



DiGA in a Nutshell.

Challenges on the Path to a Successful DiGA

Whitepaper

Spring 2021

Germany has taken over a leading role in the digital healthcare sector with the introduction of the DiGA directory.

Digital Health Applications in Germany

Situation

Germany Introducing “Apps on Prescription”

- Statutory health insurance obligated to reimburse DiGA (Digital Health Applications) since 2020
- Germany worldwide the first country with prescriptions for apps as part of the public healthcare system

Start of the DiGA Directory

- Admission via Fast Track-procedure pragmatic approval process in the medical technology sector
- First DiGA approved and added to the DiGA directory in autumn 2020 and thus almost half a year after the publication of the DiGA decree and the DiGA guide
- So far, more than 30 health applications signed up for the assessment process of the BfArM, the federal agency in charge



DiGA Guide (BfArM)

Advantages of DiGA

Digitization at the Point of Care

- Prescriptions of DiGA not affecting the physicians' budget and mostly free of out-of-pocket payments for patients
- Comprehensive supply of patients with digital solutions possible for the first time in the public healthcare system

Commercial Opportunity for Manufacturers

- Over 73 million Germans in the statutory health insurance now potential DiGA users
- Admission to the DiGA directory associated with large revenue potential for DiGA manufacturers

Key Question

What do the manufacturers of health apps need to take into account on their **way to a commercially successful DiGA?**

For long-lasting commercial success, DiGA manufacturers need to have a strategy for marketing and price negotiations in place.

Path to Commercial Success of a DiGA

Challenges

Admission to the DiGA Directory



- × **Complex admission process** due to high standards regarding security, functionality, quality, and data security
- × In addition, **proof of a positive healthcare effect required** for final listing in the DiGA directory

Marketing of the Approved DiGA



- × Processes regarding **prescription and reimbursement new** for all parties involved
- × Active marketing required as **admission to the DiGA directory not a guarantee** for demand by patients and prescriptions by physicians

Negotiation of the Permanent Price



- × Manufacturer's price **only valid in the first twelve months** after listing
- × Successful negotiation with the National Association of Statutory Health Insurance Funds on the **permanent DiGA price decisive for the long-term revenue potential**

Goal

Long-Lasting Commercial Success

- Realization of the high revenue potential **not guaranteed by being admitted to the DiGA directory**
- Developing a **marketing strategy and collecting evidence on the economic benefit of a DiGA** prerequisites for long-lasting commercial success

Compared to traditional medical products, DiGA have to be maintained and updated after their successful admission.

Challenges During the DiGA Process – Admission



1st Step

Fulfilling all requirements for
admission to the DiGA directory

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DiGA Guide In Some Parts Vague

- Many references to other regulatory norms, standards, and technical profiles
- High degree of complexity, especially for newcomers in the German digital healthcare sector

Large Coordination Effort Due to the Necessary Cooperation with Many Stakeholders

- More internal stakeholders than for traditional medical products involved in the processes around admission to the DiGA directory (e.g. developers, data security department)
- Additional cooperation with external stakeholders such as the BfArM and a research institute required

Technical Development Not Completed with Admission to the DiGA Directory

- Future extension of technical requirements necessary to ensure conformity of DiGA with other innovations in the digital healthcare sector (e.g. electronic health record)
- Manufacturers of already approved DiGA also obliged to technical retrofitting

Recommendations

- ✓ Checking the relevance of regulatory norms by **applying the DiGA guide to the specific app concept**
- ✓ Appointment of a **central DiGA manager** to facilitate coordination between internal and external stakeholders
- ✓ Early **development of an update strategy** to ensure conformity with technical requirements also after admission to the DiGA directory

Health apps have so far been rarely used in the German healthcare system which makes the marketing of an approved DiGA more difficult.

