MEDICAL VALLEY
DIGITAL HEALTH
APPLICATION CENTER

Digital Health in Germany

Healthcare System, Reimbursement Pathways & Digital Transformation Initiatives

in cooperation with

ACCIÓ
Catalonia Trade & Investment

Generalitat de Catalunya
Government of Catalonia

enterprise europe network
Business Support on Your Doorstep

Sponsored by
Bavarian Ministry of Economic Affairs, Regional Development and Energy

March 29, 2022

AGENDA

1. dmac – Medical Valley Digital Health Application Center
2. German Healthcare System
3. DiGA & DiPA
4. Outlook

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ABOUT

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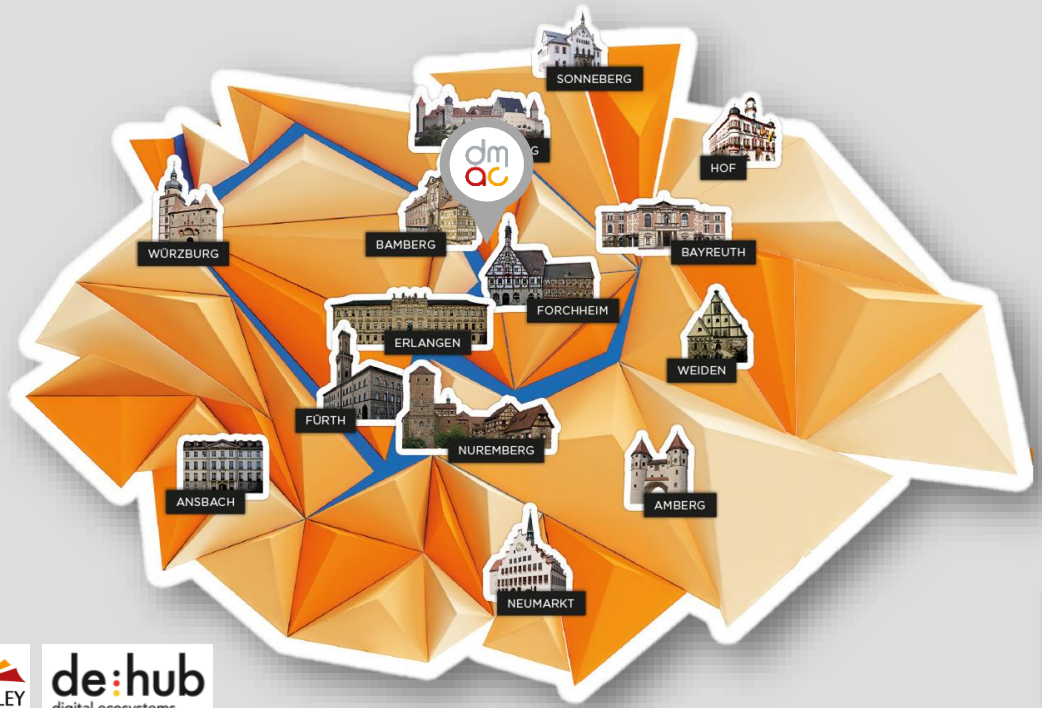
dmac is the digital health think tank of an internationally leading healthcare ecosystem

Medical Valley European Metropolitan Region Nuremberg



500+
MedTech Companies

65+
Hospitals

80+
University Institutes w/ MedTech Focus

20+
Non-University Research Institutes

4
Medical Valley Centers

MEDICAL VALLEY Europäische Metropolregion Nürnberg

de:hub digital ecosystems

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dmac is a joint venture of Medical Valley EMN and Fraunhofer IIS and builds on both partners' complementary strengths

Core Partners

Digital Health Expertise

Think tank and service provider for digital healthcare manufacturers.

Network

Internationally leading innovation ecosystem in the area of healthcare management.

Technology

Application-oriented research institute and a global leader in microelectronic and information technology system solutions and services.

