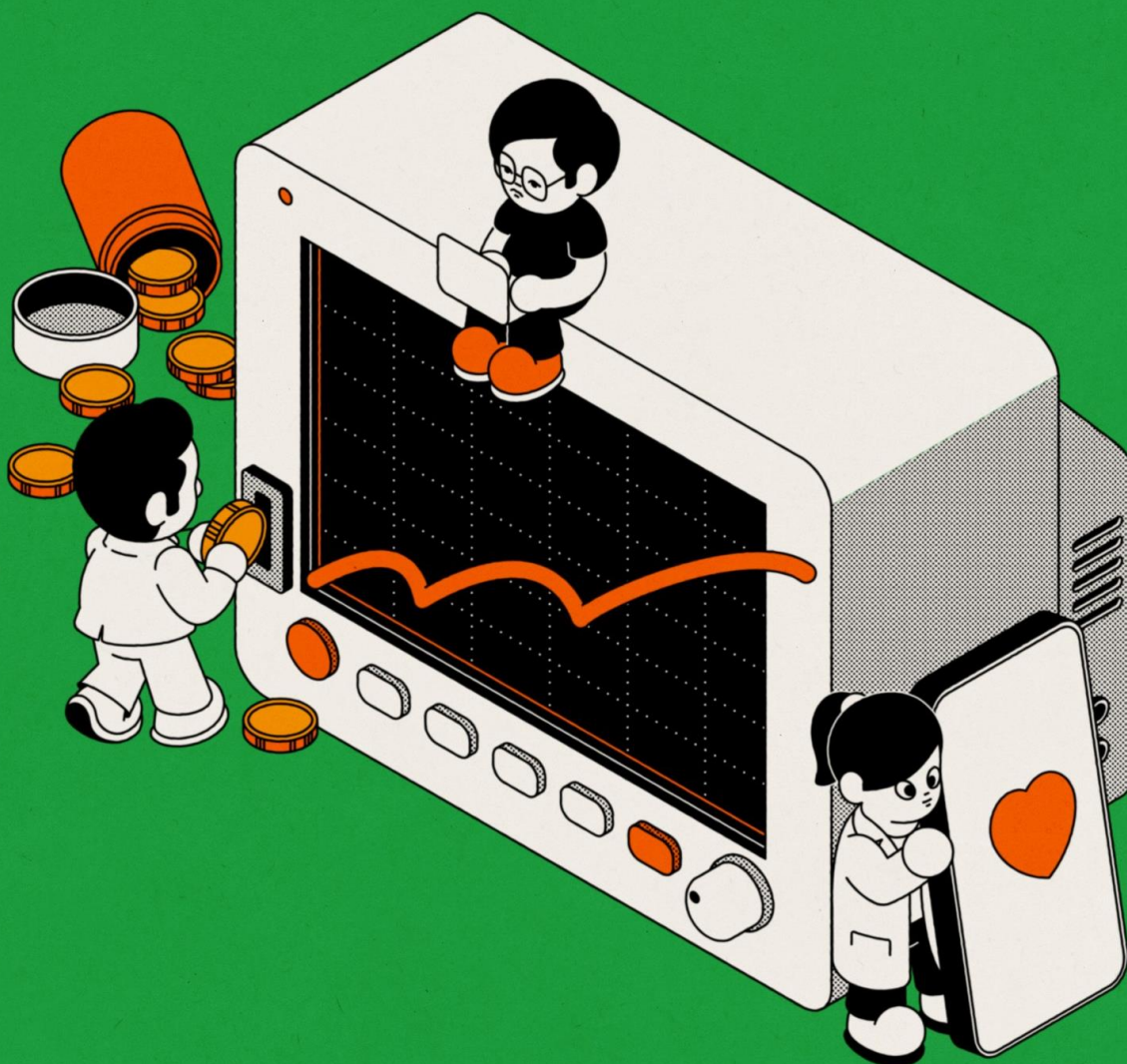


The Pulse of Germany's Digital Health Market

Insights and strategies for investors and founders

Marking four years since Germany pioneered
reimbursement for digital healthcare applications

