**Spitzenverband
Digitale
Gesundheitsversorgung**

Market Development of Digital Health Applications (DiGA Report)

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Dear readers,

for the past three years, patients in Germany have had the opportunity to use Digital Health Applications, German "Digitale Gesundheitsanwendung" (DiGA), a digital therapeutic reimbursed by health insurances, to treat various medical conditions. This innovation in the German healthcare system aims to bridge gaps in in the provision of healthcare, leading to a sustainable improvement in the lives of many patients.

DiGA comprise digital medical devices such as smartphone apps and web-based applications designed for the detection, monitoring, or treatment of medical conditions. These „apps on prescription" can be prescribed to patients by doctors or psychotherapists, with the costs covered by statutory health insurance. Germany, through this model, has taken on a pioneering role internationally, setting an example for other countries to follow.

The legal foundation for DiGA was established with the Digital Healthcare Act (Digitale-Versorgung-Gesetz or DVG)[1], which came into effect in December 2019. The first DiGA received approval from the responsible authority, the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte: BfArM), in the autumn of 2020. As of September 30, 2023, the official DiGA directory includes 49 Digital Health Applications.

This report provides an overview of the developments in this new area of healthcare during the initial three years. It examines the growth of the DiGA market, prescription volumes and key insights gained during this period. Furthermore, it assesses the implementation of the DiGA model in healthcare practice to identify areas for improvement as well as highlighting the potential of this rapidly evolving sector as a driver for growth in Germany.

The DiGA report focuses on three central findings:

1. Sustainable growth in the DiGA market:

Since the approval of the first DiGA, both the number of DiGA in the market and the number of medical and psychotherapeutic prescriptions have been steadily increasing. This market growth has been accompanied by rising employment figures, foreign direct investments and research and development. Furthermore, Germany's successful model of digitally supported healthcare with DiGA is gradually being incorporated into the legislation of other European countries.

2. One year trial phase as essential framework for introducing new DiGA into healthcare:

Preliminary listing in the DiGA directory allows DiGA to demonstrate that there are clear indications of positive healthcare effects through systematic data evaluation. The vast majority of these Digital Health Applications subsequently secures permanent inclusion through evidence from larger studies.

3. Processes with room for relevant improvement:

An optimized process for DiGA activation codes (provided by health insurance) could enable patients to use DiGA more quickly. Furthermore, a nationwide information campaign about DiGA would educate healthcare providers and patients about this new treatment option, enabling them to make informed decisions. Additional approaches to further development are outlined in this report.

Digital Health Applications are gaining broader acceptance, with an increasing number of healthcare providers and patients utilizing these medical devices. This is promising, as they are already making a significant contribution to improving healthcare provision, which is in itself increasingly constrained by staffing and financial limitations. Therefore, it is crucial that all advancements and improvements in this new area of healthcare provision are made with foresight and discretion to avoid overregulation and thus hindering progress.

As one of the leading industry associations for digital healthcare, the German Digital Health Association (Spitzenverband Digitale Gesundheitsversorgung: SVDGV) contributes its expertise and practical experience to create the right political framework for digitally supported healthcare.

We hope you enjoy reading this report.

Dr. Anna Haas
Chairwoman of SVDGV

Henrik Emmert
Chairman of SVDGV

Dr. Anne Sophie Geier
Managing Director

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[1] Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale-Versorgung-Gesetz – DVG)

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Executive summary

With this DiGA Report, the German Digital Health Association (SVDGV) provides insights into the development of the DiGA market based on manufacturer data. Being the first report of its kind, it covers the entire period after the listing of the first DiGA from October 2020 to September 2023.

In addition to the number of redeemed activation codes, the manufacturer data provides information about the age and gender distribution of DiGA users. The results of a supplementary survey among DiGA manufacturers also highlight the overall economic significance of the DiGA industry.

As of the report's cutoff date on September 30, 2023, there are 49 Digital Health Applications listed in the BfArM directory. Of those 49 enquired, data was provided for 35 of these DiGA. The majority of the data is based on information provided by manufacturers, another portion was estimated for the period from October 2022 to September 2023.

The analysis of the data available to SVDGV reveals that the DiGA market is experiencing continuous and sustainable growth. Both the number of Digital Health Applications available to patients and the range of addressed indications are steadily increasing. Nearly 50 percent of the DiGA listed in the directory as of 30. September 2023 have been permanently included because they have already demonstrated a positive healthcare effect. The existence of such a diverse DiGA market today is significantly linked to the „Erprobungsjahr" (one year trial phase). Without this path for market access, only a fraction of the Digital Health Applications currently listed would be available to patients in standard care.

The one year trial phase also provides an important framework for many manufacturers to conduct studies demonstrating the positive healthcare effect. It is worth noting that for all DiGA that have been permanently included into the DiGA directory so far, randomized controlled clinical trials have been conducted, surpassing the requirements set by lawmakers.

Since the fall of 2020, nearly 370,000 activation codes for DiGA have been redeemed by patients, according to SVDGV's conservative estimate. DiGA have thus become an important pillar in today's healthcare landscape.
The number of redeemed activation codes over the years also reflects dynamic and sustainable growth. While there was a 215 percent growth between the first and second year of DiGA, even a conservative estimate shows a 65 percent growth between the second and third year.

Digital Health Applications not only enhance care but have also become a significant economic factor for Germany, as highlighted by the results of a supplementary survey among DiGA manufacturers. Companies developing DiGA create new jobs, invest in research and development and bring forth innovative technologies.

DiGA also contribute to closing gaps in healthcare provision and enable new forms of therapy in areas with previously limited offerings. However, many processes related to the integration of DiGA into standard care need further improvement. For instance, comprehensive education of healthcare providers and patients is essential for the widespread awareness of digital therapy options. Similarly, patient access to DiGA should be simplified, allowing for immediate access without weeks of waiting. Only then can DiGA fully unleash their potential and further enhance healthcare in Germany.

1. Introduction

1.1 Legal framework

Digital Health Applications create new and innovative healthcare options for healthcare providers and patients while addressing existing gaps in healthcare provision. The Digital Healthcare Act (Digitale-Versorgung-Gesetz: DVG), which came into effect in December 2019[2], established the legal framework for the provision of Digital Health Applications (DiGA), the so called „apps on prescription".

Digital Health Applications are medical devices of low risk class (Class I or IIa) primarily based on digital technologies. They exist as smartphone apps or web-based applications. They are intended to support the detection, monitoring, treatment or alleviation of diseases, or the detection, treatment, alleviation or compensation of injuries or disabilities.

A Digital Health Application (DiGA) can be prescribed by physicians or psychotherapists. The costs for a DiGA are covered by statutory health insurance. Patients can also directly apply for a DiGA with their health insurance, provided that a medical indication is established. It is important to note that the principle of medical therapeutic freedom applies and health insurance companies are not permitted to interfere with a physician's prescription decision[3].

To be considered a Digital Health Application, an application undergoes an intensive evaluation process at the Federal Institute for Drugs and Medical Devices (BfArM). Only after this evaluation, it is included in the official DiGA directory[4], which lists all „apps on prescription" and provides relevant information transparently and comprehensively for each application. The BfArM aims to evaluate a manufacturer's request to include their application as a DiGA within three months. During this process, a detailed examination of the DiGA takes place, including aspects like data security, data protection, user-friendliness, interoperability and the demonstration of a positive healthcare effect.

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
- ✅ Digital medical product, CE certification
- ✅ Cost coverage by statutory health insurance
- ✅ Evidence of positive healthcare effects demonstrated
- ✅ Ad-free
- ✅ High standards regarding safety, functionality and quality, as well as data protection and data security

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To demonstrate their value for healthcare, every DiGA must deliver a positive healthcare effect, which can either be a medical benefit or a patient-relevant structural or procedural improvement (e.g., improved adherence or increased health literacy). There are two ways to be included in the DiGA directory: either with provisional inclusion for testing or with permanent inclusion. The difference lies in whether the positive healthcare effect for the respective application has already been sufficiently proven. The assessment considers statistical significance as well as clinical relevance. If sufficient evidence is available, such as from a completed randomized controlled clinical trial (RCT), the application is permanently included. Alternatively, if the evidence is not yet conclusive, provisional inclusion, also known as „inclusion for testing," can be chosen. In this case, the evidence must be presented within 12 months, or in exceptional cases, a maximum of 24 months.

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[2] Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale-Versorgung-Gesetz – DVG)
[3] Rundschreiben DiGA des Bundesamtes für Soziale Sicherung: "Prüfpflichten und -rechte der Krankenkassen bei der Abgabe von Digitalen Gesundheitsanwendungen (DiGA) nach § 33a SGB V"
[4] DiGA directory: https://diga.bfarm.de

For provisional inclusion, appropriate evidence of effectiveness must also be submitted. For example, the manufacturer must demonstrate with a systematic data evaluation that positive healthcare effects can be assumed. To provide this evidence, manufacturers increasingly use a control group, going beyond legal requirements. Approximately 44 percent of systematic data evaluations have already been conducted using the design of a randomized controlled clinical trial.[5]

The German Digital Health Association (SVDGV) plays a significant role in this new service area. It is one of the largest industry representatives of manufacturers of digital health and care applications and belongs to the key umbrella organizations of digital health and care application manufacturers at the federal level in Germany. The SVDGV acts as a central advocate for its members in dealings with politics, authorities and other stakeholders in healthcare in general, particularly in legislative initiatives related to Digital Health Applications. Currently, 41 out of a total of 49 DiGA are operated by SVDGV members (as of September 30, 2023).

