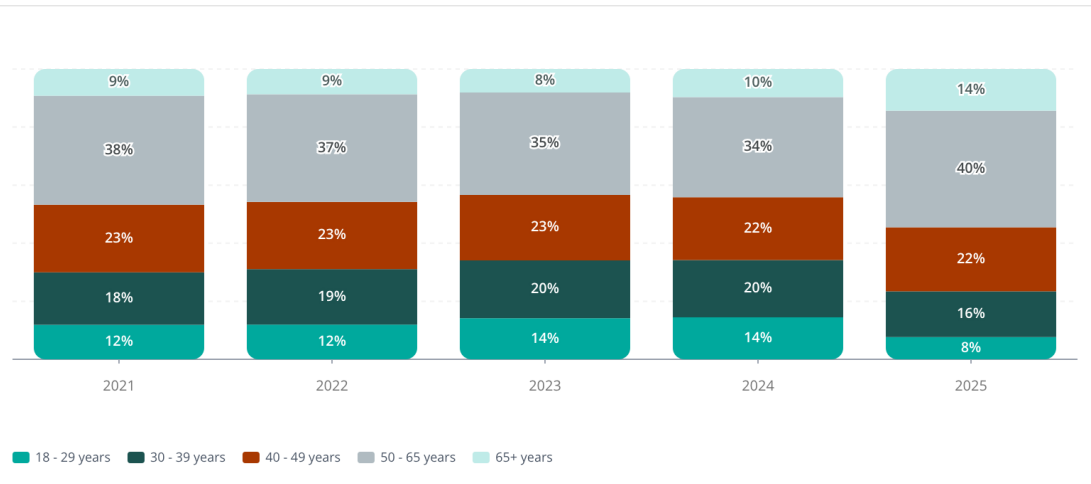
Figure 6: Redeemed activation codes by gender



The DiGA-Report 2025 confirms the observations from previous years: Adults of all age groups use DiGA.

Figure 7 shows that the share of the consistently largest age group, those aged 50 to 64, will increase over time to 40 percent in 2025. The proportion of DiGA users aged 65 and older is also rising. Possible reasons for this age trend include demographic developments (the “baby boomer generation”) and the increase in morbidity that comes with age. These findings confirm DiGA as an inclusive and evidence-based form of therapy suitable for all age groups – not just the younger generation that has grown up with digital technology.

Figure 7: Redeemed activation codes by age group



1.3. From Belgium to the USA: DiGA as an international model

The German DiGA model serves as an example for numerous other countries. Among the key factors behind this international success is the DiGA Fast Track procedure, which is unique in Germany, as the DiGA-Report 2024 detailed. The following table provides a concise overview of the programs available in other countries, including the latest developments from 2025 (Table 2). Only those countries for which there are existing national reimbursement pathways or concrete efforts to establish them are listed. For example, starting July 1, 2026, mandatory health insurance in Switzerland will cover the costs of digital Health Applications (dGA) for cognitive behavioral therapy in cases of mild to moderate depressive episodes.

Table 2: Overview of reimbursement options for Digital Medical Devices (DMD) in selected countries (as of December 31, 2025)

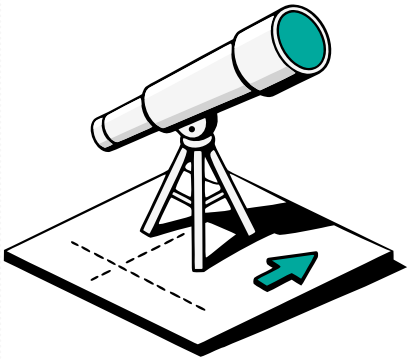
Country	Scope	Current Status of National Reimbursement	Number of products	Further Information
Germany	DiGA up to Class IIb; covers therapy, detection, and monitoring	Established, structured pathway with a national directory (DiGA directory) and mandatory reimbursement by all statutory health insurance providers	58 DiGA in various indications	BfArM DiGA directory DiGA Guidelines
France	PECAN pathway for DTx and telemonitoring (Classes I–III); LATM specifically for telemonitoring of chronic diseases	Maturing process with centralized national reimbursement via the PECAN (temporary) and LATM/LPPR (permanent) pathways	4 via PECAN (all remote patient monitoring) > 20 via LATM	G_NIUS Evaluations PECAN Guide
Belgium	"mHealth Pyramid" (M1-M3); current focus on telemonitoring (e.g., heart failure)	Established framework that provides national reimbursement for validated apps (M3 status) within specific care pathways	8 Monitoring Solutions for Heart Failure	INAMI MHealth
Switzerland	dGA	Reimbursement via established, nationally valid MiGeL	1 generic position for dGA for depression starting in July 2026	FOPH EAE criteria
South Korea	IRAS pathway for innovative medical devices (DTx, VR, AI diagnostics)	The accelerated pathway offers provisional reimbursement for up to 3–5 years to generate clinical evidence	6 DTx	HIRA Ministry
USA	SaMD/DTx (focus on mental health & chronic conditions); reimbursement for remote monitoring (RPM/RTM) and digital therapies	Fragmented but maturing: reimbursement by Medicare (new G-codes starting in 2025 for mental health), commercial insurers, and employer-sponsored plans	Not applicable	CMS
Japan	SaMD2-DASH pathway; two-stage process for innovative DTx and diagnostics	National reimbursement through public health insurance (NHI) with price incentives for early adoption and innovation	6 DTx	PMDA MHLW