December 16th



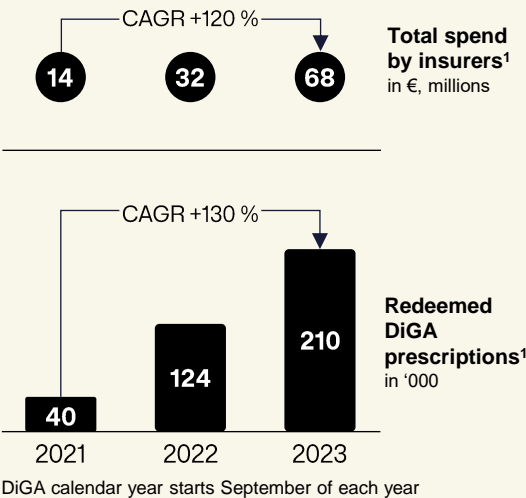
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with Heinrich Zimmermann

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for Healthcare Debugged

September 2020 marked a turning point for the commercialization of Digital Health in Germany...and worldwide. The first fully reimbursed Digital Health Applications (DiGA) were launched in Germany based on the Digital Healthcare Act (DVG) and Digital Health Applications Ordinance (DiGAV). Meanwhile several countries like Belgium, France or Austria used the German legislation as a blueprint and introduced or announced similar Digital Health initiatives. For the first time developers (and investors) saw the opportunity to bring innovative digital solutions to the market that are paid for by the national statutory health insurance system raising the expectation of steady and growing revenue streams just like for pharmaceutical products.

Let's take a closer look at the current status of the DiGA market in Germany and what remained of the gold rush atmosphere. Particularly in the light of recent acquisition of two German DiGA companies by the Icelandic digital therapeutics company **Sidekick Health**, along with the growing interest from Nordic DTx providers in tapping into the commercial potential of Europe's largest market.