1.2 New legal regulations

Following the establishment of the initial legal framework for DiGA with the Digital Healthcare Act (Digitale-Versorgung-Gesetz: DVG) in 2019, there have been further adjustments to the legal requirements, documented in the Patient Data Protection Act (PDSG)[6] from October 2020 and the Digital Healthcare and Care Modernization Act (DVPMG)[7] from June 2021. These amendments have further increased the already high requirements for Digital Health Applications in recent years. Originally, penetration tests, for example, were only required for DiGA with increased security needs. With the implementation of the DVPMG, this requirement was extended to all DiGA. In the latest version of the DiGA guideline (as of October 11, 2023)[8], this requirement is further tightened: In the future, all DiGA manufacturers must primarily have penetration tests conducted by testing bodies certified by the Federal Office for Information Security (Bundesamt für Sicherheit in der Informationstechnik: BSI). These tests must also mandatorily include code reviews and white-box tests[9].

Upon taking office, the "traffic light coalition" (German political parties: SPD/FDP/Grüne) announced further initiatives for the digitization of healthcare, which were supposed to be achieved through a digitization strategy. This strategy raised great expectations in the healthcare sector, as it included significant improvements for the DiGA model. For example, it was planned that DiGA could encompass extensive telemedical care concepts, including the involvement of physicians and psychotherapists, or that „apps on prescription" could access data from the electronic health record (EHR).

The practical implementation of the digitization strategy through the Digital Health Act[10] („Act to Accelerate the Digitization of Healthcare" - DigitalGesetz: DigiG) consequently includes several expansions of the DiGA sector. DiGA of higher risk classes, including telemonitoring, are to be introduced, DiGA are to be more integrated into disease management programs and DiGA for pregnancy are to be established. However, the DigiG also contains adjustments that increase bureaucratic efforts for all parties involved without apparent benefits, such as mandatory ongoing measurement of success. These changes have also been criticized by the National Association of Statutory Health Insurance Funds (Spitzenverband Bund der Krankenkassen: GKV-SV).[11]

SVDGV has extensively outlined its positions on the new Digital Health Act. They have proposed various amendments[12] to facilitate the practical integration into healthcare and effectively expand the new service area of DiGA. For example, there should be immediate investment in comprehensive and independent education for insured individuals and healthcare providers about DiGA. Many insured individuals and a significant number of healthcare providers still have limited knowledge about this form of care.[13] Furthermore, a simplified prescription process and an optimized process for the DiGA activation codes (provided by health insurance) should be introduced to allow patients to use their DiGA immediately and without lengthy waiting times in the future.

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[5] DiGA-Analyzer, fbeta
[6] Patientendaten-Schutzgesetz (PDSG)
[7] Digitale-Versorgung-und-Pflege-Modernisierungsgesetz (DVPMG)
[8] DiGA Leitfaden (Stand: 11.10.2023)
[9] A code review involves a manual examination of the DiGA source code at the program code level to identify security-related vulnerabilities. In a white-box test, an internal attack with insider knowledge of the IT infrastructure and application environment of the respective DiGA is simulated.
[10] Entwurf eines Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens vom 30.08.2023
[11] Stellungnahme des GKV-Spitzenverbandes vom 08.11.2023 zum Digital-Gesetz - DigiG
[12] Position des SVDGV zum Digital Gesetz
[13] Ärzteblatt, "Mangelndes Wissen über Digitale Gesundheitsanwendungen behindert Verordnungen", dated October 6, 2023

1.3 DiGA framework agreement

In a joint framework agreement[14], the key associations of DiGA manufacturers and the National Association of Statutory Health Insurance Funds (GKV-SV) have defined the criteria for negotiating reimbursement amounts for DiGA and how these price negotiations should be conducted. Since the DiGA manufacturer associations and the National Association of Statutory Health Insurance Funds could not agree on all the intended content of the framework agreement, the final determination of the framework agreement was made by the arbitration board pursuant to § 134 (3) SGB V (Volume V of the German Social Security Code) on December 16, 2021. This particularly applies to regulations on maximum amounts, which are reimbursement caps that apply until a reimbursement amount for DiGA is agreed upon. The arbitration board also provided regulations for a threshold, which determines the price level up until which no negotiation of reimbursement amounts is required.

Almost two years after the final determination of the framework agreement, it can be stated that many of the intended processes are functioning and essential objectives of the established regulations are being met. During a review, this conclusion was recently reached by the contracting parties of the framework agreement. Considering the goals pursued by the legislator, this review could have also led to the further development of maximum prices and threshold values.

Nevertheless, the framework agreement offers potential for optimization, especially with regard to the future design of reimbursement amount negotiations. This is evidenced by the numerous arbitration awards on the determination of reimbursement amounts, as agreements between DiGA manufacturers and the National Association of Statutory Health Insurance Funds are rarely reached based on the existing regulations.

2. Data baseline

As of September 30, 2023, there are 49 applications listed as Digital Health Applications in the DiGA directory. At this time, the manufacturers of a total of 41 of these DiGA are members of the German Digital Health Association (SVDGV). The data collected for this report was individually requested by SVDGV from each manufacturer for their respective DiGA. Only the SVDGV's office and the respective manufacturer's company had access to the data sheet used to inquire about the number of redeemed activation codes for each DiGA.

This DiGA Report by SVDGV is pubished for the first time. Therefore, the reporting period covers the entire period from October 1, 2020, to September 30, 2023.[15] The data analyzed in this report provides information about the development of the DiGA market, user characteristics and usage trends throughout the years. The data used in this report reflects the following metrics of SVDGV member companies:

Key Figures

- **Total number** of redeemed **DiGA activation codes**
- Distribution of reedemed **activation codes by months**
- Distribution of reedemed **activation codes by initial prescriptions and follow-up prescriptions**
- 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 - 49 years, 50 - 64 years, 65 + years, age not specified)[16]

[14] Rahmenvereinbarung nach §134 Abs. 4 und 5 SGB V
[15] The initial listing of a DiGA took place on September 25, 2020, with the inclusion of Kalmeda in the DiGA directory. However, it is assumed that no or very few activation codes were redeemed during the remaining four working days until October 1, 2020, so these four days are excluded from the observation period.
[16] The age group ‚under 18 years' was excluded from consideration here since only two DiGA are listed in this age group and the redeemed activation codes can be attributed to these two.

SVGDV received information about the number of redeemed activation codes for 35 out of 49 enquired DiGA. These data do not allow any conclusions to be drawn about individual patients or healthcare providers. Not all DiGA manufacturers collect the same metrics for their DiGA. To maximize transparency, the sample size (n) of the redeemed activation codes is provided for each metric. This clarifies on which dataset the metric is based. A breakdown by months is included in most responses. The information regarding gender and age of users is selfreported.[17] Also, the collection of initial and follow-up prescriptions varies depending on the DiGA manufacturer.[18]

To determine the total number of redeemed activation codes, all DiGA were considered, including those that have already been removed from the directory. Since SVGDV received information about the number of redeemed activation codes for 35 out of a total of 55 (current and removed) DiGA, the remainder was estimated for the latest reporting year. Given that the total number of redeemed activation codes for the periods from October 1, 2020, to September 30, 2021 (hereinafter referred to as „DiGA Year 1 (Oct '20 - Sep '21)") and for the period from October 1, 2020, to September 30, 2022, is available in the DiGA reports of the GKV-SV[19], a estimation was made only for the period from October 1, 2022, to September 30, 2023 (hereinafter referred to as „DiGA Year 3 (Oct '22 - Sep '23)").[20]

For this purpose, the growth between the second DiGA year (Oct '21 - Sep '22) and the third DiGA year (Oct '22 - Sep '23) was first calculated, based on the sums of redeemed activation codes submitted to SVGDV. This growth was then corrected for two estimates by the same coefficient and the same difference, which were also present between the growth of the submitted, redeemed activation codes and the growth of the total number of redeemed activation codes between the first DiGA year (Oct '20 - Sep '21) and the second DiGA year (Oct '21 - Sep '22).

Using these two corrected growth rates between the second DiGA year (Oct '21 - Sep '22) and the third DiGA year (Oct '22 - Sep '23), the total number of redeemed activation codes for the third DiGA year (Oct '22 - Sep '23) and thus the total number of redeemed activation codes for the entire reporting period was estimated.

In an additional survey, company-specific data from DiGA manufacturers was collected. 17 DiGA manufacturers participated in the survey. All response options were optional. Therefore, the results have different sample sizes. Only the available data were considered for each analysis and there was no extrapolation to the entire sample or the entire industry. DiGA manufacturers include both startups and established medical device and pharmaceutical manufacturers. The available data pertain, in the case of larger medical device and pharmaceutical manufacturers, solely to the DiGA business segment. In the case of startups, they pertain to the entire company.

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[17] DiGA users do this, for example, because the respective DiGA only covers certain age or gender groups.

[18] For example, there are individual DiGA that have different pharmaceutical central numbers for initial and follow-up prescriptions, as the initial prescription may include hardware. For most manufacturers, a follow-up prescription can only be identified if patients associate it with their already registered account.