List of Abbreviations for Table 2:

FOPH: Federal Office of Public Health; BfArM: BfArM; CMS: Centers for Medicare & Medicaid Services; DiGA: DiGA; dGA: Digital Health Application; DTx: DTx; HIRA: Health Insurance Review and Assessment Service; IRAS: Integrated Review and Assessment System; AI: Artificial Intelligence; LATM: List of Medical Telemonitoring Activities; LPPR: List of Reimbursable Products and Services; MHLW: Ministry of Health, Labour and Welfare; MiGeL: List of Medicines and Medical Devices; mHealth: mobile health; NHI: National Health Insurance; PECAN: Advance Coverage of Digital Medical Devices; PMDA: Pharmaceuticals and Medical Devices Agency; SaMD: Software as a Medical Device; SaMD-DASH: Digital Transformation Action Strategies in Healthcare for SaMD; VR: Virtual Reality; EAE: Effectiveness, Appropriateness, and Economic efficiency

Summary of the status of reimbursement options for DMDs in other countries

- **Italy:** There is a lack of national framework conditions; decisions are made at the regional level, although centralization is currently being considered.
- **England:** Reimbursement is decentralized via regional budgets (ICBs), based on NICE evaluations; a nationally funded "HealthTech" pathway is planned starting in 2026.
- **Australia:** There is currently no formal national pathway; reimbursements are made on an ad hoc basis, with a revision of the processes expected in the next 2–3 years.
- **Denmark:** The country is among the “followers” in Europe who are actively working on developing specific processes for assessment and reimbursement.
- **Austria:** As part of the eHealth Strategy 2025, preparations are underway to introduce a dedicated reimbursement pathway for DTx in 2026.
- **Netherlands:** The focus is on scaling hybrid care formats via the "Digizo.nu" platform, supported by specific innovation budgets.



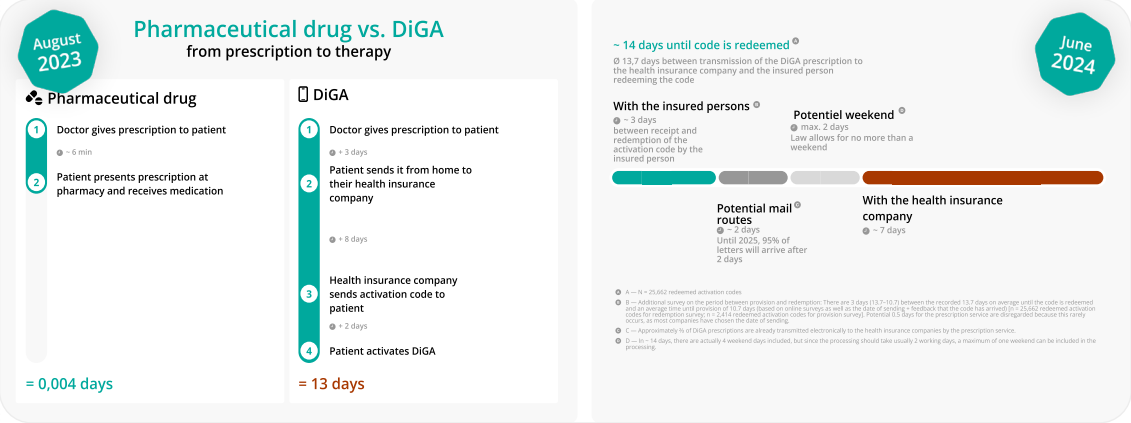
2. Future Prospects for DiGA – What Does It Take for a Successful Tomorrow?

2.1. Why access to DiGA must be simple and digital

Current data on the development of DiGA care confirm that this newest service area has successfully established itself in healthcare in just five years. Now it is important to create the conditions for a sustainable DiGA care system.

As already described in the DiGA-Reports 2023 and 2024, **access to DiGA care** for patients remains complicated, fragmented, and non-digital even in the fifth year. According to SVDGV member surveys in 2023 and 2024, it took an average of 14 days from the issuance to the fulfillment of a DiGA prescription (Figure 8). In 2025, the SVDGV did not conduct a new analysis of the prescription process, as the process remains unchanged and patients continue to regularly report receiving letters from their health insurance provider stating that the processing time for activating a prescribed DiGA can take several weeks. For a long time, the SVDGV has been calling for simple, direct, and digital access to DiGA in the interest of patients. This means, for example, activating a DiGA immediately after it is prescribed without (in some cases still manual) intermediate steps on the part of health insurance companies. It is unacceptable that patients for whom the prescription of a DiGA confirms an obviously acute need for treatment must wait weeks to begin their therapy. These comparatively long wait times can also impair patients' motivation and adherence to therapy.

