



# DiGA in a Nutshell.

Challenges on the Path to a Successful DiGA

**Whitepaper**

November 2020

# 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 March 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



### 1<sup>st</sup> Step

Fulfilling all requirements for  
**admission to the DiGA directory**

## Insights DIGITAL OXYGEN Management Consultants

### 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



### 2<sup>nd</sup> Step

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

## Insights DIGITAL OXYGEN Management Consultants

### 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



### 3<sup>rd</sup> Step

### Successful **negotiation of the permanent price**

#### Insights DIGITAL OXYGEN Management Consultants

##### **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](https://digital-oxygen.com/de/diga)

Or contact us **directly**:

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