Exhibit 01 | DiGA prescriptions and spend

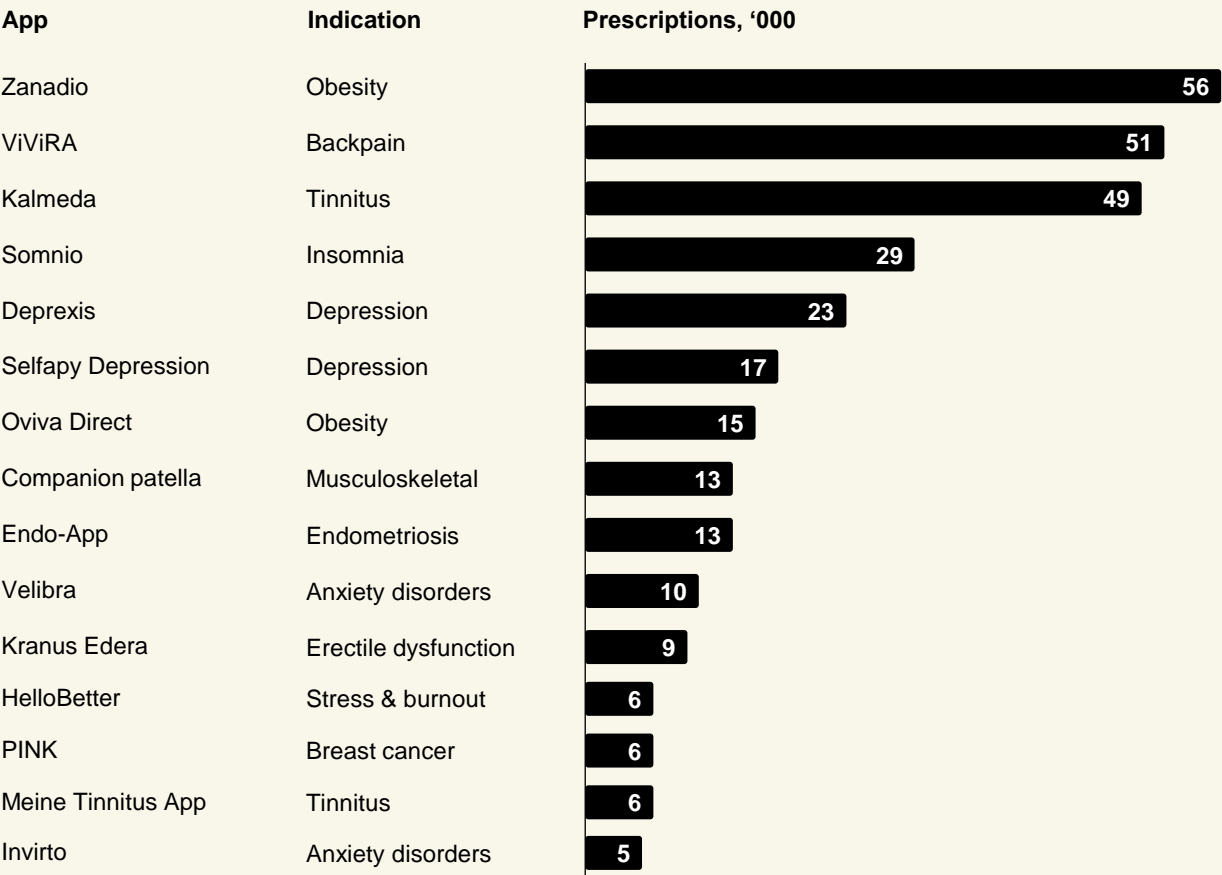


1. Status Quo of the DiGA Market in Germany

The DiGA Landscape in a nutshell

- Most DiGA are mobile applications based on cognitive behavioral therapy
- DiGA cover a large variety of indications with mental health/neuro/psych being the most crowded therapy area
- As of Dec 2024, 56 DiGA are listed in the DiGA Directory, 36 permanently listed and 20 with a preliminary listing
- HelloBetter, Selfapy and Gaia have successfully launched multiple DiGA, others are currently a one or two product company, some of them with a solid product development roadmap
- Three months is the standard treatment period covered by one prescription, while repeat prescriptions are possible.
- Across all DiGA, only 13% of prescriptions are repeat prescriptions.
- The average price set by the DiGA companies for the first 12 months (assessment period) is €529, dropping to €221 after negotiations with the health insurer association
- On average, 89% of DiGAs are prescribed by doctors, while 11% are patient-applied, making B2B/HCP the primary sales channel
- With 71%, the majority of DiGA users are female

Exhibit 02 | DiGAs with accumulated Rx¹ volume 5,000+ (Sept 2020-Sept 2023)



1: Rx: Prescriptions; in this case, submitted prescriptions.

The “Macro-Environment” for digital health applications in Germany

The initial hype for DiGAs among investors and developers has worn off, with patients, prescribers, and payers now generally more conservative or slightly bearish on the case. Meanwhile, the majority of patients remain unaware of DiGA as a treatment option for specific indications, with 60% of the population unaware of digital health offerings in 2023.

Awareness among prescribers is improving slowly over time. Healthcare professionals (HCPs) expressed concerns about the high prices of DiGAs relative to their clinical value for patients.

In addition, many criticized the lack of adequate monetary compensation for the time and effort required to educate patients, prescribe the DiGA, and follow up with them.

Overall, the availability of DiGA (respectively digital therapies in general) as a therapy option is still perceived as a positive development. Major cornerstones of the DiGA regulatory framework (pricing and clinical evidence requirements) are, nonetheless, viewed as highly controversial by key stakeholder groups, creating political and regulatory headwinds for the DiGA industry.

2. Commercial challenges for DiGA Go-to-Market

As illustrated above, the total Rx/revenue volume for individual DiGAs did not skyrocket, contrary to early predictions from consultancies and investors. Even the market leader zanadio “only” achieved 28k Rx in the third year on the market which equates to €6.1m gross revenue (as for all DiGAs the negotiated price of €218 includes VAT). The aidhere website (provider of zanadio) stated that during the same period, the company had over 150 employees. Even though this may not be equivalent to 150 FTEs, it is clear that the Rx volume market leader must have been far from profitability with this level of labor cost.