[19] Report of the GKV-Spitzenverbandes, "Über die Inanspruchnahme und Entwicklung der Versorgung mit digitalen Gesundheitsanwendungen", Reporting Period: 01.09.2020-30.09.2022
Report of the GKV-Spitzenverbandes, "Über die Inanspruchnahme und Entwicklung der Versorgung mit digitalen Gesundheitsanwendungen", Reporting Period: 01.09.2020-30.09.2021

[20] To calculate the total number of redeemed activation codes for the second DiGA year (Oct '21 - Sep '22), the difference between the number of redeemed codes in the period Oct '20 - Sep '22 and the period Oct '20 - Sep '21 was calculated.
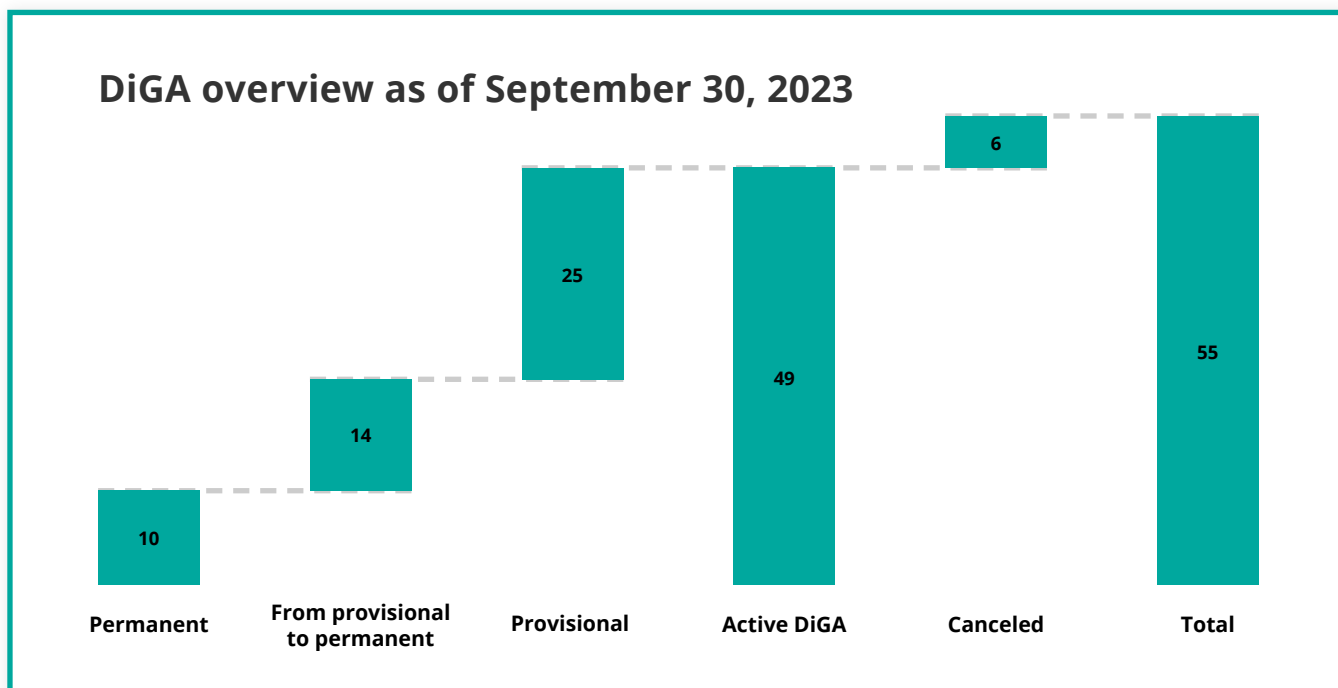
3. Data analysis & interpretation

3.1 DiGA overview

As of September 30, 2023, BfArM's DiGA directory includes 49 Digital Health Applications from eleven different categories. Among these, 24 applications are permanently listed, while 25 DiGA are temporarily listed in the directory and are thus in the "testing phase". The largest group of DiGA addresses mental health conditions, but there is also a relevant number of applications listed in the „Muscles and Joints" category.

In addition to the sheer number of listed DiGA, the diversity of addressed indications is steadily increasing. One year after the start of the DiGA Fast Track procedure, primarily DiGA for mental health conditions, obesity and muscle and joint complaints were available. However, there are now also DiGA available for alcohol addiction, endometriosis or smoking cessation.[21] This digitally supported healthcare through DiGA offers a broader spectrum of support options for healthcare providers, psychotherapists and patients.

Other European countries also recognize the added value of digital healthcare offerings. France has already launched its own approval path called „PECAN",[22] through which Digital Health Applications are expected to become reimbursable in France in the future.[23] Austria is also actively discussing the reimbursement of Digital Health Applications, with implementation possibly in 2024.[24] Furthermore, other European countries are considering introducing DiGA as well.[25] In addition, there are efforts to establish a harmonized approval pathway within Europe. A dedicated task force was established for this purpose in 2022. It focuses on harmonizing the nomenclature and taxonomy of Digital Medical Devices, creating a common framework for clinical evidence evaluation and developing proposals for integration into healthcare systems.[26]

DiGA overview as of September 30, 2023

Source: DiGA Directory of the BfArM

Permanent	From provisional to permanent	Provisional	Active DiGA	Canceled	Total
10	14	25	49	6	55

[21] DiGA directory: https://diga.bfarm.de
[22] PECAN (Prise en Charge Anticipée Numerique des Dispositifs Médicaux) can be translated as „Early Access to Cost Reimbursement for Digital Medical Devices".
[23] Handelsblatt Inside Digital Health, „Neuer Markt für deutsche Firmen? Wie attraktiv ist die französische DiGA?", 08.05.2023
[24] Gesundheitswirtschaft.at, „Digitale Gesundheits-Apps – Bei DiGA nur 2. Liga"
[25] Handelsblatt Inside Digital Health, „Gesundheitsapps werden zum Exportschlager"
[26] EIT Health, European Taskforce for Harmonised Evaluations of Digital Medical Devices (DMDs)

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DiGA	Initial Inclusion	Status as of September 30, 2023
Kalmeda	25.09.2020	Permanently included
velibra	01.10.2020	Permanently included
somnio	22.10.2020	Permanently included
Vivira	22.10.2020	Permanently included
zanadio	22.10.2020	Permanently included
Invirto- Die Therapie gegen Angst	03.12.2020	Permanently included
elevida	15.12.2020	Permanently included
Selfapys Online-Kurs bei Depression	16.12.2020	Permanently included
deprexis	20.02.2021	Permanently included
Mindable: Panikstörung und Agoraphobie	29.04.2021	Permanently included
vorvida	06.05.2021	Permanently included
Selfapys Online-Kurs bei Generalisierter Angststörung	19.06.2021	Permanently included
NichtraucherHelden-App	03.07.2021	Permanently included
Mawendo	09.08.2021	Permanently included
Oviva Direkt für Adipositas	03.10.2021	Permanently included
HelloBetter Stress und Burnout	18.10.2021	Permanently included
HelloBetter Diabetes und Depression	11.12.2021	Permanently included
HelloBetter ratiopharm chronischer Schmerz	18.12.2021	Permanently included
Kranus Edera	18.12.2021	Permanently included
HelloBetter Vaginismus Plus	04.02.2022	Permanently included
HelloBetter Panik	03.04.2022	Permanently included
Selfapys Online-Kurs bei Binge-Eating-Störung	05.01.2023	Permanently included
Selfapys Online-Kurs bei Bulimia Nervosa	05.01.2023	Permanently included
Kaia Rückenschmerzen - Rückentraining für Zuhause	03.02.2023	Permanently included
companion patella powered by medi - proved by Dt. Kniegesellschaft	04.10.2021	Provisionally included
Novego: Depressionen bewältigen	10.10.2021	Provisionally included
Cara Care für Reizdarm	26.12.2021	Provisionally included
neolexon Aphasie	06.02.2022	Provisionally included
Meine Tinnitus App - Das digitale Tinnitus Counseling	06.03.2022	Provisionally included
Vitadio	15.04.2022	Provisionally included
PINK! Coach	27.06.2022	Provisionally included
optimune	14.07.2022	Provisionally included
re.flex	29.09.2022	Provisionally included
Endo-App	09.10.2022	Provisionally included
sinCephalea - Migräneprophylaxe	10.10.2022	Provisionally included
HelloBetter Schlafen	18.12.2022	Provisionally included
edupression.com®	26.12.2022	Provisionally included
elona therapy Depression	26.12.2022	Provisionally included
Kaia COPD: Meine aktive COPD Therapie	26.12.2022	Provisionally included
levidex	07.01.2023	Provisionally included
Smoke Free - Rauchen aufhören	29.01.2023	Provisionally included
My7steps App	17.02.2023	Provisionally included
priovi - digitale Unterstützung der Borderline-Behandlung	05.03.2023	Provisionally included
Novego: Ängste überwinden	24.03.2023	Provisionally included
Selfapys Online-Kurs bei chronischen Schmerzen	21.04.2023	Provisionally included
NeuroNation MED	13.05.2023	Provisionally included
ProHerz	15.05.2023	Provisionally included
mebix	14.07.2023	Provisionally included
Orthopy bei Knieverletzungen	09.09.2023	Provisionally included
M-sense Migräne	16.12.2020	Deleted
Rehappy	29.12.2020	Deleted
Mika	25.03.2021	Deleted
CANKADO PRO-React Onco	03.05.2021	Deleted
Selfapys Online-Kurs bei Panikstörung	19.06.2021	Deleted
ESYSTA App & Portal – Digitales Diabetesmanagement	04.07.2021	Deleted

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One year trial phase and evidence

As of September 30, 2023, there are a total of 49 Digital Health Applications in the DiGA directory. Among these, 24 DiGA are permanently included in the directory, accounting for approximately 50 percent of the listed applications. At the same date, 25 applications are provisionally included in the directory.