Figure 8: Timeline of the activation process for DiGA based on a 2024 SVDGV survey of DiGA manufacturers, as well as in August 2023[i]



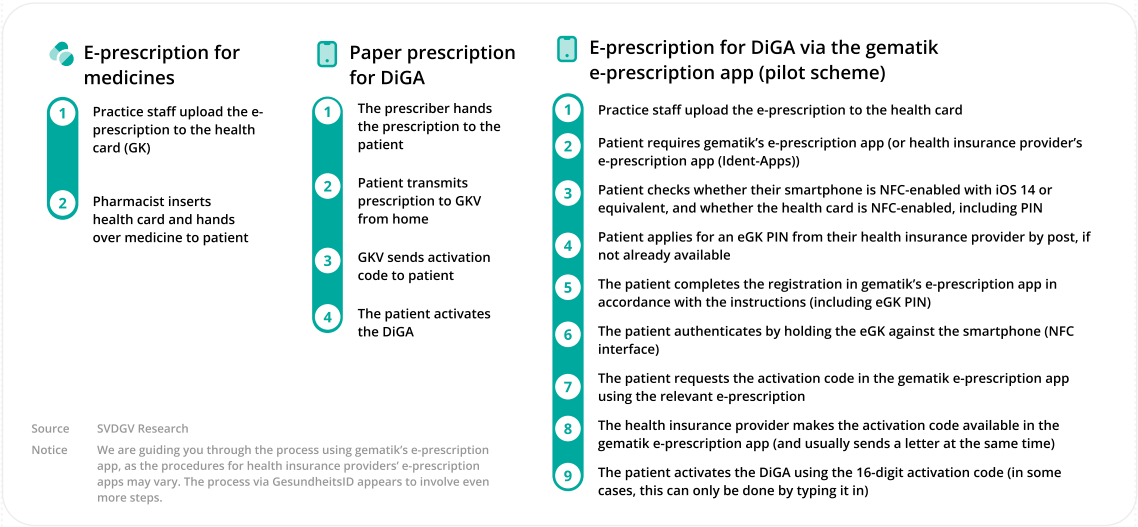
E-prescriptions for DiGA generally offer a potential solution for improving access. Their original implementation date of January 1, 2022, was first postponed to April 1, 2024, under the Hospital Nursing Relief Act (KHPflEG), and then to January 1, 2025, under the subsequent Digital Health Act.[ii] However, by the time this DiGA-Report was published, the parties involved had not been able to agree on a functioning technical implementation. From the SVDGV's perspective, it is desirable to create a user-friendly digital process rather than simply replicating an analog process digitally without modification. The most recent pilot concept by gematik, involving redemption via the e-prescription app and health insurance apps, revealed that there is still significant room for improvement in this area.

Figure 9 compares the currently existing redemption methods for drug and DiGA prescriptions with the piloted redemption method for DiGA prescriptions via gematik's e-prescription app. While

patients with an e-prescription for drugs can obtain their medication at a pharmacy in just two steps, the process for DiGA – which is currently still paper-based – involves four steps. Redeeming an e-prescription via gematik's app required more than twice as many steps as before (nine), as tested in the pilot in the Hamburg model region. As a result, despite additional training for practices, only 12.6 percent (15 out of 119) of the issued DiGA e-prescriptions were redeemed fully digitally there.

Through the piloted approach, the actual rate of treatment initiation thus lags significantly behind the redemption rates of 50 to 70 percent previously typical with paper based prescriptions. The cause lies in the significant barriers to access that arise from the non-self-explanatory process, which many patients find unreasonable. For example, they must install additional apps, apply for a PIN for their health card, or set up a health ID with their health insurance provider. By the end of December 2025, only 3.5 percent of those with statutory health insurance had installed the e-prescription app, and just under 6 percent had registered for the health ID. The piloted DiGA prescription process also continues to require health insurance companies to review the physician-issued DiGA e-prescription before patients receive their activation codes. This procedure unnecessarily delays the start of digital therapy, creates significant administrative burdens, and has already prompted multiple clarifications from the Federal Social Security Office (BAS).[7] Therefore, the SVDGV urgently calls for a comprehensive revision of the e-prescription procedure for DiGA – **prior** to a nationwide rollout and the mandatory use of e-prescriptions. With redemption rates like those from the pilot, DiGA could not be offered to patients in the long term.