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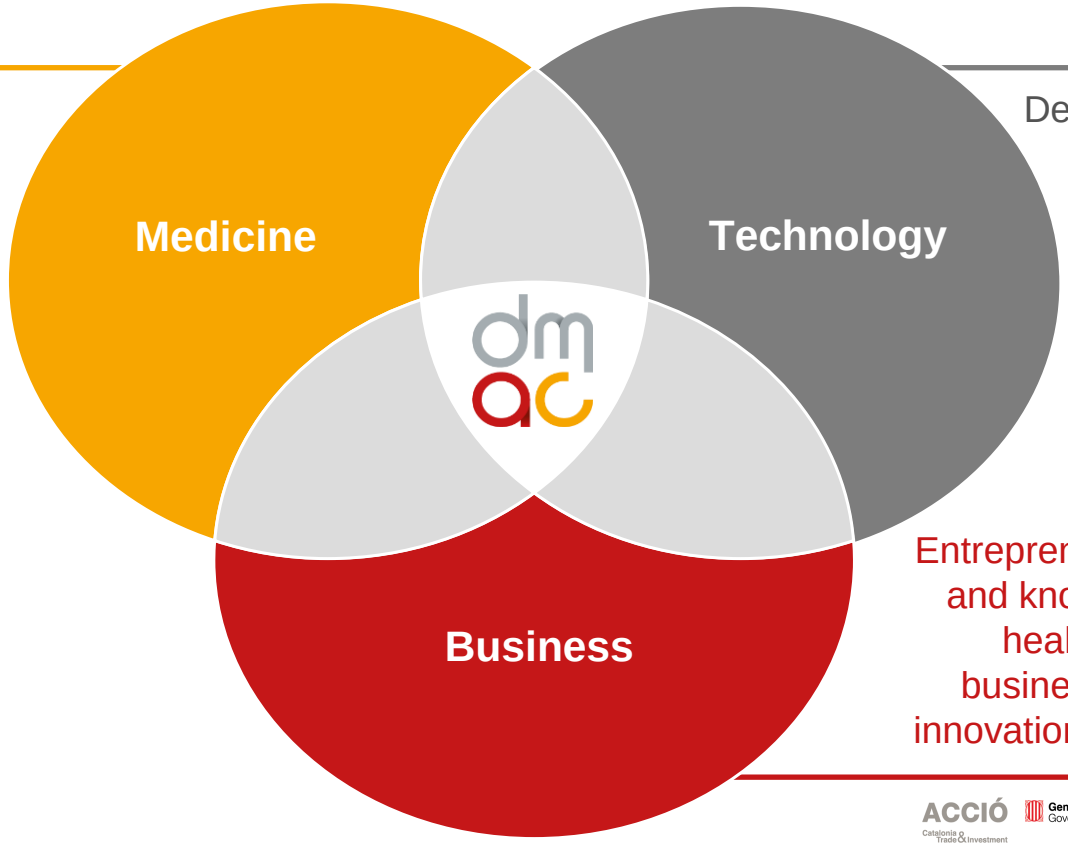
dmac combines expertise from medicine, business and technology for a holistic view on healthcare

Areas of Expertise

Focus on the well-being of the patient and experience in medical care and clinical research



Deep understanding of digital technologies, required skills and transformation processes

Entrepreneurial mindset and knowledge on the healthcare market, business models and innovation management

