

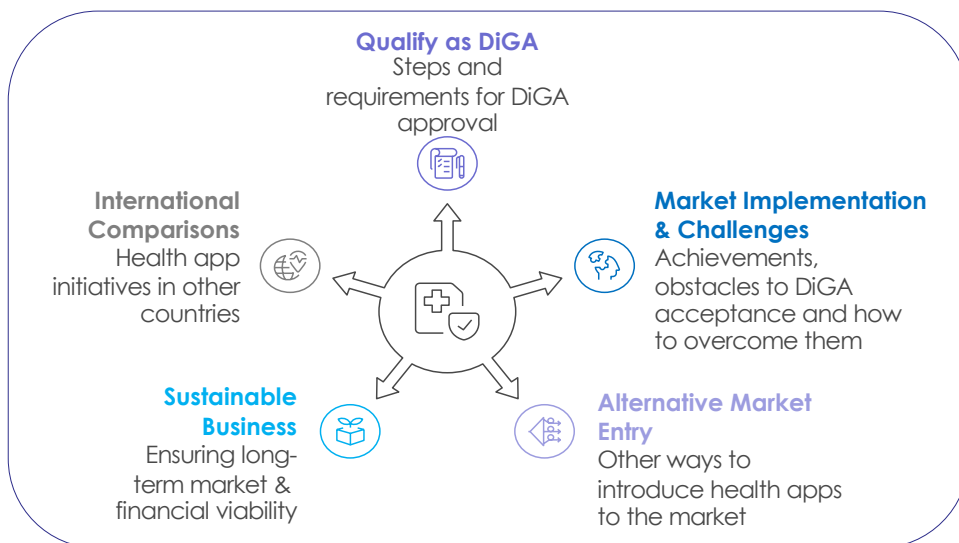
# DiGAs in Germany – a golden opportunity for digital health apps?

Did the DiGA initiative establish itself in the German healthcare system and created business opportunities for digital health start-ups?

Rainer Herzog  
University of Geneva, May 07, 2026

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## What do we want to look at today?



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## DiGA – where are we today?

SINCE SEPTEMBER 2020, CERTIFIED DIGITAL HEALTH APPLICATIONS (DIGAs) CAN BE PRESCRIBED AND REIMBURSED

- 59 digital health applications are reimbursable under the DiGA scheme (April 2026)
- Improved quality of life (62%)
- Improved health outcomes (56%)
- Increased disease understanding (69%)
- **But: Criticism** from doctors` associations and payers regarding cost/benefit and proof of evidence



Source: DiGA Report 2025, self assessment DiGA users  
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## What is a DiGA?

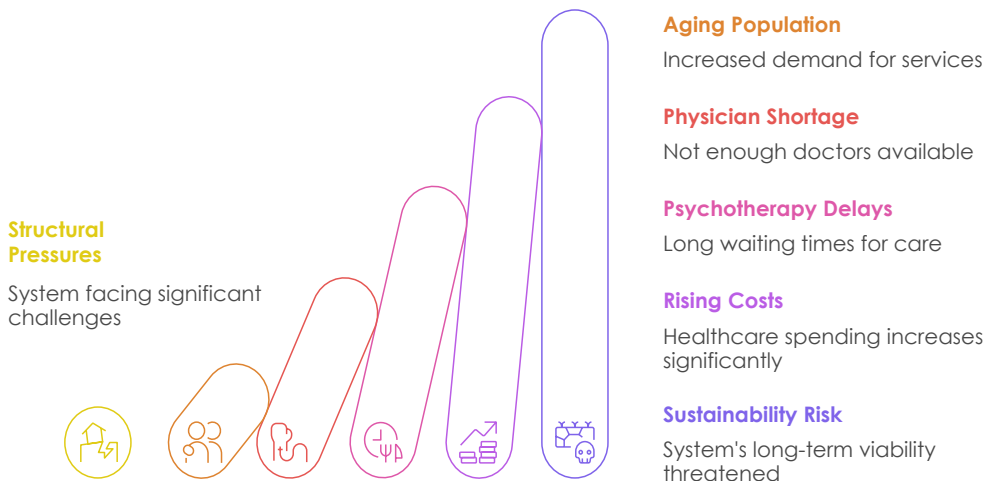
A DiGA Must be listed in the official DiGA directory maintained by BfArM (Federal Agency for Drugs & Medical Products) to be reimbursable