Looking at the history of DiGA approvals, it becomes evident that since the early days of autumn 2020, the majority of initially provisionally included Digital Health Applications have successfully transitioned to permanent inclusion by demonstrating positive healthcare effects. Out of 20 DiGA that were provisionally included since October 1, 2020, and subsequently applied for permanent inclusion, 14 applications have now achieved „permanent inclusion" status. Only six Digital Health Applications have been removed from the directory.[27]

DiGA admissions over time

Legend: Provisional, Permanent, Deleted
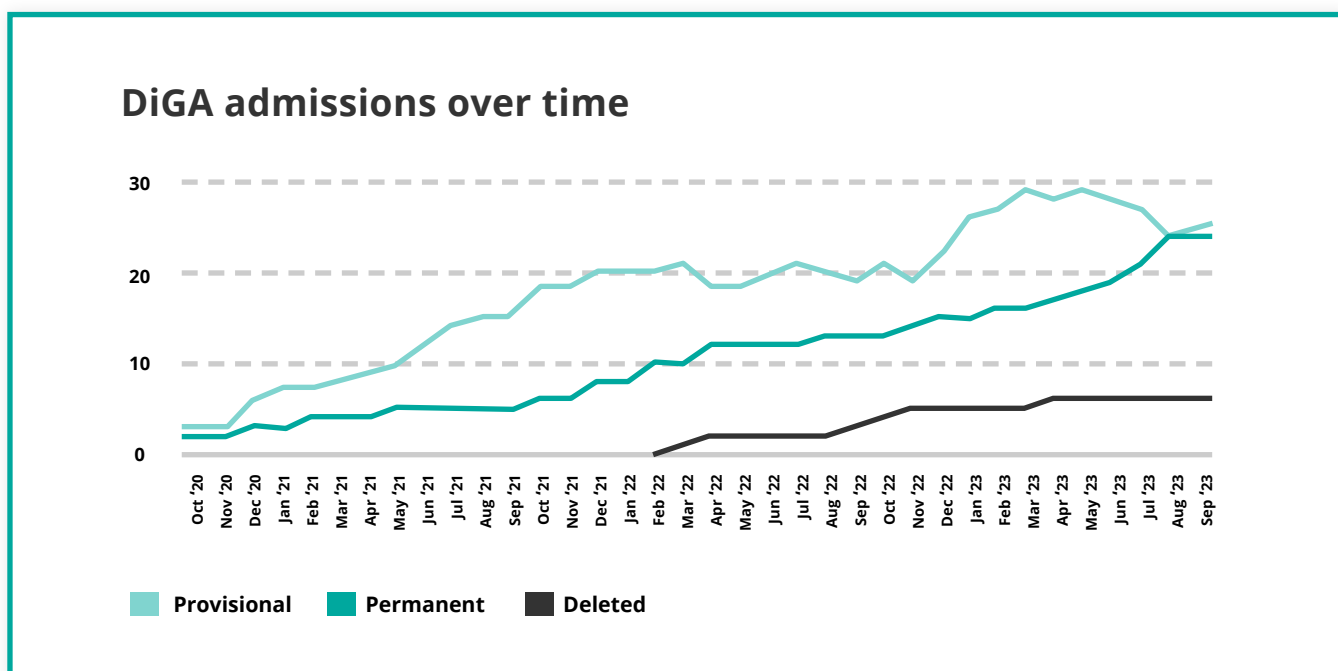
The chart of DiGA admissions over time shows that the ratio between provisionally included DiGA and permanently included DiGA is increasingly converging. The reason being that more and more provisionally included DiGA are achieving permanent inclusion into the DiGA directory. Newly added DiGA predominantly continue to choose provisional inclusion and provide evidence of positive healthcare effects during the one year trial phase.

Thus, the one year trial phase has proven to be a crucial factor in building a diverse DiGA market with a wide range of digital care offerings. Without the one year trial phase, it is likely that the DiGA market would currently include only the 10 applications that directly applied for and received permanent inclusion. Consequently, there would possibly be no digital care options available in the statutory health insurance system for numerous medical conditions, including those with high prevalence. Applications for the treatment of obesity, endometriosis, irritable bowel syndrome or migraines would not be available as DiGA and an essential component of healthcare would only be accessible to self-payers.

The evidence provided by DiGA manufacturers for positive healthcare effects during the one year trial phase also adheres to the highest scientific standards: 100 percent of all Digital Health Applications that have been included (both initially provisionally included and directly permanently included applications) have conducted randomized controlled clinical trials to demonstrate the positive healthcare effects of their DiGA.[28] This means that the manufacturers go far beyond the legislative requirements for study quality. According to legal requirements, studies with lower levels of evidence would also suffice.

[27] DiGA directory: https://diga.bfarm.de
[28] DiGA directory: https://diga.bfarm.de

100%

For 100% of the Digital Health Applications (DiGA) currently listed, the manufacturers have conducted randomized controlled clinical trials (RCTs) to demonstrate the positive healthcare effect.

In particular for startups, the one year trial phase has proven to be an essential component for entering the DiGA market: it provides the foundation for generating the necessary revenue needed to cross-finance the high study costs. Without this trial year, many startups would find it challenging to afford the significant initial investments required for conducting a clinical trial. By comparison, it's worth looking at the market for digital nursing applications (Digitale Pflegeanwendungen: DiPA): There is no one year trial phase or opportunity to provide scientific evidence for nursing benefits alongside practical use. This is one of the key reasons why, as of September 30, 2023, and over two years after its introduction, there isn't a single reimbursable DiPA available in Germany.

So, the one year trial phase for DiGA serves an important purpose in making innovations available to patients quickly and with low barriers, just as envisioned by the Digital Healthcare Act.

3.2 DiGA usage

Three years after the introduction of the first Digital Health Application, DiGA have become part of the healthcare offering: Approximately 370,000 DiGA activation codes were redeemed during this time and the new digital therapy options have been used by thousands of patients.
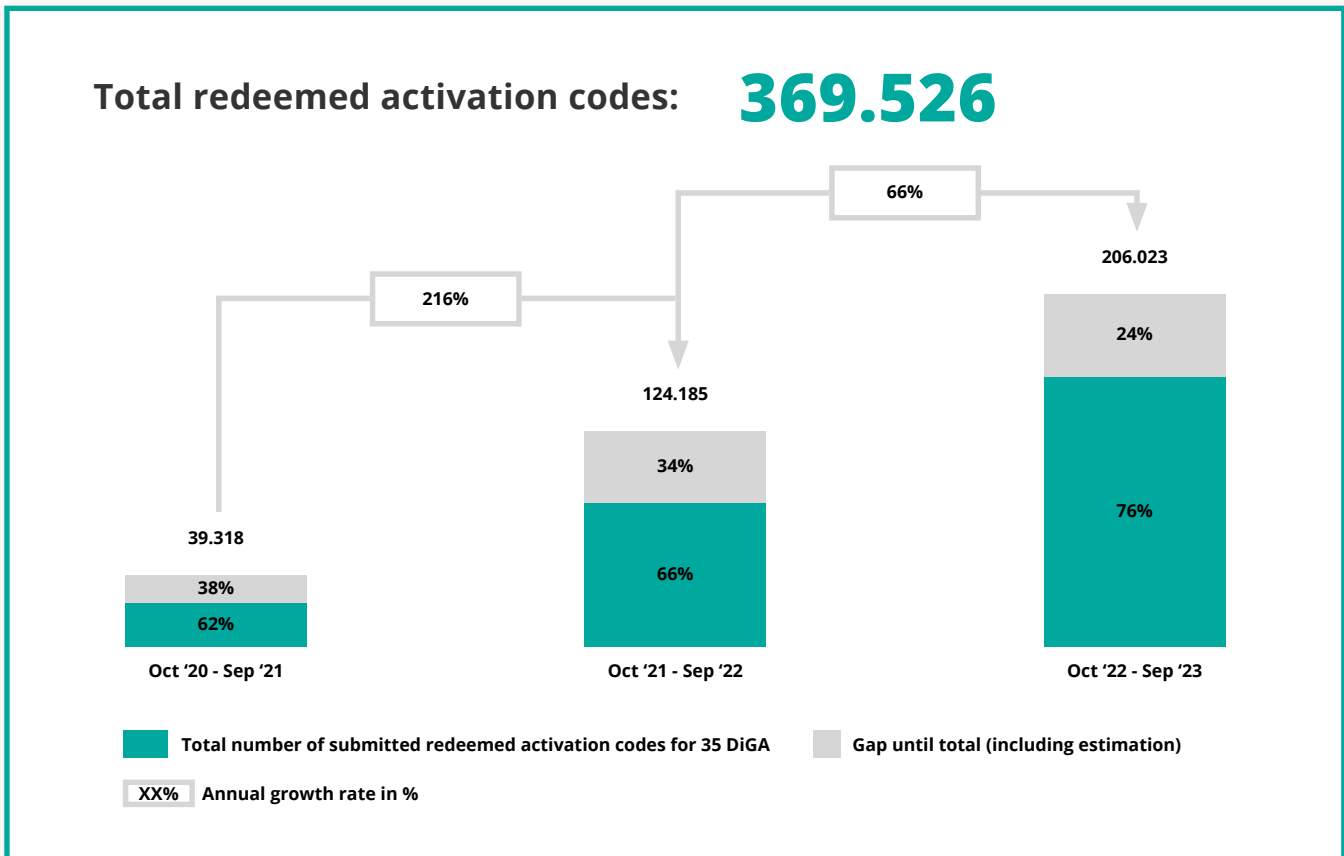
When examining the development of the total number of redeemed activation codes over the years, it shows a dynamic and sustainable growth: While the growth between the first DiGA year (Oct '20 - Sep '21) and the second DiGA year (Oct '21 - Sep '22) was approximately 215 percent, even conservatively estimated there is growth of 65 percent between the second DiGA year (Oct '21 - Sep '22) and the third DiGA year (Oct '22 - Sep '23).[29]

This includes a 25 percent estimate for the third DiGA year (Oct '22 - Sep '23) to reach a total of approximately 206,000 redeemed activation codes in that year. More than half of all activation codes were redeemed in the third DiGA year (Oct '22 - Sep '23).

