

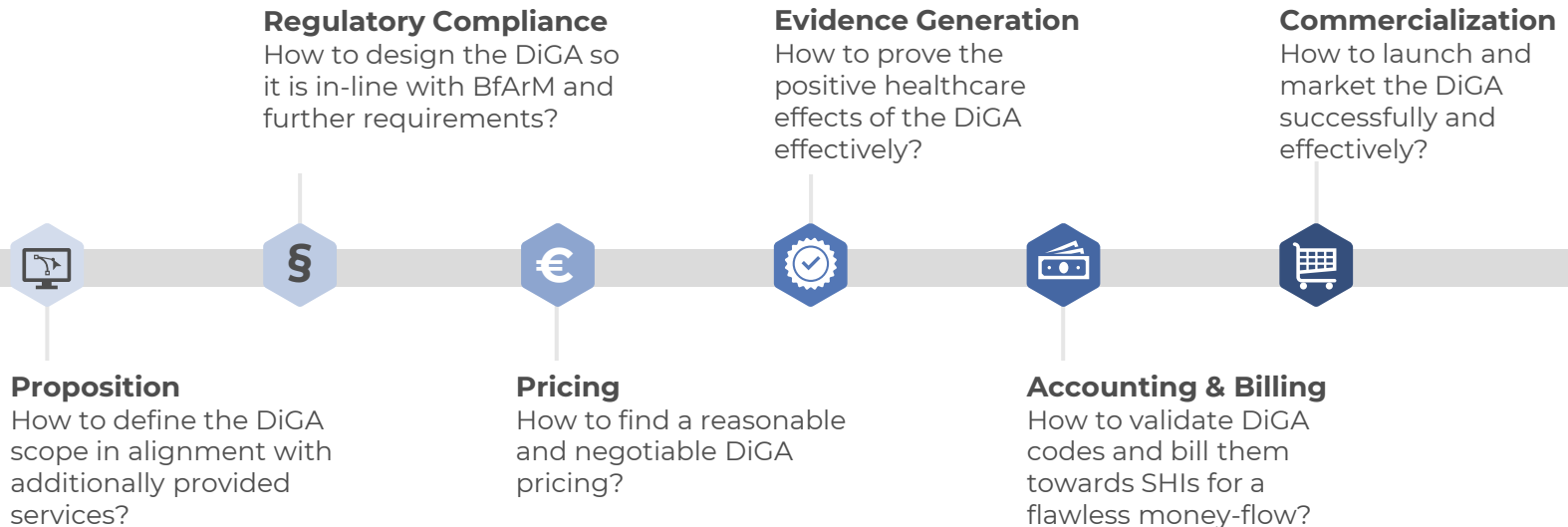
Digital Oxygen

DiGA Success Factors

Whitepaper

Digital Oxygen offers DiGA consulting services following the e2e success factor chain from proposition to commercialization.

E2E DiGA Success Factor Chain



Our ways-of-working adapt to the individual client's needs and wishes. Together with a wide-ranging expert network we deliver value-add.

Ways of Working

Different styles of collaboration

Spectrum of project roles



External Advisor

Explicitly external expert role; only involved in carrying out specific work-packages

Example: Evaluating a company's DiGA profile attractiveness or running a strategic gap review

Involvement depending on client needs and wishes



Full Project Member

Execution of team role within project organizations

Example: Full-time coordination of different workstreams in a multi-national MedTech DiGA-prospect



Access to a wide-ranging expert network

Exemplary Network Contacts



Data Privacy

In case of specific questions around healthcare-related data privacy or when external DPO services are needed, we act as a connector of expertise



Evaluation Concept

As per request of the BfArM, evaluation concepts for evidence generation need to be written by independent scientific institutes. We partner with a re-known institute familiar with BfArM's requirements.



Price Negotiations with the Statutory Insurance

Together with a specialized partner consultancy, we develop convincing negotiation strategies and pricing models to the statutory health and care insurance

We evaluated the concept of a potential DiGA and refined the target group and market access path with a voice-of-customer study for a diabetes-care company.