|   |   |  |
|---|---|--|
| <p><b>CE-Marked Medical Device</b></p> <p>A DiGA is a CE-marked medical device with MDR risk class I, IIa or IIb.</p> | <p><b>Digital Technologies</b></p> <p>Its main function is based on digital technologies.</p> | <p><b>Supports Health &amp; Positive Healthcare Effect</b></p> <p>It is patient-centric &amp; supports the detection, monitoring, treatment, or alleviation of diseases.</p> |
|---|---|--|

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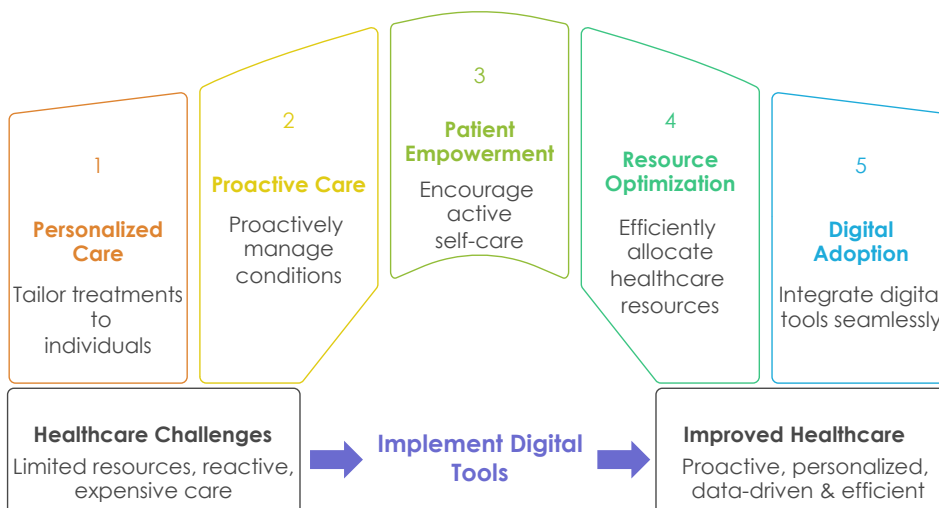
## Why DiGA has been introduced – well, patients but also...

GERMANY'S HEALTHCARE SYSTEM FACES STRUCTURAL PRESSURE FROM DEMOGRAPHICS, WORKFORCE SHORTAGES, AND RISING COSTS



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## What were the objectives of launching DiGA?



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## What is the difference between a wellness / fitness app and a medical app?

THE DISTINCTION IS NOT ABOUT TECHNOLOGY — IT'S ABOUT INTENDED PURPOSE, REGULATORY STATUS AND RISK PROFILE


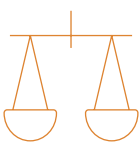

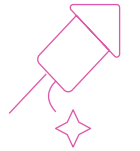
| Dimension                  | Fitness App                         | Medical Device Software              |
|----------------------------|-------------------------------------|--------------------------------------|
| <b>Purpose</b>             | General health, lifestyle, fitness  | Diagnosis, monitoring, treatment     |
| <b>Regulation</b>          | Consumer product (low regulation)   | Strict MDR compliance                |
| <b>Clinical evidence</b>   | Not required                        | Required                             |
| <b>Risk classification</b> | None                                | Class I, IIa, IIb, III               |
| <b>User group</b>          | General population                  | Patients (often prescribed)          |
| <b>Claims allowed</b>      | "Improve fitness", "track activity" | "Reduce symptoms", "treat condition" |
| <b>Reimbursement</b>       | No                                  | Possible (e.g., DiGA in Germany)     |