Figure 9: Comparison of the required process steps from the issuance of a prescription/e-prescription to the dispensing of a medication or to the activation of a DiGA



The goal of a digital redemption process should be to enable patients to start their time- and location-independent therapy immediately after the prescription is issued. Technically, this would be possible. The SVDGV already proposed a solution in July 2024: Using the Proof of Patient Presence (PoPP) service and the electronic health card, the concept enables patient-centered, low-threshold, and barrier-free access to therapy. This would allow patients to begin their digital therapy within minutes of the doctor's prescription. In addition, insured individuals could use the piloted solution described by gematik as an alternative means of access. Further process improvements are conceivable: for

example, an e-prescription app from gematik that would enable lower-threshold access in the future, without a PIN or Health ID, as well as support options for redemption by the DiGA provider.

The SVDGV's proposals would ensure easier access to DiGA care for patients while simultaneously reducing the administrative burden on practices and health insurance companies. Therefore, the SVDGV calls for replacing the transitional solution that has been in place for five years with a simplified modern and patient-friendly process, thereby removing barriers to access. Only in this way can patients best benefit from the significant advantages of digital therapies.

In addition to a renewed smooth prescription process, **further changes** are needed to ensure that as many patients as possible can benefit from the advantages of DiGA:

- **Increasing Awareness**: According to the results of the "Healthcare Digitalization Monitor" conducted by the German Pharmaceutical Association (Verband Pharma Deutschland e.V.) in November/December 2025, only 27 percent of the approximately 5,000 respondents had ever heard of DiGA. A year earlier, this figure stood at 71 percent in a survey conducted by the digital industry association bitkom. This significant difference may be attributed to the respective survey methods used. Regardless, it is clear that a high level of awareness and understanding of DiGA can help ensure that more patients benefit from digital therapies. This also applies to physicians and psychotherapists. As explained in the DiGA-Report 2024, it is important to strengthen their digital competence as early as during their training.
- **Hybrid care models and integration into existing structures**: DiGA can effectively complement existing medical and psychotherapeutic care structures. For example, gaps in psychotherapy care can be closed with DiGA. In addition, blended care approaches can improve psychotherapy outcomes. Studies show that the combination of in-person video sessions and app-based exercises can significantly alleviate depressive symptoms. Hybrid care approaches also benefit the medical profession, as shown by a survey of nearly 14,000 German primary care physicians regarding the treatment of obesity. According to the survey, physicians who regularly prescribe DiGA for obesity therapy are significantly more optimistic about treatment outcomes than colleagues who do not prescribe DiGA: 54 percent of respondents who prescribe DiGA were (very) satisfied with the results of their treatment, compared to 34 percent in the group that does not prescribe DiGA ($p<0.001$).
- **Reimbursement for medical services related to DiGA**: Currently, physicians and psychotherapists receive EBM reimbursement of 64 points (currently 8.15 euros) for only a few DiGA, for example for follow-up monitoring, evaluation, or the customization of content. The DiGA prescription itself is covered by the basic and insured person's flat-rate fees. Therefore, new reimbursement concepts are essential for additional services related to patient education and therapy support within the DiGA care framework. Only in this way can we ensure that DiGA is even better integrated into care and treated on par with other therapeutic approaches in the future.

2.2. Ongoing Outcome Measurement: Why Value-Based Healthcare Doesn't Need a Bureaucratic Monster

In Chapter 1, the 2nd DiGAV-ÄndV was already presented as one of the legal changes for 2025. With its entry into force on February 01, 2026, DiGA manufacturers will be required, among other things, to conduct Ongoing Outcome Measurement on a regular basis in the future. The results are intended to form the basis for future performance-based price components amounting to 20 percent of DiGA reimbursement; the specific design is left to the contracting parties. With this, the legislature is introducing a value-based healthcare approach into the German healthcare system for the first time.

The SVDGV welcomes the objectives of the Ongoing Outcome Measurement regarding improvements in the quality and transparency of care. However, there is a risk of misinterpretation: First, the Ongoing Outcome Measurement requires extensive data on the pure usage statistics of DiGA without an evidence-based reference to their intended purpose. These regulations undermine the weight of scientifically proven benefits, which were demonstrated through evidence of a positive healthcare effect for permanent listing. Furthermore, the surveys conducted according to rigid guidelines create an assessment context outside of the therapeutic setting, which can disrupt the therapeutic process, particularly for vulnerable patients. In its currently stipulated implementation, Ongoing Outcome Measurement will inevitably lead to misinterpretations of the benefits of a DiGA, which have been substantiated by randomized controlled trials.

Furthermore, there is a high risk that Ongoing Outcome Measurement will impair DiGA usage and patient adherence, as some manufacturers have already observed due to the new data security requirements of BSI TR-03161 (Chapter 2.3).