An alternative estimate leads to a growth rate of approximately 80 percent when considering the same coefficient instead of the same difference in growth rates. This perspective results in around 225,000 redeemed activation codes for the third DiGA year (Oct '22 - Sep '23), bringing the total across all three periods to almost 400,000 redeemed activation codes.
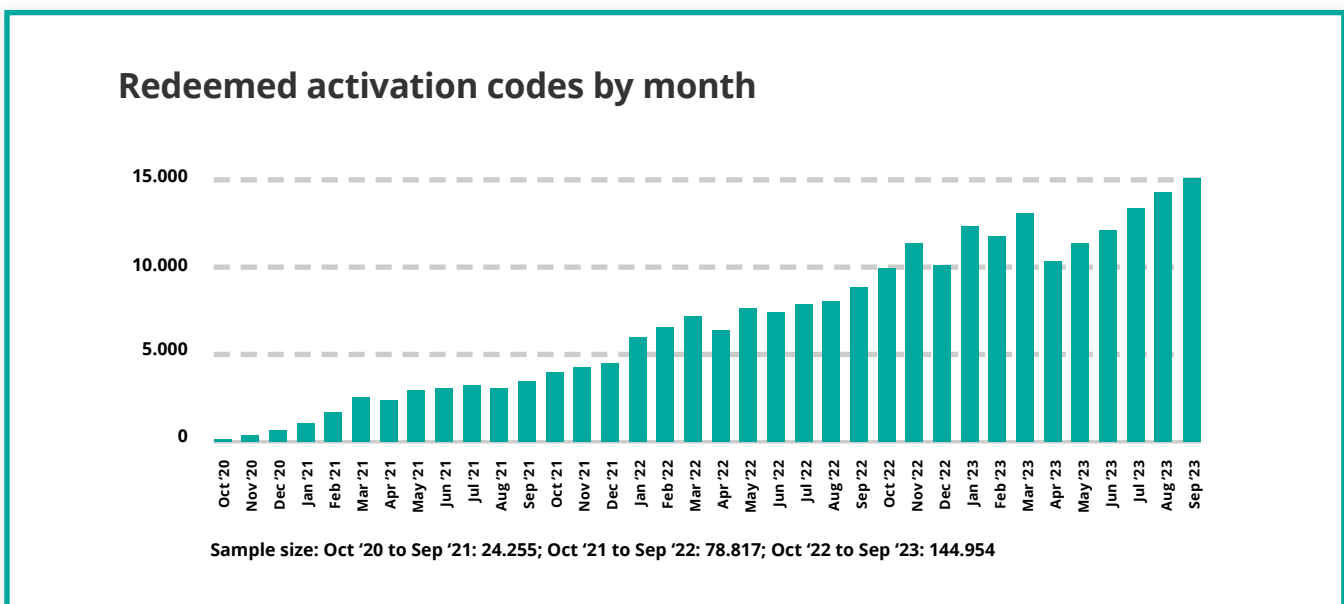
[29] The data reported to SVDGV indicates a growth of approximately 90 percent for the third DiGA year (Oct '22 - Sep '23). Since it is assumed that the overall growth for the current period is lower than the growth of the data reported to SVDGV, SVDGV considers this estimate to be conservatively robust. The growth between the first DiGA year (Oct '20 - Sep '21) and the second DiGA year (Oct '21 - Sep '22) was approximately 240 percent for the reported redeemed activation codes to SVDGV vs. approximately 215 percent for the total number of redeemed activation codes.

Total redeemed activation codes: **369.526**

66%

216%

206.023
- 24%
- 76%

124.185
- 34%
- 66%

39.318
- 38%
- 62%

Oct '20 - Sep '21   Oct '21 - Sep '22   Oct '22 - Sep '23

■ Total number of submitted redeemed activation codes for 35 DiGA   ■ Gap until total (including estimation)

[XX%] Annual growth rate in %

Source: GKV-SV and SVDGV

Looking at the development by month, September is consistently the strongest month in the annual cycle from October to September for each period. This suggests an overall steady growth of individual DiGA throughout the year. The Compound Monthly Growth Rate (CMGR)[30] of approximately 19 percent over the 36 months considered shows a healthy average growth.

Redeemed activation codes by month

Sample size: Oct '20 to Sep '21: 24.255; Oct '21 to Sep '22: 78.817; Oct '22 to Sep '23: 144.954
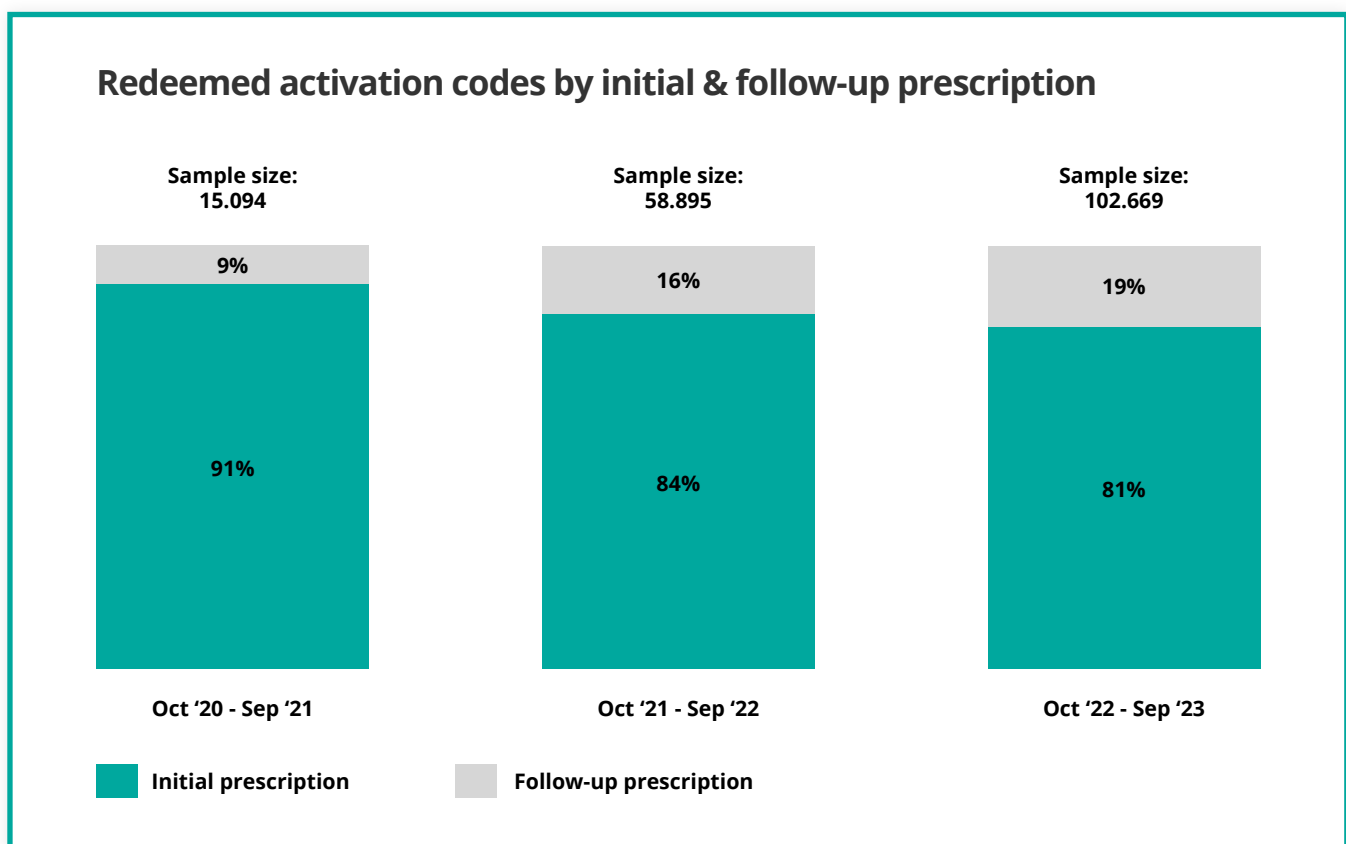
Source: SVDGV

[30] CMGR (Compound Monthly Growth Rate): same as CAGR (Compound Annual Growth Rate) for average monthly growth.

Data analysis & interpretation | DiGA Report 2023

As per feedback from DiGA manufacturers, the decline in the number of redeemed activation codes from March 2023 to April 2023 can be attributed to a disruption in DiGA services for patients, caused by a cyberattack on Bitmarck (service provider for social insurance carriers with exclusive participation from health insurance associations providing IT services in the field of statutory health insurance). Public reports on this matter emerged for the first time in April 2023. As part of the measures to prevent further damage, customer and internal systems were taken offline. Consequently, many health insurance companies were unable to generate new DiGA activation codes or validate previously generated ones.

As expected, the majority of redeemed activation codes are initial prescriptions. In the first DiGA year (Oct '20 - Sep '21), they accounted for approximately 90 percent of the data reported to SVDGV. In the third DiGA year (Oct '22 - Sep '23), they accounted for around 80 percent. On the one hand this indicates that patients continue to use DiGA beyond a single prescription period, especially for chronic conditions. On the other hand, some DiGA may not require follow-up prescriptions as the therapeutic benefit for certain applications can be achieved within a quarter (DiGA get prescribed per quarter of a year).