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## The DiGA scheme can include applications in MDR classes I-IIb

| Class I   | Class IIa   | Class IIb  | Class III   |
|---|---|--|---|
| Low risk, self-certification, minimal evidence, fast and low cost.                  | Medium risk, Notified Body, moderate evidence, standard DiGA class.                 | Higher risk, extensive clinical data, strict review, high cost and time.             | Highest risk, full clinical trials, maximum scrutiny, longest approval.               |
|  |  |  |  |
| Average cost: € 50K<br>Average duration: 6m   | Average cost: € 170K<br>Average duration: 14-18m                                    | Average cost: € 325K<br>Average duration: >18m                                       | Average cost: € 1250K<br>Average duration: 54m+                                       |

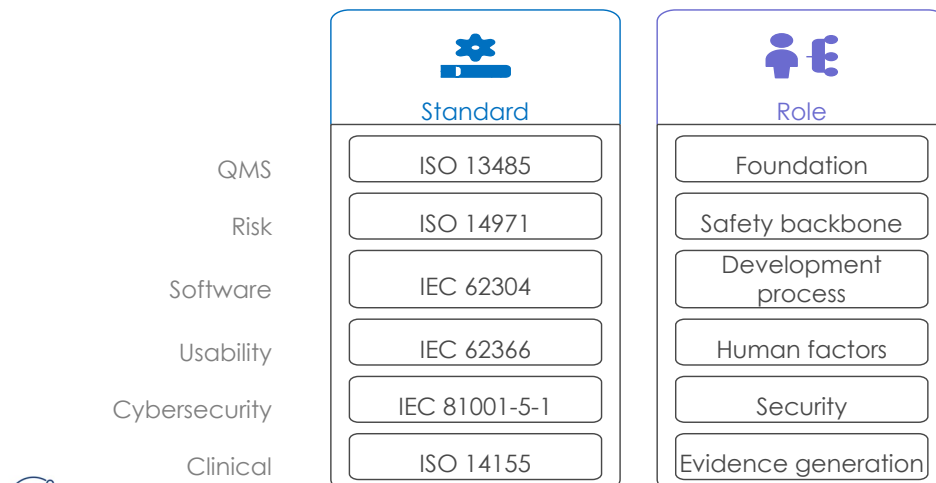


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## How you certify your QMS - ISO and IEC standards

THIS IS AN OVERVIEW OF „INTERNAL“ STANDARDS YOU NEED TO COMPLY WITH TO PASS MDR CERTIFICATION

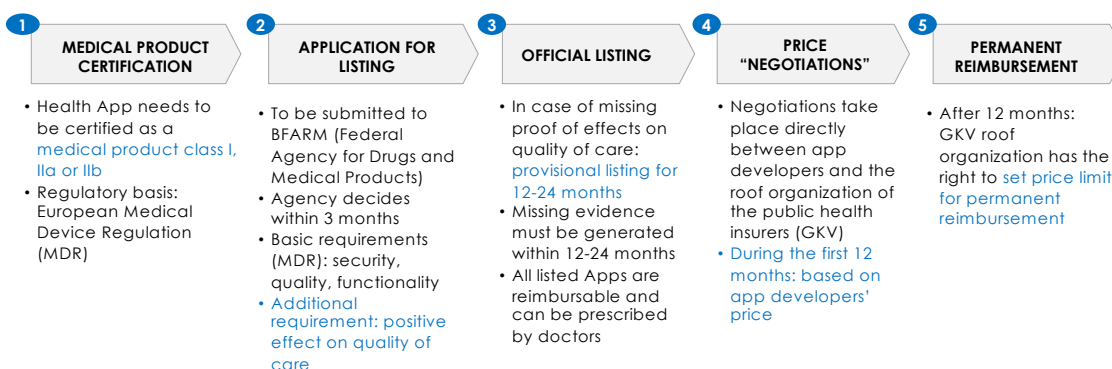


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## The DiGA fast track approval process in Germany