This makes the regulations of the 2nd DiGAV-ÄndV all the more likely to raise substantial questions regarding the design of the Ongoing Outcome Measurement (Ongoing Outcome Measurement). Under the Ongoing Outcome Measurement framework conditions according to the 2nd DiGAV-ÄndV, large amounts of data are generated at great expense, yet this data has limited informative value and will not yield reliable results. Consequently, in its current form, the Ongoing Outcome Measurement yields no new insights for patients, healthcare providers, or the healthcare system, nor for health insurance companies and manufacturers.

Overall, the limited informative value of the Ongoing Outcome Measurement in its current form is offset by a high administrative burden. To consistently pursue the shared goal of reducing bureaucracy, the SVDGV suggests adapting the content of the Ongoing Outcome Measurement and streamlining the process. Optimizing the efficiency of the current concept would increase the benefits of Ongoing Outcome Measurement while also helping to allocate the resources of all parties involved more effectively toward substantive outcomes.

In addition, the insights hoped for from the Ongoing Outcome Measurement are already being obtained through other means. For example, the new Research Data Center (Forschungsdaten-zentrum: FDZ) for Health will begin collecting data in 2026. It can be assumed that health economic analyses of DiGA will be conducted on this basis in the future. Furthermore, the scientific community is increasingly addressing the health economic implications of DiGA, and initial studies have already demonstrated corresponding benefits. For instance, a cost-effectiveness and cost-utility analysis of

the DiGA companion®patella confirmed a more favorable cost-effectiveness ratio and cost-utility ratio compared to standard care with conventional physical therapy. Health economic analyses were also presented during price negotiations regarding the DiGA elevida and velibra.[1]

From the SVDGV's perspective, the currently planned structure of the Ongoing Outcome Measurement (AbEM) misses its actual target and, due to its considerable additional bureaucratic burden, hinders the introduction of DiGA. This is because the BfArM's personnel resources allocated to the Ongoing Outcome Measurement are urgently needed for the DiGA application procedures.

Against the backdrop of the Ongoing Outcome Measurement introduction and in view of upcoming developments resulting from the 2nd DiGAV-ÄndV, ensuring that the BfArM is adequately staffed is becoming increasingly important. Therefore, the SVDGV advocates for strengthening the BfArM's personnel capacities to permanently ensure the reliability and efficiency of the proven DiGA Fast Track procedure. Since the current volume of applications already poses major challenges for the BfArM team, additional resources are essential to keep processing times predictable for all parties involved. This is because swift processing is a key prerequisite, particularly for young companies and new providers, to successfully balance innovation cycles and high investments with the introduction of DiGA.

2.3. How to strike a balance between data security and therapeutic feasibility

Since January 1, 2025, DiGA manufacturers have been required to certify DiGA in accordance with Technical Guideline (TR) 03161 of the Federal Office for Information Security (BSI). By mid-2025, the first DiGA had received their BSI TR-03161 certificate.

With mandatory certification, the legislature is pursuing the laudable goal of protecting sensitive health data as effectively as possible. At the same time, the implementation of the certification process entails significant disadvantages for patients.

For instance, BSI TR-03161 contains several requirements that impair the usability of DiGA and thus contradict the DiGAV's requirement for simple and intuitive operation for patients.[2] For example, patients are automatically logged out after a short period of inactivity, requiring them to log in again several times a day. Such requirements can create an insurmountable hurdle, particularly for patients of advanced age, those with cognitive impairments, or those with mental health conditions, thereby preventing the initiation and ongoing use of digital therapy.

Overall, the mandatory BSI TR-03161 certification extends the application process for DiGA from the previously announced three months to at least nine months, thereby marking the end of the exemplary German DiGA Fast Track procedure.

These examples of the impact of BSI TR-03161 on DiGA care highlight the need for modern data security concepts that ensure maximum protection for health data while also keeping the barrier-free implementation of digital therapies in mind. It is also important not to impose more data security requirements on patients than they desire after receiving thorough information. In this context, they should also be allowed to decide for themselves whether to use their DiGA with an older

digital device, including an outdated operating system, that does not meet the requirements of BSI TR-03161.

Therefore, DiGA manufacturers are working together with the BSI to make the requirements of BSI TR-03161 more practical. In the meantime, agreement has been reached on several pragmatic adjustments, for example:

- The BSI intends to simplify the release processes for apps. In doing so, the proposal by DiGA manufacturers to certify internal company software release processes rather than every single product update will be taken into account.
- For both web-based and native apps, Two-factor authentication via a so-called passkey has been approved as a valid method. This will eliminate the tedious password entry process in the future.
- Due to critical feedback from DiGA manufacturers, the BSI is reviewing several additional requirements of TR-03161 that currently stand in the way of barrier-free and equitable access to DiGA for all patients. It remains to be seen what specific improvements will be made in the interest of patients.