So, what makes commercializing DiGAs successfully (=profitable) so difficult?

Three critical factors can be identified:

- Factors you can influence:
Company Set-up
- Factors you can deal with:
Market Conditions
- Factors you can't do anything about:
Regulatory Framework

Company Set-up

Team and culture

Most founder teams of DiGA companies consist of medical doctors and/or software developers. Very rarely will you find someone with a commercial background, such as from leading consulting firms or with sales and marketing experience in healthcare or life sciences.

The therapeutic and technical expertise is a great combination to develop a Digital Health product and to convince investors. However, for most DiGA companies **it turned out that this founder team composition was a major challenge in developing and deploying a successful go-to-market strategy**, simply because none of them ever launched a prescription product in a highly regulated market.

In theory this could have easily been addressed by the right hiring strategy but most DiGA companies thought that they “have a digital product and will market it primarily digitally”. So they hired sales and marketing leaders with a D2C/performance marketing and/or SaaS background instead of B2B/healthcare/pharma experts.

A questionable strategy if B2B/HCP is the dominant sales channel and it took most of the DiGA companies a long time to realize that they need to adopt pharma sales and marketing tactics. And still today as a recent poll on LinkedIn amongst DiGA founders indicates, the majority believes that R&D is their core competency instead of sales & marketing.

Exhibit 03 | LinkedIn poll – Core competencies of a Digital Health company



Result from 57 votes on the question “what is the #1 key competency for a Digital Health / DiGA company?”

Indication in scope

Making the right decision regarding the portfolio of indications is crucial for commercial success. Four parameters can be identified to predict the commercial potential of a DiGA (Exhibit 03).

Exhibit 04 | Success factors for indications in scope

Limited, non-digital therapies (drug therapy / psychotherapy) and/or high burden of disease

High unmet medical need / burden of disease

Patients can be “reached” by their doctors and are generally open for (digital) therapies

Addressable patient target population

Unmet need

Patients

Prescribers

Mode of action

Small HCP target group

Main prescriber target group is secondary care, not general practitioners (GPs)

Immediate patient benefit

The digital DiGA mode of action leads to a direct, positive patient perception

Two examples for the implications of the choice of focus indications



Indication with good commercial potential

Overactive Bladder in women (multiple DiGAs are in development for this indication)

There are only limited drug therapies available, most of them have side effects and overactive bladder is associated with a significant reduction in quality of life. The main prescribers are gynecologists and urologists. Women, as the primary patient target group, are the main users of digital therapies. Since the cause of OAB is a miscommunication between the bladder and brain, digital behavioral therapy is highly effective for this indication.



Indication with commercial challenges

High Blood Pressure (only one DiGA on the market)

There are many inexpensive and effective drug therapies available. Most patients with mild to moderate high blood pressure do not experience noticeable symptoms and are thus undiagnosed. The main prescribers are GPs, and patients are often male. The mode of action focuses on supporting long-term lifestyle changes, with very limited short-term effects.

Second and third movers in an indication lag far behind first movers' Rx levels

Market conditions

Low “carryover” for DiGAs

With an average of only 13% of all DiGA Rx being repeat prescriptions for the same patient (actual repeat Rx numbers vary between low single digit percentages e.g. for many mental health DiGAs and a max of 37% for zanadio/obesity), it is obvious that DiGA revenue and growth can only come from new patients which explains high sales and marketing cost in order to deliver Rx growth.

For comparison, in typical chronic conditions (e.g., high blood pressure or diabetes), pharma products with ongoing repeat prescriptions have a carryover (revenue generated in the next period without any sales activity) of between 80% and 90%. This allows pharma sales to focus on generating incremental sales.