Redeemed activation codes by initial & follow-up prescription

Sample size: 15.094	Sample size: 58.895	Sample size: 102.669
9%	16%	19%
91%	84%	81%
Oct '20 - Sep '21	Oct '21 - Sep '22	Oct '22 - Sep '23

■ Initial prescription　　　■ Follow-up prescription

Source: SVDGV

3.3 DiGA users

Adult DiGA users span across all age groups and genders. However, based on the dataset available to SVDGV, female patients are the most frequently represented. Depending on the reporting period, between 50 and 70 percent of DiGA users identified as female. The reasons for this high percentage of female users in the dataset can be diverse. Firstly, some of the listed DiGA are exclusively intended and approved for female users, such as Hello-Better Vaginismus Plus or EndoApp, designed for the treatment of endometriosis. Additionally, some conditions addressed by DiGA are more frequently diagnosed in female patients. For example, there are now six DiGA listed for the treatment of depression, a condition diagnosed twice as often in women as in men.[31] Furthermore, there are differences in healthcare provision and use of medical prevention offerings: surveys have consistently shown that women are more likely to seek medical help earlier[32] when experiencing symptoms and undergo regular preventive check-ups more frequently than men.[33] As a result, they receive prescriptions, including those for Digital Health Applications, more quickly.

Redeemed activation codes by gender

Sample size: 14.682	Sample size: 60.548	Sample size: 108.209
34%	19%	9%
0,3%	0.5%	0,3%
15%	20%	22%
50%	61%	69%
Oct '20 - Sep '21	Oct '21 - Sep '22	Oct '22 - Sep '23

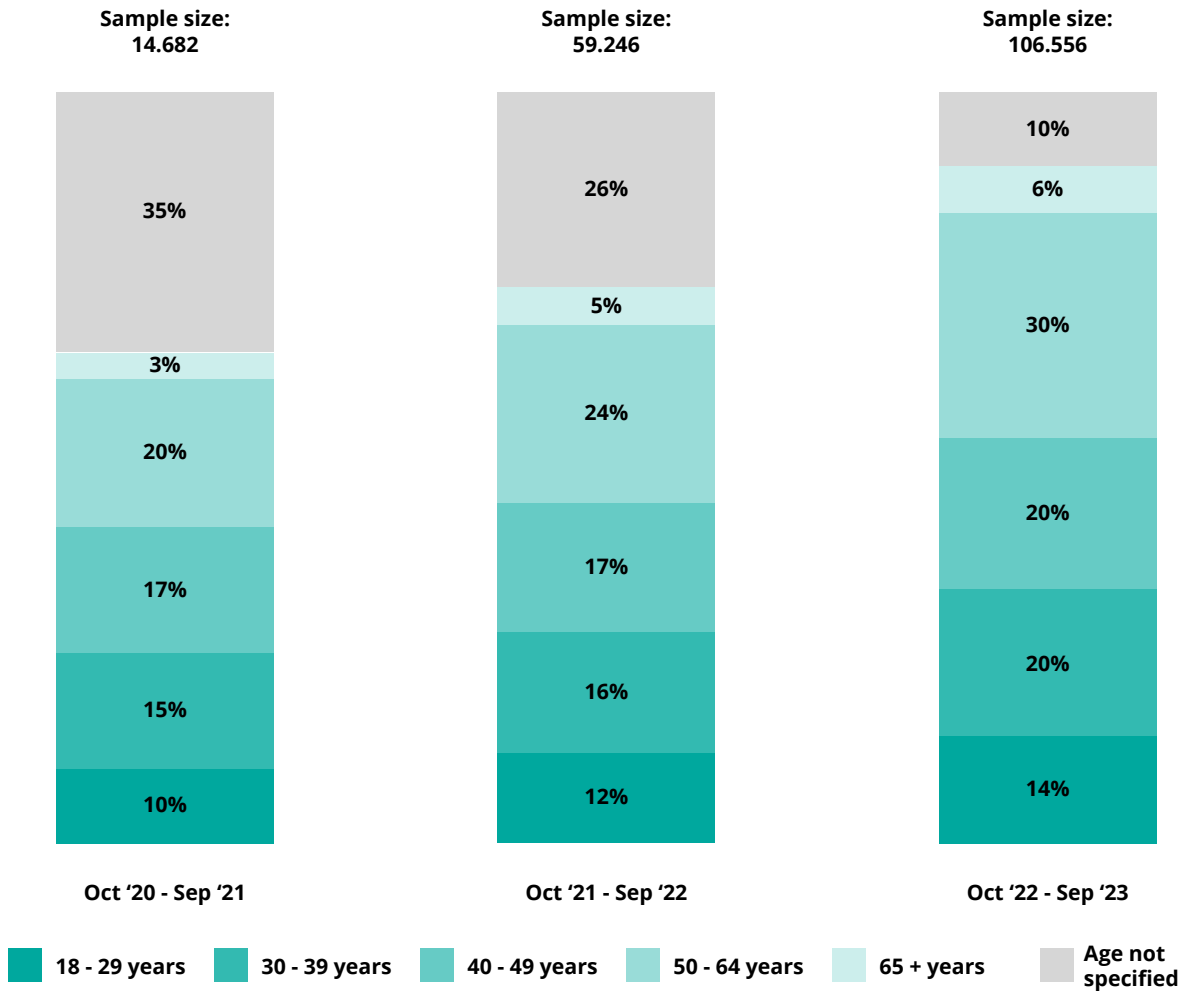Female   Male   Diverse   Gender not specified

Source: SVDGV
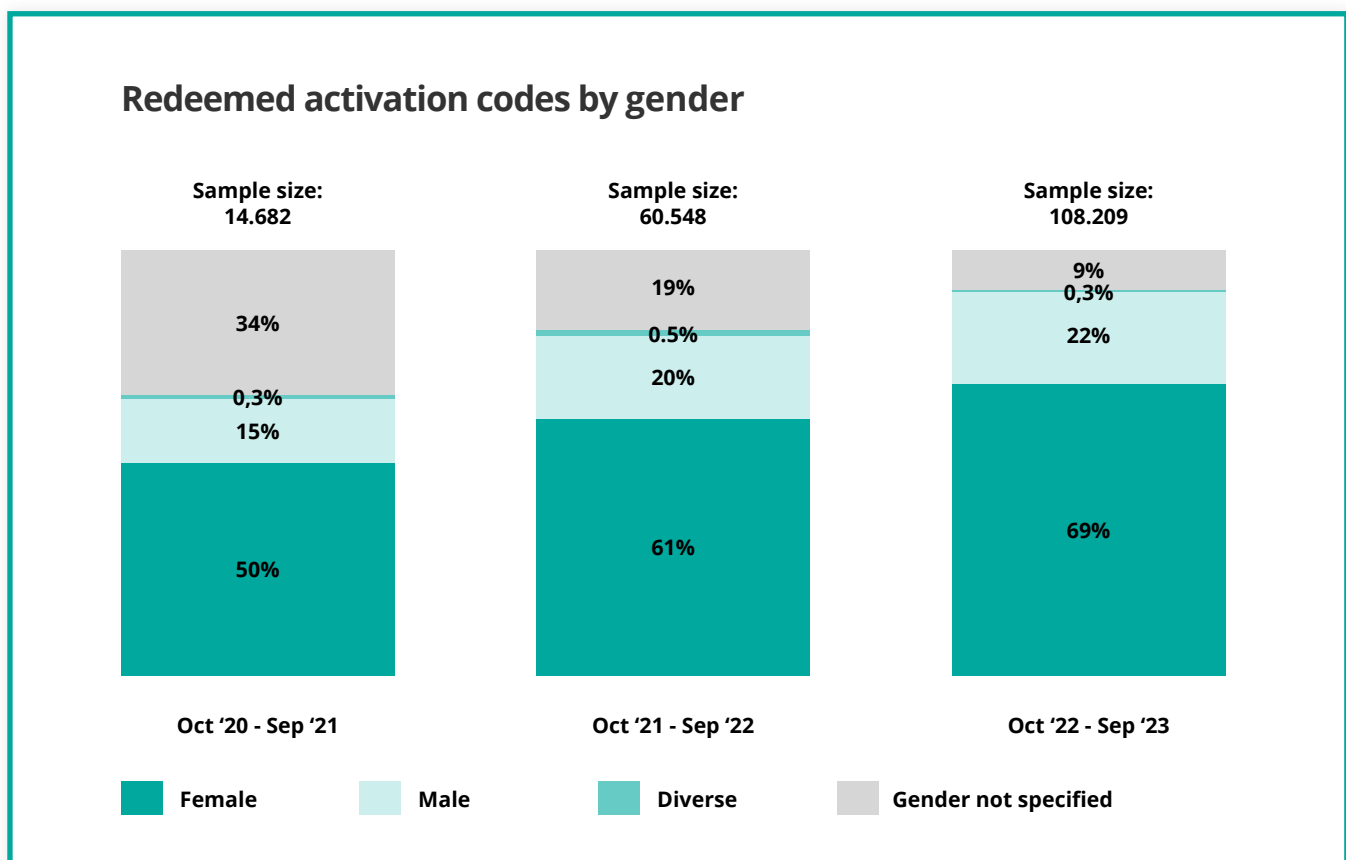
Looking at the age distribution of users, it becomes evident that DiGA are used across all age groups. The data presented here shows that users aged 50 to 64 years constituted the largest share in all three analyzed DiGA years. The shares by age groups increase steadily from the 18-29 years age group to the 50-64 years age group. This trend may be explained by the fact that some diseases and diagnoses tend to occur more frequently later in life.