Regardless of the technical adjustments described, the SVDGV recommends a policy review of the necessity for BSI TR-03161 certification of low-risk medical devices. Even before its introduction, DiGA manufacturers were required to demonstrate an ISO-certified information security management system, a quality management system, and annual penetration tests. It is also important to involve DiGA manufacturers in defining an appropriate level of data security that equally meets various requirements: the protection of sensitive health data, the feasibility of therapy as well as the accessibility for patients, without excluding older, socially disadvantaged, or less tech-savvy individuals from DiGA care. It is crucial that patients be allowed to manage their data autonomously. This includes taking a nuanced view of health data, as not all of it is equally sensitive.

2.4. Clear evidence requirements in Germany support urgent European harmonization

Over the past five years, DiGA manufacturers have demonstrated that their products meet the high evidence requirements of the DiGAV and the BfArM. This clear regulatory framework for DiGA in Germany supports a Europe-wide harmonized assessment of digital therapies.

2.4.1. Five years of successful evidence-based validation in Germany

Under the European Medical Device Regulation (MDR), DiGA are medical devices placed on the market that are fit for purpose and safe. In Germany, there are additional high requirements for demonstrating evidence for DiGA. As part of the application process for inclusion in the DiGA directory pursuant to Section 139e of the German Social Code, Book V (SGB V), the BfArM comprehensively reviews and evaluates the presence of a positive healthcare effect and the quality of the submitted studies. This review takes place within the framework of the application process, which typically lasts six months. To demonstrate the pEV, manufacturers must submit the study results in the form of a comprehensive study report in accordance with recognized scientific standards.

Over the past five years, DiGA manufacturers have met the demanding requirements of the DiGAV and the BfArM for evidence through their studies, as the following background information shows.

1. RCTs are the gold standard in study design

According to Section 10 of the DiGAV, comparative studies, including retrospective comparative studies and studies with intra-individual comparisons, are generally acceptable for demonstrating positive healthcare effect. However, the BfArM generally welcomes randomised controlled trials (RCTs) and, for methodological reasons, recommends conducting them to demonstrate the positive healthcare effect. **Accordingly, for all permanently listed DiGA to date**, **at least one prospective RCT has been submitted** that demonstrates the positive healthcare effect and thus substantiates the benefit of the respective DiGA. At the same time, the number of manufacturers submitting multiple RCTs to the BfArM to demonstrate a positive healthcare effect – or conducting further RCTs after already achieving successful listing – is increasing. Even in the context of provisional listing, manufacturers have submitted RCT results for the majority of DiGA to demonstrate the plausibility of the positive healthcare effect. In doing so, they meet the growing requirements for studies on provisional inclusion, which are largely identical to those for pilot studies on permanent inclusion in the DiGA directory.

2. Choice of comparators reflects real-world care

According to Section 10(1) of the DiGAV, studies to demonstrate the positive healthcare effect of DiGA must compare the DiGA with the non-use of the respective DiGA. However, this does not mean that all DiGA are studied in comparison to no treatment. Rather, Section 10(4) of the DiGAV stipulates that the comparator in all studies **must correspond to** the current **reality of care. Consequently, the comparator in DiGA studies varies depending on the indication and the area of application of the DiGA. For example, many DiGA are implemented in care settings where there are currently no or insufficient treatment options available. Therefore, standard care (care-as-usual) is frequently used as the control setting.** In this case, all study participants continue to have access to treatments according to the current standard of care, such as drug therapy. The intervention group additionally uses the DiGA. The treatments utilized during the intervention period are recorded, reported, and, if necessary, examined in further sensitivity analyses.

3. DiGA studies meet high quality standards

The vast majority of DiGA studies is of high quality, which the BfArM critically evaluates as part of the application process. This comprehensive evaluation is based on the detailed study reports prepared in accordance with scientific standards, as well as the underlying pre-specified study protocols and statistical analysis plans, which must be submitted to the BfArM.

In general, the Risk of Bias 2 (RoB-2) tool is frequently used to analyze the quality and potential for bias in studies. It was originally developed for drug studies. Although the BfArM does not conduct a systematic assessment of the risk of bias according to the RoB-2 tool as part of the application process, relevant content from its individual domains is reviewed; these are summarized in tabular form in the following appendix.

In the context of the RoB-2 tool, domain D4, “Outcome Measurement,” is frequently discussed. Accordingly, all DiGA studies would inevitably carry a high risk of bias, since almost all of them lack blinding of study participants (see the note below for details) and, at the same time, use patient-reported outcome measures (PROMs). However, this overlooks the fact that **blinding patients in DiGA studies is generally not methodologically feasible, or is only possible to a limited extent, or not at all. Against this backdrop, it seems questionable whether the RoB-2 tool, which is used as standard, is also suitable for DiGA studies. The authors of a recently published systematic review on DiGA studies also raise the question of whether the RoB-2 tool, with its rating system, is justified and appropriate for DiGA studies. Thus, in other research areas where blinding of study participants is typically not possible (e.g., psychotherapy research), the aspect of blinding is increasingly not taken into account in meta-analyses when the risk of bias is assessed using the RoB-2 tool.**

Side Note: "Risk of Bias Assessment and the Weaknesses in DiGA Studies"

Using the domains of the RoB-2 tool as an example, this section illustrates the requirements that the BfArM regularly examines during the application review process.