ALL OFFICIALLY LISTED APPS CAN BE PRESCRIBED AND REIMBURSED



**CHALLENGES FOR APP DEVELOPERS**

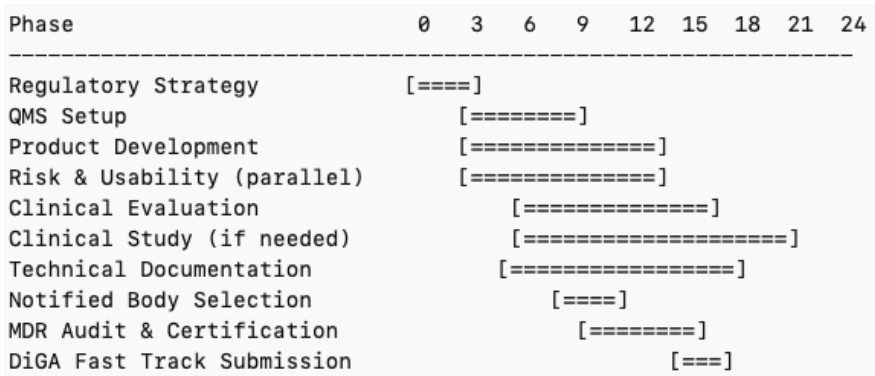
- (High) documentation needs to obtain MDR Class I, IIa or IIb
- Necessity to create additional evidence data on the quality of care (medical benefits and/or improvements on care structures & processes)
- Price limits set after 12 months

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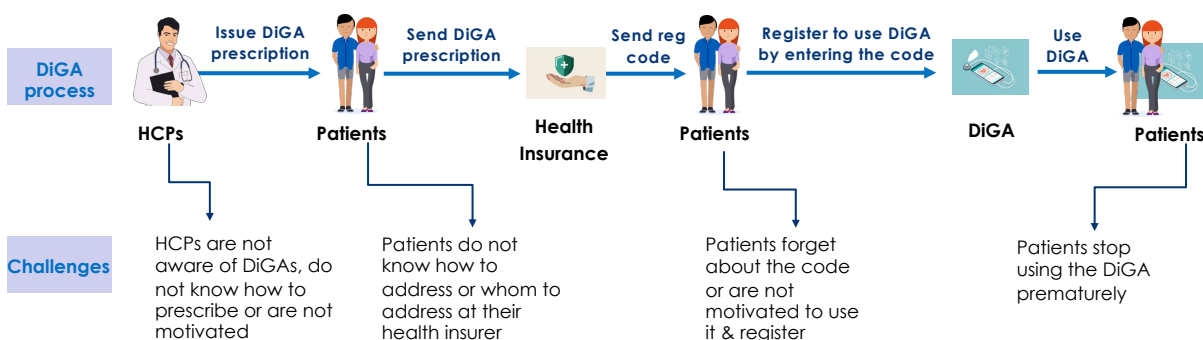
## How this translates into a timeframe for DiGA development & market access

BELOW IS A MINIMUM VIABLE ROADMAP FOR A DIGA TARGETING MDR CLASS IIA (TYPICAL CASE)



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## DiGA prescription – still not as easy as prescribing standard medication



Since April 2025: Patients can apply directly to their health insurance for using a DiGA and being reimbursed for it. The prerequisite for this is medical documentation to proof medical necessity.

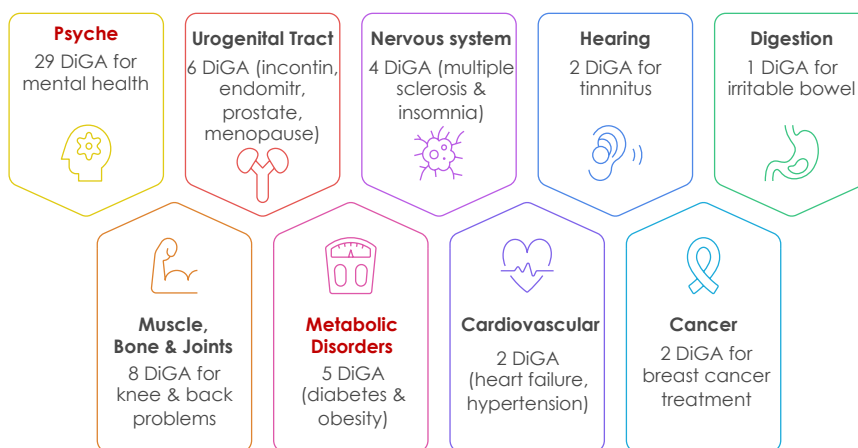


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## The number of listed DiGA's remains on a stable level – momentum for new entries is slowing