Challenges During the DiGA Process – Marketing



2nd Step

Successful **marketing of the approved DiGA** among physicians and patients

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Positive Attitude of Physicians Towards DiGA No Guarantee for Prescriptions

- Only few health apps recommended by physicians ahead of the DiGA directory start, as medical benefit and own advantage often not perceived
- Introduction of the DiGA directory mainly seen positively, but not a sufficient reason for a sudden large interest in the use of digital solutions
- Physicians more open towards the use of apps in case of active patient demand for a specific app

Patients Generally Open-Minded Towards Health Apps

- Majority of patients with chronic diseases interested in using DiGA
- Convenient use during everyday life and quick success requirements for long-term use

Knowledge Regarding DiGA Regulations Not Widely Spread

- DiGA a term to most physicians, but detailed knowledge only rarely available
- Patients rarely informed about the existence of the DiGA directory

Recommendations

- ✓ Early inclusion of the **opinions of physicians and patients** in the development process
- ✓ Focus on creating **immediate value-add** for both **patients (users)** and **physicians (consumers)**
- ✓ Development of a marketing concept focused on **generating patient demand**
- ✓ Provision and active dissemination of a **free testing option for physicians**

Providing evidence on the economic benefit of a DiGA is essential for a successful negotiation of the permanent reimbursement price.

Challenges During the DiGA Process – Price Negotiation



3rd Step

Successful **negotiation of the permanent price**

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Proof of a Positive Healthcare Effect Often Not a Sufficient Basis for Price Negotiations

- National Association of Statutory Health Insurance Funds mostly focused on economic benefit of medical products during price negotiations
- Proof of positive healthcare effect needed for admission to the DiGA directory only concentrated on benefits for patients and explicitly not on economic performance indicators

First Year After Admission to the DiGA directory Important for Further Data Collection

- Data based on everyday operations good foundation for price negotiations
- Further studies on economic benefit potentially required

High Requirements Regarding Data Collection

- Separate consent of the DiGA user for collection of health economic data required
- Collection and further processing of the data only possible under consideration of the specifications of the DiGA guideline and the GDPR

Recommendations

- ✓ **Collection of data on economic benefits** in the first 12 months after (preliminary) admission to the DiGA directory
- ✓ **Early identification** of relevant data and possible collection methods
- ✓ Development of a **strategy to justify the desired permanent price** based on collected data

Digital Oxygen knows the DiGA challenges in detail and has experience with the application process and the needs at the point of care.

Digital Oxygen – DiGA-Expertise

Challenges



**Admission to the
DiGA Directory**



**Marketing of the
Approved DiGA**



**Negotiation of the
Permanent Price**



Selected Projects by Digital Oxygen



Regulatory Consulting

Support of the DiGA Admission Process

- ✓ Analysis of the technical requirements with respect to the existing app concept
- ✓ Planning and execution of coordination meetings with the BfArM and preparation of all necessary documents for the DiGA application



Go-to-Market Consulting

App Concept Evaluation at the Point of Care

- ✓ Conducting qualitative interviews with physicians, medical staff and patients on the existing app concept
- ✓ Derivation of concrete recommendations for the DiGA market entry strategy



Health Economics Consulting

Analysis of the Economic Benefit of Digital Medical Products

- ✓ Detailed evaluation of existing analogue processes at the point of care
- ✓ Quantification of the economic benefit of digital solutions based on realizable process improvements

From the initial concept evaluation to the navigation through the application process: Digital Oxygen is the central contact point for your DiGA.

Digital Oxygen – DiGA-Service Portfolio



Process Guidance

- We **guide our clients through the paragraph jungle** of the Fast Track-procedure **and support them with a comprehensive network** of medical and regulatory experts.



Specification Analysis

- We **check our customers' applications for the various requirements of the DiGA guide** so that nothing stands in the way of a successful admission.



Product Relaunch

- Together with our customers, we develop the appropriate **concept for necessary adaptations of existing health apps**, define the roadmap and translate abstract guidelines into user stories.



Project Management

- Our project management **experts take care of all issues concerning DiGA** - and our customers concentrate on their core topics.



Go-to-Market Consulting

- We **know the existing dynamics between the stakeholders** and develop appropriate go-to-market strategies with our customers to **ensure the commercial success of a DiGA**.



Further Information

Visit **our website** for further information regarding DiGA:

digital-oxygen.com/de/diga

Or contact us **directly**:

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