- **Domain 1 – Randomization:** The BfArM verifies whether randomization was conducted in accordance with recognized scientific standards. This requires ensuring allocation concealment (i.e., that the persons conducting the study are blinded) as well as variable block lengths where necessary. In addition, the unpredictability and non-manipulability of group assignment must be guaranteed (see Chapter 4.3.4 of the DiGA Guidelines).
- **Domain 2 – Deviations from the Intervention:** The BfArM requires that the intervention and control intervention are defined in the study protocol. In addition, any concomitant care that may influence the study results must be recorded and presented in the study report. If necessary, the BfArM may request post-hoc sensitivity analyses. The study report also details the number of protocol deviations and violations among participants in both study groups, such as whether the study was terminated early or participants could no longer be reached (dropouts and lost to follow-up). The primary analysis is conducted according to the intention-to-treat (ITT) principle.
- **Domain 3 – Missing Data**: The BfArM requires an ITT analysis in accordance with recognized scientific standards, in which patients are evaluated according to their initial group assignment and missing values are replaced using at least one conservative imputation method (e.g., reference-based imputation with a jump-to-reference approach). **In addition, sensitivity analyses using alternative imputation methods, as well as comparisons between dropouts and patients who completed the study as per protocol (completers), are routinely required. Thus, missing data are analyzed comprehensively and conservatively overall.**
- **Domain 4 – Outcome Measurement**: A common point of criticism in the evaluation of DiGA studies using the RoB-2 tool concerns the lack of blinding in conjunction with the collection of PROMs, as this combination can lead to a high risk of bias according to Dimension D4 of the RoB-2 tool. It must be noted here that **blinding patients in DiGA studies, particularly in the psychotherapeutic field, is generally not methodologically feasible or is only possible to a limited extent, if at all.** Since DiGA typically involve educational content or therapeutic exercises and techniques that are applied in patients' daily lives, it is usually obvious which group they have been assigned to in a study. **Furthermore, typical DiGA content complicates the design of a so-called sham app for several reasons. Either the app is designed too "simply," making it obvious to patients that they have received the sham app, or it includes content or exercises that themselves have a therapeutic effect. In the second case, however, there is a risk that the effect of the sham app will then exceed the placebo effect itself.** There are further arguments against the use of sham apps. On the one hand, **the use of ineffective interventions can raise ethical concerns. On the other hand the comparator in DiGA studies must be based on real-world care, which largely rules out the use of sham apps.**
  At the same time, PROMs are used in the majority of DiGA studies. They are generally well-established in the respective research fields and are essential and irreplaceable for many

endpoints due to the lack of objective measurement instruments. Examples include endpoints such as pain or quality of life. In these cases, PROMs are essential for data collection, as the (perceived) burden or limitation experienced by the affected individuals is the primary focus.
In other research areas as well, participant blinding is not taken into account in several meta-analyses when assessing the potential for bias. These include, for example, studies in psychotherapy, in which blinding is generally not possible.

- **Domain 5 – Selection of reported results**: When applying for inclusion in the DiGA directory, the prespecified study protocol must be submitted to the BfArM, including the comprehensive statistical analysis plan prepared prior to data access with prespecification of all evaluated variables, endpoints, and associated analytical methods. As part of its review of the study report, the BfArM also assesses whether all pre-specified analyses have been submitted by the manufacturer and whether any deviations and additional analyses are reported fully and transparently. **The BfArM frequently requests comprehensive additional sensitivity analyses as well, so that the length of study reports often exceeds 100 pages.** The published, peer-reviewed articles on DiGA studies usually represent only a fraction of the analyses and results submitted to the BfArM. This is because the level of detail required by the BfArM would exceed the scope of any scientific publication.

2.4.2. European harmonization as an important next step

Despite all legitimate criticism, the DiGA Fast Track procedure is a proven system with relatively clear and reliable criteria for demonstrating evidence. True to the saying *"If you can make it here, you can make it anywhere"* it could serve as the foundation for Europe-wide harmonization of reimbursement requirements for digital therapies.

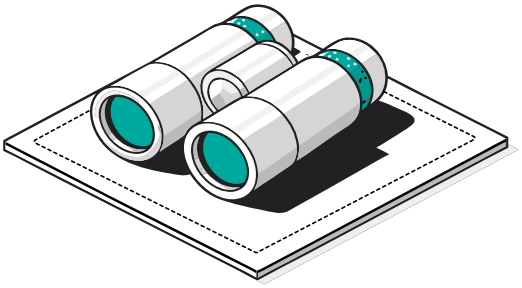
Only with harmonized reimbursement frameworks – including the mutual recognition of clinical trials – can a European healthcare landscape for digital medical devices continue to develop, and innovations benefit all patients in Europe more quickly. This European digital healthcare landscape also strengthens Germany (and Europe) as a business location. Patients in other countries could more easily benefit from the innovative digital therapies developed here.