59 health apps have been certified and officially listed (April 2026):

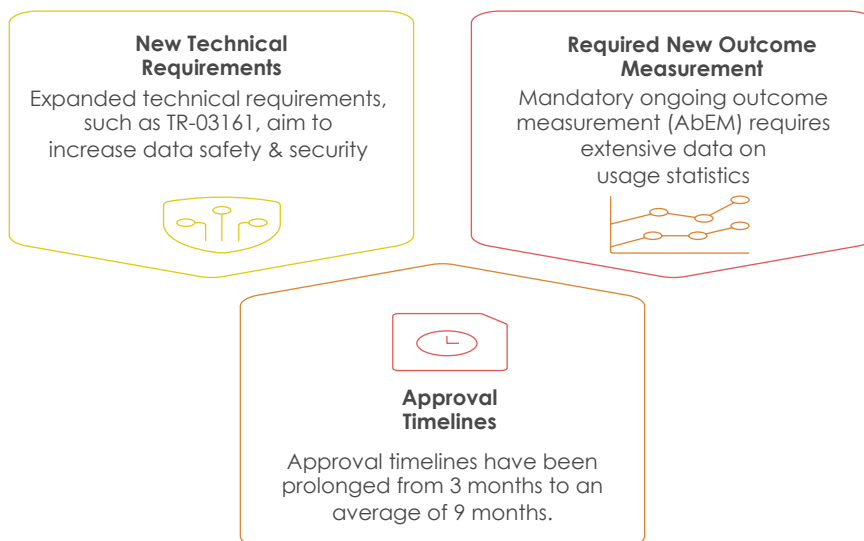
(<https://diga.bfarm.de/de/verzeichnis>)



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## Increasing the number of DiGAs- why momentum is slowing down



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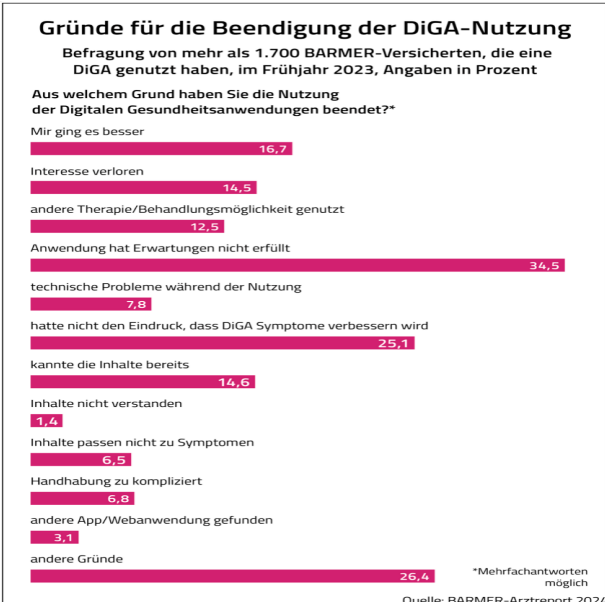
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## What are the reasons for quitting DiGA usage prematurely?

### Top 3 reasons for premature discontinuation of use:

- App did not meet my expectations
- No perceived improvement of symptoms
  - I was feeling better

Premature discontinuation can be addressed by adherence management



## Addressing the barriers: an example of modular patient support to improve utilization patterns

### Basic Patient Support

- Providing list of health insurance companies, contacts & contact persons
- Providing application to upload and send prescriptions to health insurers
- Integration on the DiGA supplier's website

### Patient Support\*

- Basic support
- Checking & submitting prescriptions to health insurance companies
- Following up with health insurers & clarifying non-issued/delayed approvals
- Assisting users to redeem their registration codes

### Patient Concierge Support

- Basic support & support +
- Adherence support through **personal contact / contact centre and via eMail**
- **Motivational support and follow-up**