The aforementioned tendency of most DiGA companies to allocate too much resources to DTC/direct to patient channels has a negative effect on profitability because B2C customer acquisition cost (CAC) are higher and show little economies of scale compared to B2B/HCP sales. Of course there are strategic opportunities in therapeutic area coverage, product design and positioning to increase the Rx repeat prescription share and thus reduce the cost pressure from new customer acquisition. The room for improvement is unfortunately limited here.

The biggest lever, is the development and execution of a highly targeted sales and marketing strategy that maximizes output and optimizes return on investment (ROI).

Competitive situation

Until now, the 'first to market' DiGA has captured the majority of the market share. The second or third in an indication have not come close to reaching the Rx levels of the market leader. Four factors could explain this.

There is typically little differentiation between DiGAs in the same indication, and any new DiGA is often perceived as a 'me too' product. This is because there is limited room for real innovation (e.g., mode of action) when DiGAs follow medical guidelines, where cognitive behavioral therapy is often the first-line treatment. Its principles are then transferred into a digital application.

As a consequence of the approval process, DiGAs entering the market 12 months after the first movers are more expensive (due to preliminary listing with a higher, provider-set price in the first 12 months) compared to the permanently listed market leader, which has a lower negotiated price after that period. Although prescribing a DiGA does not count against an HCP's budget, many doctors still use DiGA prices as a reference point for their prescribing decisions. Permanently listed market leaders have already provided full clinical evidence, whereas new competitors typically launch with a preliminary listing and 'weaker' clinical evidence.

DiGA early adopters in the HCP universe have already developed into loyal prescribers of the first to market DiGA if their experience was positive. However, if outcomes or patient feedback were unfavorable, it becomes significantly more difficult to convince HCPs to try a new DiGA product within the indication area. Understanding the consequences of these market dynamics is crucial for developing an efficient strategy for a second to market product.

Regulatory framework

Prescription process

The German DiGA legislation has many positive aspects, but the prescription process is over-complicated and leads to many inefficiencies. If a doctor prescribes a DiGA, the patient receives a paper script which they have to submit to their health insurance. The health insurance then issues an activation code and sends this to the patient by mail which used to take up to two weeks (a recent change requires insurers to provide the activation code within two days).

Using this activation code, the patient can then start their digital therapy. This complicated process results in a significant loss, with over 40% of prescriptions not converting into treatments, which means insurers are not paying for it. With the introduction of the electronic health record and the electronic prescription in Germany, this could improve. That said, the initial technical concept developed by gematik (German National Agency for Digital Medicine) for a new prescription process does not look very promising and will hopefully go through some iterations towards a more efficient process.

Upcoming regulatory changes

One of the major regulatory changes with direct commercial impact that will come into effect in January 2026 is the introduction of an “Accompanying Success Measurement” component. Based on the „Act to Accelerate the Digitalization of Healthcare“ (Digital-Gesetz - DigiG), DiGA companies will need to conduct an Accompanying Success Measurement, the results of which will be regularly published in the DiGA directory. Key metrics include:

- Duration and frequency of use
- Patient satisfaction regarding the quality
- Patient-reported health status during the use

Detailed provisions on data submission deadlines, methods, processes, and content of the success measurement, as well as on publication in the

DiGA directory, are to be regulated in an upcoming amendment to the DiGA Ordinance (DiGAV).

Most importantly, at least 20% of the final reimbursement price will be based on the results of the success measurement. This can be a significant revenue risk for the DiGA providers depending on the final results of the negotiations on the exact terms for the introduction of the Accompanying Success Measurement framework between the National Association of Statutory Health Insurance Funds and the Associations representing the DiGA companies.

In general, the market environment for developing a commercially successful DiGA business in Germany is quite challenging.

Although most DiGA founders consider R&D and therapy development the core competency of a DiGA company, sales and marketing are, in fact, the real challenge and the main value driver.

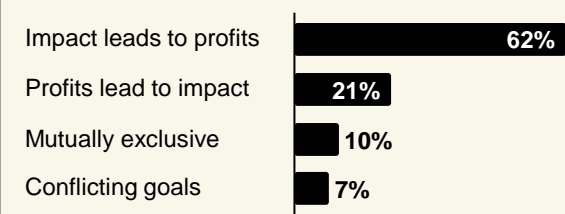
3. Is DiGA an interesting investment case?