The SVDGV has long advocated for European harmonization – for example, through the EIT Health network initiative, in the run-up to the 2025 federal elections, in the 2024 DiGA-Report, and at a variety of events such as panel discussions.[7] Furthermore, the SVDGV is among the more than 110 organizations, companies, and individuals who have signed a joint declaration on harmonization by September 30, 2025. In it, European decision-makers call for a pragmatic, convergent European assessment framework for digital medical devices (DMD) starting in 2026. They are pushing for comparable criteria for the clinical evaluation and reimbursement of DMDs. Harmonizing the currently fragmented evaluation frameworks of individual EU member states is a prerequisite for the cross-border scaling of European DMDs and thus ensures Europe's technological sovereignty. It is also important that a harmonized evaluation framework be designed pragmatically so that it enables the fastest possible access for innovative technologies within a maximum of two to three years.

Germany and France, which have the largest healthcare systems in Europe, play a key role in the harmonization of the assessment framework. Both countries have been collaborating since 2023 on a roadmap for digitalization in the healthcare sector. However, the views of the respective relevant authorities differ regarding the procedure for the reimbursement eligibility of DMDs. For instance, the president of the Haute Autorité de Santé (HAS) criticized the BfArM's DiGA Fast Track procedure as being too market-oriented and unsuitable for France. Nevertheless, in June 2025, the BfArM and the HAS, as well as the German and French Ministries of Health, signed a letter of intent announcing a strengthening of cooperation in the evaluation of digital medical devices. They also agreed on concrete steps for the years 2025 and 2026. These include joint workshops among the four signatory institutions and an exchange of experts to better understand each other's evaluation procedures. This collaboration is driven by the goal of creating a uniform evaluation framework for digital medical devices in the EU in the future.

The SVDGV has long been actively involved in the process of regulatory harmonization and welcomes the current steps toward aligning the regulatory frameworks. A direct comparison between Germany and France illustrates how much both healthcare systems can benefit from cross-border exchange. While France has already established a standard for medical telemonitoring with the list of activités de télésurveillance médicale (LATM), Germany offers an impressive variety of digital therapy options with around 60 available DiGA.[7] In contrast, the French PECAN procedure, with currently four reimbursable telemonitoring applications, is still in the early stages of scaling up, while in Germany, the integration of DiGA and telemonitoring shows further potential for development.[7] These

complementary strengths provide the ideal foundation for jointly raising digital patient care in both countries to a new level of quality through the harmonization of requirements.



3. Outlook

After half a decade, the delicate DiGA seedling has grown into a thriving young plant now caring for **well over a million patients** and beginning to bear its first fruits, as this impressive record shows:

- With DiGA, Germany has assumed an international **pioneering role** in the field of Digital Health that serves as a model worldwide.
- **Awareness of DiGA** among patients and healthcare providers **is** steadily **increasing**, as confirmed by the number of activation codes redeemed.
- With the success of DiGA, numerous innovative companies have established themselves, creating **thousands of highly skilled jobs**.

For DiGA to grow into a strong tree, **additional improvements** to its framework conditions are now needed. Because only with digital offerings like DiGA can effective healthcare for all people be guaranteed today and in the future.

- On the one hand, it is necessary to overcome a number of **hurdles** that are slowing the further growth of DiGA **in Germany**. For example, a streamlined e-prescription concept, similar to that used for medications, would significantly simplify access to DiGA care for patients. Furthermore, it is important that innovative improvements to existing digital health applications (DiGA) benefit patients as quickly as possible. Bureaucratic requirements such as the lengthy BSI TR-03161 certification process, the announced BfArM data protection certificate, and the process surrounding "substantial changes" should therefore be critically reviewed for their practical feasibility.
- On the other hand, it is crucial for future development that DiGA "made in Germany" also become accessible to patients in other countries. Among the indispensable prerequisites for this is **harmonized access across Europe** with comparable standards and evaluation frameworks for reimbursement eligibility.

Finally, with regard to the European Union's AI Regulation (EU AI Act), DiGA and the entire German healthcare system face the challenge of making sensible use of the **possibilities offered by artificial intelligence (AI)**. After all, AI technologies are already present in various areas of medicine and healthcare today. In the future, they will play an increasingly important role.

This **five-year review** gives cause for celebration and impressively demonstrates how positively DiGA care has developed in Germany in such a short time. At the same time, it highlights areas for improvement to further embed DiGA within healthcare structures.

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