Prescription management & adherence

Source: Atlantis Health Deutschland & DiGA Finder

## DiGA in the healthcare system - some facts & figures for supporters and critics

|  |   |
|--|---|
| <b>Total number of DiGAs listed (April 2026)</b>           | <b>59</b>   |
| Number of DiGAs activated by users (2020-2025)             | 1,6 million (strong growth in 2025: 690.000)                |
| Yearly public health expenditures for DiGA in 2025         | € 171 mill (total for all drugs in 2025: € 59 bill)         |
| Conversion of DiGA prescriptions (i.e. usage of reg. code) | On average 70% (depending on disease condition)             |
| Continued usage of DiGA for 90 days                        | 75%   |
| Discontinued usage   | 25% often during of after the first month                   |
| Average reimbursement for a DiGA (per quarter)             | On average € 540 dropping to € 229 after payer negotiations |
| Currently most expensive DiGA (per quarter)                | Levidex (Gaia) at € 2077 (MS patients)                      |

Source: Barmer, DiGA Report 2025, DiGA Providers



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## Future success of DiGA depends on regulatory refinement, care integration and stakeholder adoption



### What this means:

- DiGA needs to become part of patients' **overall care & therapy regimen**
- **Patient support** needs to be integrated into DiGA, e.g. through (tele) assistance and/or personal contact (**hybrid & blended care**)
- **Outcome & technical requirements** need to be adjusted (usage statistics are not useful, data security needs to be de-weaponized)
- **Awareness**, knowledge and motivation on the **healthcare professional** side needs to be improved
- **Access to DiGA prescription** needs to be simplified

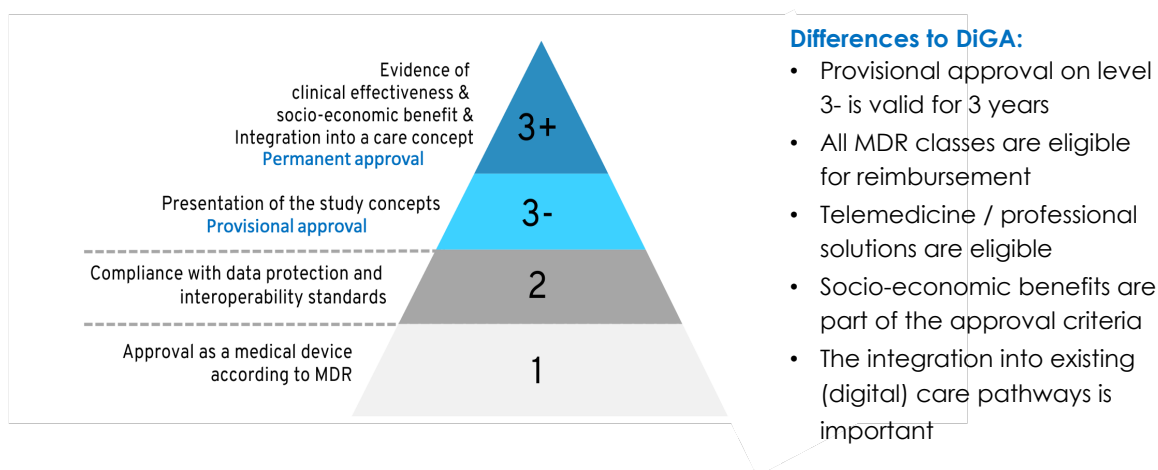


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## PECAN – DiGA exported to France

| DiGA & PECAN / DMD in Comparison                 | DiGA  | PECAN  |
|--|--|---|
| Approvable risk classes                          | I, IIa and IIb   | All   |
| MDR /CE certification required                   | Yes  | Yes   |
| Reimbursement by public health insurance         | Yes  | Yes   |
| Amount of reimbursement                          | Negotiations with insurers   | Max. € 780 / year   |
| Deadline to prove benefits for permanent listing | 12-24 months   | 12 months   |
| Central registers                                | DiGA Directory   | LPPR (therapeutic) / LATM (monitoring)  |
| Approval proof points                            | Clinical benefits or structures & process improvements                                 | Clinical benefits or organizational & structural improvements                             |
| Compatibility & portability of health data       | Perspective: "Electronic Patient Record (ePA)" (2025 onwards)                          | INS (French national eHealth ID) & Mon Espace Santé                                       |
| Prescription process                             | Defined  | Still to be defined   |