Project Reference: DiGA Voice-of-Customer Study

Proposition



Study with medical professionals and patients at different stations of the patient’s therapeutic journey:

- 25 one-on-one expert interviews with specialized physicians, general practitioners, nurses, and patients to verify feature benefits and gain insights on user behavior and market acceptance
- Consecutive triads to deep-dive into aspects identified in the interviews and discuss patients’ and practitioners’ perceptions on common challenges in the patient therapy in a group setting

Project Objectives

Evaluation of the value proposition of the planned DiGA towards healthcare professionals and patients:

1. Verification of pain points experienced by medical professionals and patients with solutions already available
2. Assessment of the planned app features’ value-add
3. Understanding of stakeholders’ acceptance and usage of the planned app

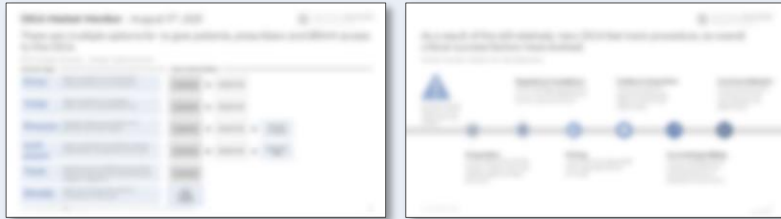
Exploration of reimbursement price and market access path:

1. Understanding of professionals’ willingness to prescribe the proposed solution, and patients’ willingness to recommend it
2. Exploration of medical professionals’ reimbursement sensitivity, price estimations, and concerns with app reimbursement
3. Preparation of decision on target group and positioning in the market
4. Identification of pitfalls in marketing the planned DiGA
5. Derivation of potential market access path

Our continuous support of the DiGA process ensured compliance with all regulatory and technical requirements for a large MedTech client.

Project Reference: Advisory on Technical DiGA Requirements

Regulatory Compliance



Continuous analysis of technical requirements and exchange with BfArM for an industrial MedTech client:

- Weekly calls to support the client's DiGA development team in the US
- Translation of regulatory requirements into use cases and user stories comprehensible to software developers

Project Objectives

Analysis of regulatory requirements for DiGAs and review of the technical specifications:

1. Analysis of underlying regulations and exchange with BfArM and other regulatory bodies regarding:
 - Accessibility
 - Data exportability
 - Interoperability
 - Data protection needs
 - Reimbursement back-end processes
2. Review of the technical specifications and guidance of the client's development team on how to fulfill them
3. Support of the client's data privacy officer regarding the data protection need analysis (Schutzbedarfsanalyse)

With a detailed profitability analysis and implementation of the SHI-facing processes, we prepared a client for the DiGA reimbursement.

Project Reference – Economic Argument Preparation

Pricing 



Support of the "payor" workstream of an international DiGA candidate:

- Preparation and conduction of interviews with physicians and medical staff on the prescription drivers
- Calculation of the savings potential for health insurers in preparation for the price negotiations with the GKV-Spitzenverband (National Association of Statutory Health Insurance Funds)

Project Objectives

Convincing key stakeholders in the healthcare system with economic arguments:

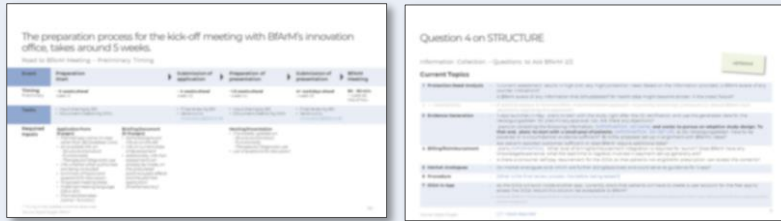
Identification of economic benefits of the DiGA for health care providers and health insurers

1. Determination of the key benefits in the daily work of medical offices to prepare the DiGA marketing strategy towards physicians and medical assistants
2. Data-based estimation of the savings potential for health insurers enabled by DiGA usage

Digital Oxygen worked with a scientific institute to provide an evaluation concept which is required for the DiGA application.