[31] Deutsche Depressionshilfe
[32] Datenanalyse der Kaufmännischen Krankenkasse (KKH), 2021
[33] Daten und Fakten zur Männergesundheit in Deutschland. Bundeszentrale für gesundheitliche Aufklärung (BZgA); 2022

Redeemed activation codes by age

Sample size: 14.682	Sample size: 59.246	Sample size: 106.556

Oct '20 - Sep '21   Oct '21 - Sep '22   Oct '22 - Sep '23

■ 18 - 29 years   ■ 30 - 39 years   ■ 40 - 49 years   ■ 50 - 64 years   ■ 65 + years   ■ Age not specified
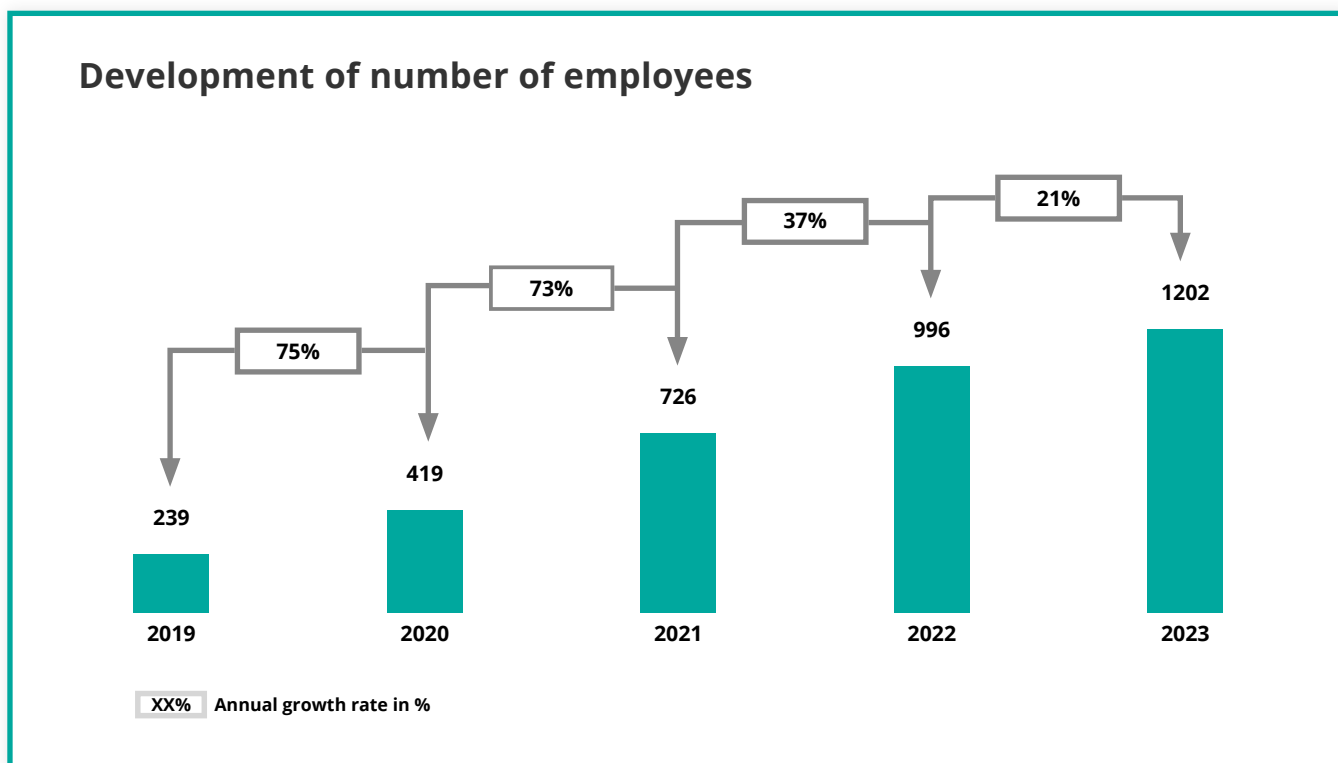
Source: SVDGV

4. DiGA as economic factor

Digital Health Applications (DiGA) have the potential to significantly improve patient healthcare as well as to become a relevant economic factor. Most DiGA manufacturers are technology startups: either developing organically or backed by venture capital. Since the introduction of the Digital Healthcare Act (DVG), these companies have experienced significant growth, creating numerous modern jobs, fostering innovative technologies and conducting clinical trials.

Before the introduction of the DVG in 2019, DiGA manufacturers averaged 16 employees. By 2023, this number had grown to an average of 80 employees. In total, the 15 companies that provided information about their company size employed 239 people in 2019 and 1,202 people in 2023. This represents a Compound Annual Growth Rate (CAGR) of 50 percent.

Development of number of employees

239 — 2019
419 — 2020
726 — 2021
996 — 2022
1202 — 2023

75% | 73% | 37% | 21%

XX% Annual growth rate in %

Source: SVDGV

DiGA manufacturers create new jobs and provide highly modern working conditions. They offer employee participation programs, such as virtual employee stock option plans (VESOP), hybrid work options working from office and home and part-time models. With an average female workforce participation rate of 55 percent, 15 DiGA manufacturers significantly exceed the German national average of 46.8 percent.[34]

36%

On average, 36% of the employees at 15 DiGA manufacturers work part-time. This allows employees to engage in other activities, such as caregiving or community involvement

Digital Health Applications are highly regulated, often highly innovative technology products that must meet the highest standards of quality and evidence. In addition to internal research and development activities, many DiGA manufacturers collaborate with external research institutions. For example, 12 DiGA manufacturers have received a total of approximately € 64.4 million in funding. During product development, they routinely involve healthcare professionals, psychotherapists, patients and patient advocacy groups.

As mentioned, several other European countries are planning to introduce similar reimbursement pathways for incorporating digital therapeutics into standard healthcare. This is reflected in the SVDGV survey, as nearly all DiGA manufacturers included in the analysis intend to become active within the European Union or are already doing so. Additionally, around 30 percent of manufacturers plan to expand into the United States in the near future. There is also interest in expanding into Asia and other countries.

In summary, Digital Health Applications have given rise to a flourishing industry that contributes to the improvement of healthcare in Germany, offers modern job opportunities and contributes to Germany's position as a research hub.

[34] Destatis, "Teilhabe von Frauen am Erwerbsleben 2022"

5. Further development for DiGA

The data presented in this report clearly shows that the young sector of Digital Health Applications has been steadily and sustainably growing in the last three years. With an increasing number of DiGA and indications, more people can benefit from the possibilities of low-threshold, digitally supported healthcare. This is particularly encouraging because there will be growing gaps in healthcare provision in the coming years: thousands of doctors will be lacking in Germany partially due to demographic changes - all while the demand for healthcare provision is increasing.[35]

At the same time, DiGA were designed from day one as a learning system. Early integration into healthcare practice was intended to provide rapid and effective support for those affected and, at the same time, allow the model to be improved directly through insights gained from practice. There are still aspects and processes related to DiGA that require optimization.

Information and education
As this is a novel form of care, today, not all patients, doctors and psychotherapists are sufficiently familiar with DiGA. The lack of knowledge among healthcare providers leads to less frequent prescription of DiGA, as shown by a survey conducted by the Essener Forschungsinstitut für Medizinmanagement (Essen Research Institute for Medical Management).[36] Moreover, many citizens are still largely unaware of the available DiGA options; a 2023 representative survey by the auditing firm Deloitte found that 57% of respondents were not familiar with Digital Health Applications.[37] When doctors or psychotherapists prescribe a DiGA, they take on a significant portion of patient education about these digital applications. This additional effort should be duly compensated, for example, by reintroducing or refining the GOP 01470 fee (Gebührenordnung für Psychotherapeut*innen: scale of fees for psychotherapists). Furthermore, health insurances should provide their clients with neutral information about DiGA, their use and their evidence.

Easy access to DiGA
Digital Health Applications should be as easy and low-threshold as possible to obtain, as has been envisioned since the beginning of digital healthcare. However, the process to access a DiGA is neither particularly easy nor low-threshold. On the contrary, after submitting a prescription to their health insurance provider, patients must wait for an activation code that the health insurance provider will transmit to them. The DiGA can only be activated with this code. While this process was originally implemented as a transitional solution, it practically results in patients waiting an average of 13 days, almost two weeks, for their activation code.[38] This waiting time between prescription and the start of usage of a digital therapeutic can lead to delays in initiating necessary therapy steps. Furthermore, it does not meet the demand for prompt and effective care and it risks leaving health problems unresolved.

13 Days

On average, patients wait 13 days for the issuance of their DiGA activation code by their health insurance company

While some patients have to wait a long time for the activation of their DiGA, others are being unpromptedly "advised" by their health insurance companies: Patients have repeatedly reported back to DiGA manufacturers that some health insurance providers actively discouraged them from using the prescribed DiGA or delayed the issuance of the necessary activation codes.[39] Health insurance providers attempt to convince their clients to use software products that neither meet the requirements for data protection, data security and interoperability that apply to DiGA, nor have demonstrated positive healthcare effects. Policyholders are not adequately educated about the difference between „health insurance apps" and DiGA that have been reviewed by BfArM. This behavior is unlawful and constitutes an interference with the physician's medical therapeutic freedom as well as the rights of health insurance policyholders. To stop this unlawful behavior by health insurance providers, the

[35] Ärzteblatt, "Ärztemangel - schlechte Aussichten", Vol. 119, 2022
[36] Ärzteblatt, "Mangelndes Wissen über digitale Gesundeitsanwendungen behindert Verordnungen", October 6, 2023
[37] Gegenwind für die Digitalisierung im Gesundheitswesen, Representative Survey on Digitalization in Healthcare 2023, Deloitte
[38] Internal survey conducted by SVDGV in August 2023, involving 17 DiGA manufacturers who are members of SVDGV.
[39] Frankfurter Rundschau, "Neue Vorwürfe gegen Krankenkassen - So wird Patienten der Zugang zu neuen Therapien verwehrt", October 25, 2023

company aidhere, which operates the DiGA zanadio, filed a cease-and-desist lawsuit against a health insurance provider where this behavior had occurred repeatedly.[40] To curb this unlawful behavior by health insurances, the Federal Office for Social Security (Bundesamt für Soziale Sicherung: BAS) also had to publish a clarification letter to all statutory health insurance providers in June 2023.[41]

Lengthy waiting times and delays in accessing a prescribed DiGA lead to the statutory right to prompt and direct care not being fulfilled. Therefore, a simpler and more user-friendly prescription and activation process needs to be developed to ensure that patients can receive immediate support through DiGA. This could be achieved, for example, by requiring health insurance providers to provide DiGA activation codes within two business days.