Investing in a DiGA company is not a straightforward case. The founders, or management team, are fundamental to success. They need to have a clear and focused go-to-market strategy in place and ideally concentrate on commercially attractive indications. **Platform companies with multiple DiGAs have a clear advantage over single-product companies.** By offering a portfolio of complementary products for the same HCP target group, they can achieve economies of scale in sales.

Overall, the DNA of a DiGA company needs to be commercial-first. What is often found instead is a purpose/impact-first approach, as illustrated by a recent LinkedIn poll among digital health and

DiGA founders. This might lead to suboptimal portfolio decisions prioritizing nice to have indications or irrational go-to-market model decisions neglecting basic ROI considerations. When asked about the relationship between impact and profitability, nearly two-thirds answered that impact drives profitability.

Exhibit 05 | LinkedIn poll on relation between impact & profits



Result from 29 votes on the question "How are the goals of impact and profitability related?"

From an investment horizon (and multiple expectations) perspective, there are three main strategies (not mutually exclusive): **Fast exit**, (short term, 3 years), **build a profitable business** in Germany (mid-term, 3-5 years), **scale globally** (long-term, 5+ years).

Fast Exit

We have recently witnessed a few fast exits in the German DiGA market and generally there are three different scenarios for this strategy: Exit to a life sciences company, exit to a Digital Health company, or consolidation with a competitor

The three scenarios with cases examples are outlined in **Exhibit 06**.

Exhibit 06 | Fast exit scenarios

Scenario A	Scenario B	Scenario C
Exit to Pharma / MedTech	Exit to international Digital Health companies	Consolidation or exit to German competitor
<ul style="list-style-type: none">American ResMed acquired Mementor / somnio (Insomnia) in August 2022 (2 years on the market)German Pohl-Boskamp acquired mynoise/ Kalmeda (Tinnitus) in May 2023 (2 ½ years on the market)	<ul style="list-style-type: none">Icelandic Sidekick acquired aidhere / zanadio (Obesity) in October 2023 (3 years on the market) after aidhere filed for bankruptcy and PINK! (Breast Cancer) in June 2024 (2 years on the market).American Mahana Therapeutics acquired CaraCare (IBD) in March 2024 (2 ½ years on the market)	<ul style="list-style-type: none">This has not yet been the case but this will only be a matter of time

Build a profitable business

A few companies have succeeded in building a profitable DiGA business in Germany. Kranus Health is an example of a provider with a clear commercial focus and a DiGA platform strategy that paves the way to profitability. The company focuses on urology and has already launched two DiGAs with several others in development.

Scale globally

GAIA and Kaia are two German Digital Health/DiGA companies with a strong footprint in the US. Scaling internationally as a prescription DTx/DiGA under newly introduced approval and reimbursement schemes, such as PECAN in France, will take time and may not be as straightforward as initially expected. The recent negative assessment of HelloBetter's Insomnia DiGA by French authorities illustrates this challenge.

Nevertheless we are expecting a steep learning curve here for the DiGA companies leading to a gradual globalization of their revenues. Commercialization issues on a global scale are likely to be similar to those in Germany.

In summary, the prerequisites for a successful DiGA investment are as follows:

- **The founder team has a “commercial first” mindset**
- **The therapeutic area/indications are commercially interesting**
- **Founders and investors have a clear and common value creation strategy**

About the author:

Marcus Bergler currently serves as advisory board member and jury chair at MEDKAP Investors, a Swiss non-profit association for private & institutional investors

Marcus is a globally recognized thought leader for go-to-market in the Life Sciences industry. His professional experience encompasses leadership positions with Cegedim, Veeva Systems, and IMS Health (now IQVIA).

In his various advisory board and consulting roles, he supports investors and startup founders in life sciences and Digital Health in developing sustainable business models.

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