## How to obtain reimbursement under the Belgian mHealth Programme



Source: Quickbird Medical

## How about Switzerland?



- The adoption of digital health applications in Switzerland is **still at an early stage**
- **No fully institutionalized "apps on prescription" model yet**
- Compared to Germany's established DiGA Fast Track, **Switzerland lacks a standardized, scalable reimbursement pathway**
- Starting July 1, 2026, mandatory health insurance in **Switzerland will reimburse „deprexis“**, an application for the treatment of **mild to moderate depression** (based on cognitive behavioral therapy)
- Deprexis is already a DiGA in Germany



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## Successful medical apps are built around the following principles

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### BUILT AROUND A SOLID SCIENTIFIC MODEL:

- E.g. Cognitive Behavioural Therapy (CBT)

2



### BACKED BY CLINICAL EVIDENCE:

- Peer-reviewed studies and/or publications

3



### APPROVED & CERTIFIED:

- CE-Marking/MDR, national authority clearance

4



### ASSESSED VALUE:

- Analysis of innovation fit & health-economic value

5



### COOPERATION & INTERACTIVITY:

- Payers, care providers, investors, academics, other app providers or platforms

6



### INCLUSIVE & INTERACTIVE:

- Contains a number of relevant features, highly professional user interfaces



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## What App developers & providers need to consider when entering the German market

- ✓ **Shall we aim at obtaining DiGA status or at concluding separate selective care contracts with individual health insurers? In the latter case:**
  - Additional features such as user support, adherence assistance or tele assistance may be reimbursed (hybrid care)
  - The health insurer may become a go-to-market partner

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- ✓ **Does our business model and needed pricing fit to the DiGA reimbursement range, especially after the 12 months introductory period?**

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- ✓ **Do we possess all the necessary evidence (effects on quality of care) and certifications (MDR) needed to obtain DiGA approval?**

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- ✓ **If not,**
  - Do we invest in creating evidence (quantitative & comparative controlled studies)?



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## What App developers & providers need to consider when entering the German market

- ✓ **Which part of the healthcare system do we target for market access with our business model – in-patient care (hospital) or ambulant care?**
  - Select either one – working at the intersections is not advisable

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- ✓ **Does our value proposition really fit to the target's interests and needs?**
  - It is e.g. not a good idea to talk about shorter length of stay to hospitals or outpatient monitoring after discharge

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- ✓ **Who could act as my go-to-market partner or market entry facilitator?**
  - Health insurers, large hospitals /chains, independent care, patient or stakeholder organisations, networks, opinion leaders...
  - My market & business development budget needs to be adapted & realistic (big market – considerable efforts)



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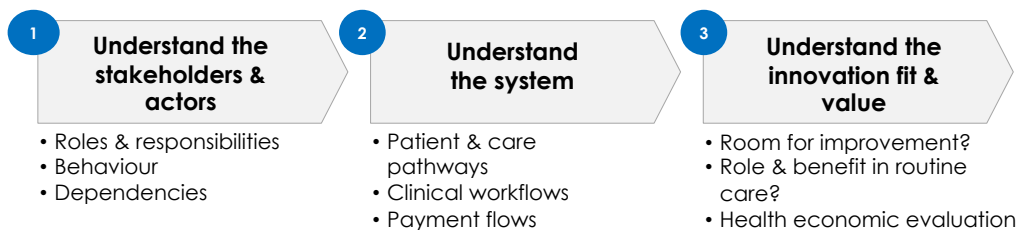
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## Assessing digital & technology innovation (HTA)

You have a great idea for an app or DiGA – excellent, but before you steam ahead, determine its value:

- Should you spend your money on developing the app?
- How are the chances to convince investors and bring it to the market?

The Health Technology Assessment helps you to determine value & viability of your idea



Methods for data collection & models for data analytics to create evidence



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Rainer Herzog  
Digital Health Partners

[rh@bauernfeind-partner.com](mailto:rh@bauernfeind-partner.com)  
+49 178 534 0067

Let us embark on your digital health journey



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