Reducing bureaucracy
In addition to waiting times and delays until activation, other factors prevent DiGA from fully contributing to optimal care. The DiGA Fast Track procedure also entails significant administrative burdens for the BfArM. Reports from manufacturers indicate that delays occur regularly. Urgent improvements are needed in this regard, e.g., by increasing staffing levels.

Moreover, at the time of writing this report, additional bureaucratic measures are being planned. The Digital Health Act provides for mandatory ongoing outcome measurement, including the collection of usage frequency data. However, the proposed ongoing outcome measurement is immature and unscientific. User satisfaction or usage frequency is not related to the positive therapeutic effect of a DiGA and does not represent the success of an application. SVDGV and its member companies are very open to concepts of Value-Based Healthcare, but these must be based on a solid scientific foundation, which is currently lacking. Therefore, a consortium should first undertake the development of a scientific framework and then define relevant endpoints for outcome measurement.

Blended care approaches
DiGA are intended for joint use by patients and healthcare providers. This is particularly important because vulnerable groups may require human support when using DiGA. The approval of blended/hybrid care models, i.e., the combination of innovative technology and human empathy, is already provided for in the Digitalization Strategy[42] of the German Federal Ministry of Health (Bundesministerium für Gesundheit: BMG).

In healthcare practice, important prerequisites are already being established to harness the benefits of blended care. Thanks to interoperable structures, DiGA will be able to retrieve vital data from aids and incorporate them directly into therapy. Integration with the Telematics Infrastructure (TI) will enable DiGA to arrange doctor's appointments or conduct video consultations directly through the application.

The practical foundations for hybrid care are thus increasingly being laid. Nevertheless, combinations of DiGA with human services are largely rejected by the BfArM.[43] There is an urgent need for improvement in this regard. It remains to be hoped that the promised expansions of hybrid care models and clear guidelines for their introduction and implementation, as announced in the explanatory memorandum of the Digital Health Act, will follow.

[40] Handelsblatt Inside Digital Health, "Streit um DiGA-Folgeverordnung", October 16, 2023
[41] Letter on DiGA from the Federal Office for Social Security: "Prüfpflichten und -rechte der Krankenkassen bei der Abgabe von Digitalen Gesundheitsanwendungen (DiGA) nach § 33a SGB V"
[42] Bundesministerium für Gesundheit: Digitalisierungsstrategie für das Gesundheitswesen und die Pflege
[43] Handelsblatt Inside Digital Health, "Ärzte werden bei DiGA noch schlecht eingebunden", July 8, 2022

Outlook

For the first time, SVDGV has provided insights into the market of Digital Health Applications using manufacturer data through this DiGA Report. It demonstrates that the DiGA market is in a state of steady and sustainable growth, with both the number of available DiGA and the range of addressed health indications steadily increasing. DiGA already make an important contribution to healthcare provision and they do so based on verified evidence.

However, the legal and regulatory frameworks for this form of healthcare provision still require optimization. Only then can digitally supported healthcare through DiGA become as easily accessible and effective as envisioned by the legislator at the time of introduction.

Three years after the introduction of „apps on prescription" for digital healthcare, DiGA are now internationally recognized. Other countries are taking inspiration from this example and are already developing their own DiGA processes. Germany has thus demonstrated its innovation potential and shown how healthcare can be sustainably improved through digital solutions. It is now time to harness this potential and make digital therapeutic offerings accessible to as many healthcare providers and patients as possible.

Footnote Index | DiGA Report 2023

[1] Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale-Versorgung-Gesetz – DVG)

[2] Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale-Versorgung-Gesetz – DVG)

[3] Rundschreiben DiGA des Bundesamtes für Soziale Sicherung: "Prüfpflichten und -rechte der Krankenkassen bei der Abgabe von Digitalen Gesundheitsanwendungen (DiGA) nach § 33a SGB V"

[4] DiGA directory: https://diga.bfarm.de

[5] DiGA-Analyzer, fbeta

[6] Patientendaten-Schutzgesetz (PDSG)

[7] Digitale-Versorgung-und-Pflege-Modernisierungsgesetz (DVPMG)

[8] DiGA Leitfaden (Stand: 11.10.2023)

[9] A code review involves a manual examination of the DiGA source code at the program code level to identify security-related vulnerabilities. In a white-box test, an internal attack with insider knowledge of the IT infrastructure and application environment of the respective DiGA is simulated.

[10] Entwurf eines Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens vom 30.08.2023

[11] Stellungnahme des GKV-Spitzenverbandes vom 08.11.2023 zum Digital-Gesetz - DigiG

[12] Position des SVDGV zum Digital Gesetz

[13] Ärzteblatt, "Mangelndes Wissen über Digitale Gesundheitsanwendungen behindert Verordnungen", October 6, 2023

[14] Rahmenvereinbarung nach §134 Abs. 4 und 5 SGB V

[15] The initial listing of a DiGA took place on September 25, 2020, with the inclusion of Kalmeda in the DiGA directory. However, it is assumed that no or very few activation codes were redeemed during the remaining four working days until October 1, 2020, so these four days are excluded from the observation period.

[16] The age group ‚under 18 years' was excluded from consideration here since only two DiGA are listed in this age group and the redeemed activation codes can be attributed to these two.

[17] DiGA users do this, for example, because the respective DiGA only covers certain age or gender groups.

[18] For example, there are individual DiGA that have different pharmaceutical central numbers for initial and follow-up prescriptions, as the initial prescription may include hardware. For most manufacturers, a follow-up prescription can only be identified if patients associate it with their already registered account..

[19] Report of the GKV-Spitzenverbandes, "Über die Inanspruchnahme und Entwicklung der Versorgung mit digitalen Gesundheitsanwendungen", Reporting Period: 01.09.2020-30.09.2022
Report of the GKV-Spitzenverbandes, "Über die Inanspruchnahme und Entwicklung der Versorgung mit digitalen Gesundheitsanwendungen", Reporting Period: 01.09.2020-30.09.2021

[20] To calculate the total number of redeemed activation codes for the second DiGA year (Oct '21 - Sep '22), the difference between the number of redeemed codes in the period Oct '20 - Sep '22 and the period Oct '20 - Sep '21 was calculated.

[21] DiGA directory: https://diga.bfarm.de

[22] PECAN (Prise en Charge Anticipée Numerique des Dispositifs Médicaux) can be translated as „Early Access to Cost Reimbursement for Digital Medical Devices".

[23] Handelsblatt Inside Digital Health, "Neuer Markt für deutsche Firmen? Wie attraktiv ist die französische DiGA?", May 5, 2023

[24] Gesundheitswirtschaft.at, "Digitale Gesundheits-Apps – Bei DiGA nur 2. Liga"

[25] Handelsblatt Inside Digital Health, "Gesundheitsapps werden zum Exportschlager"

[26] EIT Health, European Taskforce for Harmonised Evaluations of Digital Medical Devices (DMDs)

[27] DiGA directory: https://diga.bfarm.de

[28] DiGA directory: https://diga.bfarm.de

[29] The data reported to SVDGV indicates a growth of approximately 90 percent for the third DiGA year (Oct '22 - Sep '23). Since it is assumed that the overall growth for the current period is lower than the growth of the data reported to SVDGV, SVDGV considers this estimate to be conservatively robust. The growth between the first DiGA year (Oct '20 - Sep '21) and the second DiGA year (Oct '21 - Sep '22) was approximately 240 percent for the reported redeemed activation codes to SVDGV vs. approximately 215 percent for the total number of redeemed activation codes.

[30] CMGR (Compound Monthly Growth Rate): the average monthly growth rate similar to CAGR (Compound Annual Growth Rate) but calculated on a monthly basis

[31] Deutsche Depressionshilfe

[32] Datenanalyse der Kaufmännischen Krankenkasse (KKH), 2021

[33] Daten und Fakten zur Männergesundheit in Deutschland. Bundeszentrale für gesundheitliche Aufklärung (BZgA); 2022

[34] Destatis, "Teilhabe von Frauen am Erwerbsleben 2022"

[35] Ärzteblatt, "Ärztemangel - schlechte Aussichten", Vol. 119, 2022

[36] Ärzteblatt, "Mangelndes Wissen über digitale Gesundeitsanwendungen behindert Verordnungen", October 6, 2023

[37] Gegenwind für die Digitalisierung im Gesundheitswesen, Representative Survey on Digitalization in Healthcare 2023, Deloitte

[38] Internal survey conducted by SVDGV in August 2023, involving 17 DiGA manufacturers who are members of SVDGV..

[39] Frankfurter Rundschau, "Neue Vorwürfe gegen Krankenkassen - So wird Patienten der Zugang zu neuen Therapien verwehrt", October 25, 2023

[40] Handelsblatt Inside Digital Health, "Streit um DiGA-Folgeverordnung", October 16, 2023

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[42] Bundesministerium für Gesundheit: Digitalisierungsstrategie für das Gesundheitswesen und die Pflege

[43] Handelsblatt Inside Digital Health, "Ärzte werden bei DiGA noch schlecht eingebunden", July 8, 2022