Project Reference – DiGA Reimbursement

Evidence Generation 



Design of an evaluation concept for preliminary listing:

- Evaluation concept including study protocol and further scientific documents in line with all DiGA requirements and ready for DiGA submission together with a specialized and independent scientific institute

Project Objectives

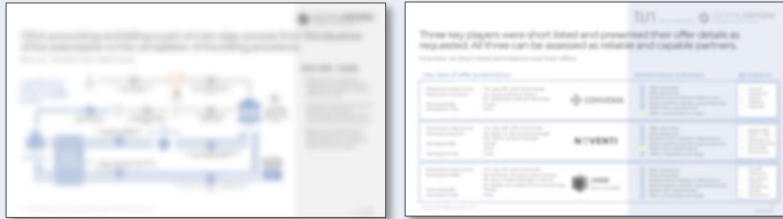
Clear guidance for the medical study and fulfillment of the key requirements for preliminary DiGA listing

1. Development of the study design and creation of the evaluation concept including all other related scientific documents required for DiGA submission in cooperation with an independent scientific institute
2. Reflection of economic efficiency argumentation for later price negotiations in study design
3. Acting as the main point of contact for the scientific institute to minimize the overhead for the client

Digital Oxygen supported a client in a multi-step approach to find a suitable DiGA accounting partner and ensure launch operations.

Project Reference – DiGA Reimbursement

Accounting & Billing 



E2E preparation of the DiGA code validation and accounting operations:

- Internal process-design to handle DiGA code validation, invoicing of validated codes with statutory health insurers through a 3rd party service provider and billing relations with that provider outlined. RfP conducted to select service provider with best-fit

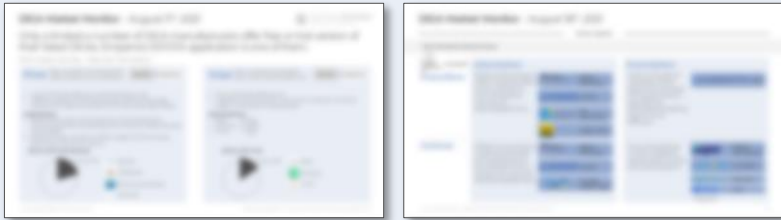
Project Objectives

Implementation of the DiGA code validation and billing in cooperation with an independent service provider:

- Workshop to explain GKV framework on DiGA code validation and invoicing with Germany statutory health insurers as well as identification of relevant stakeholder within the multi-national matrix organization of the DiGA manufacturer
- Internal process design including the conduction of 15 interviews with different stakeholders
- Market screening and contacting of potential service providers
- Preparation and conduction of a full request-for-proposal (RfP) process with the client-internal purchasing team
- Guidance of the implementation efforts

Early on during the DiGA development, we assisted a client with preparing and conceptualizing its sales concept.

Project Reference – DiGA Launch Preparation



Preparation of the commercial launch concept for a DiGA:

- Analysis of possible distribution channels for fully digital medical devices
- Support in prioritizing and deciding on the preferred distribution concept

Commercialization



Project Objectives

Understanding the opportunities and limitations in DiGA marketing:

1. Benchmarking of sales activities of other, comparable DiGAs
2. Monitoring of market trends (even during DiGA development)
3. Analysis of DiGA marketplaces and information portals for patients and prescribers
4. Business case analysis for sales by own sales force
5. Potential analysis for sales collaborations

Prioritization of potential sales channels for launch and subsequent sales ramp-up:

1. Prioritization of attractive sales channels in terms of timing
2. Detailing of individual concepts and time allocations for the launch and sales roadmap



DIGITAL OXYGEN
Management Consultants

Digital Oxygen GmbH
Weißburger Straße 25
81667 Munich
www.digital-oxygen.com



Torsten Christann
Partner

Email: tch@diox.de
Mobile: +49 172 45 43 310



Alexander Voigt
Project Manager

Email: avo@diox.de
Mobile: +49 151 4671 9665