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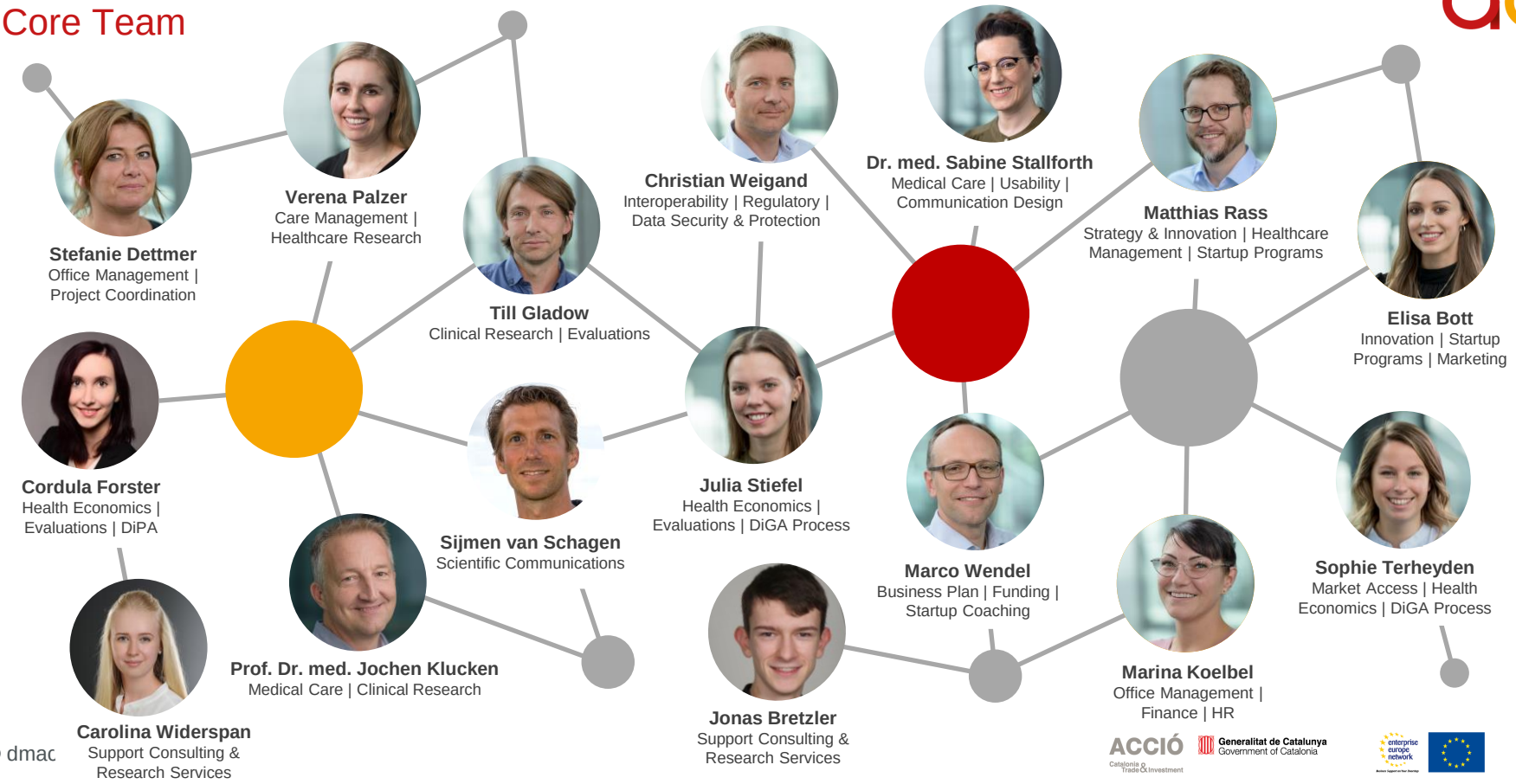
Our key asset is a multidisciplinary team of digital health enthusiasts with a proven track record in the industry

Core Team



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We offer a portfolio of complementary services and tools to provide a holistic yet tailored experience for every partner

Business Areas & Services

Strategy & Innovation

Customized **consulting services** for digital healthcare providers and proven **innovation programs** for startups

Clinical Research

Modular **research services** for digital healthcare providers **from conceptualization to implementation**

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Our services are modular and can be customized to each company's needs

Service Categories

Market Access & Reimbursement

Health Economics

Proof of Evidence

Focus: DiGA

Focus: DiPA

Focus: Startup Innovation Programs

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German Healthcare System

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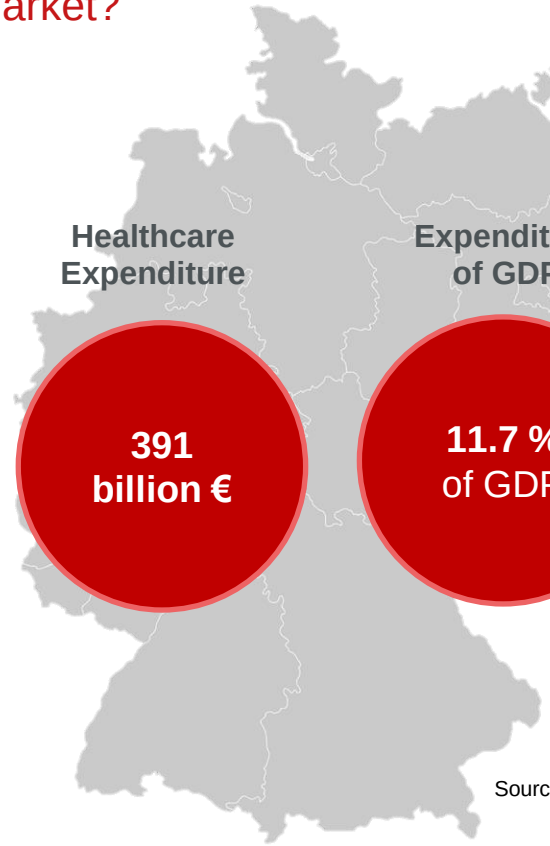
German Healthcare Market

What Is the Structure of the Market?



Inhabitants

83.2 million

Healthcare Expenditure

391 billion €

Expenditure of GDP

11.7 % of GDP

Expenditure per Person

4,711 € per Person

Source: Bundesgesundheitsministerium. Daten des Gesundheitswesens 2020

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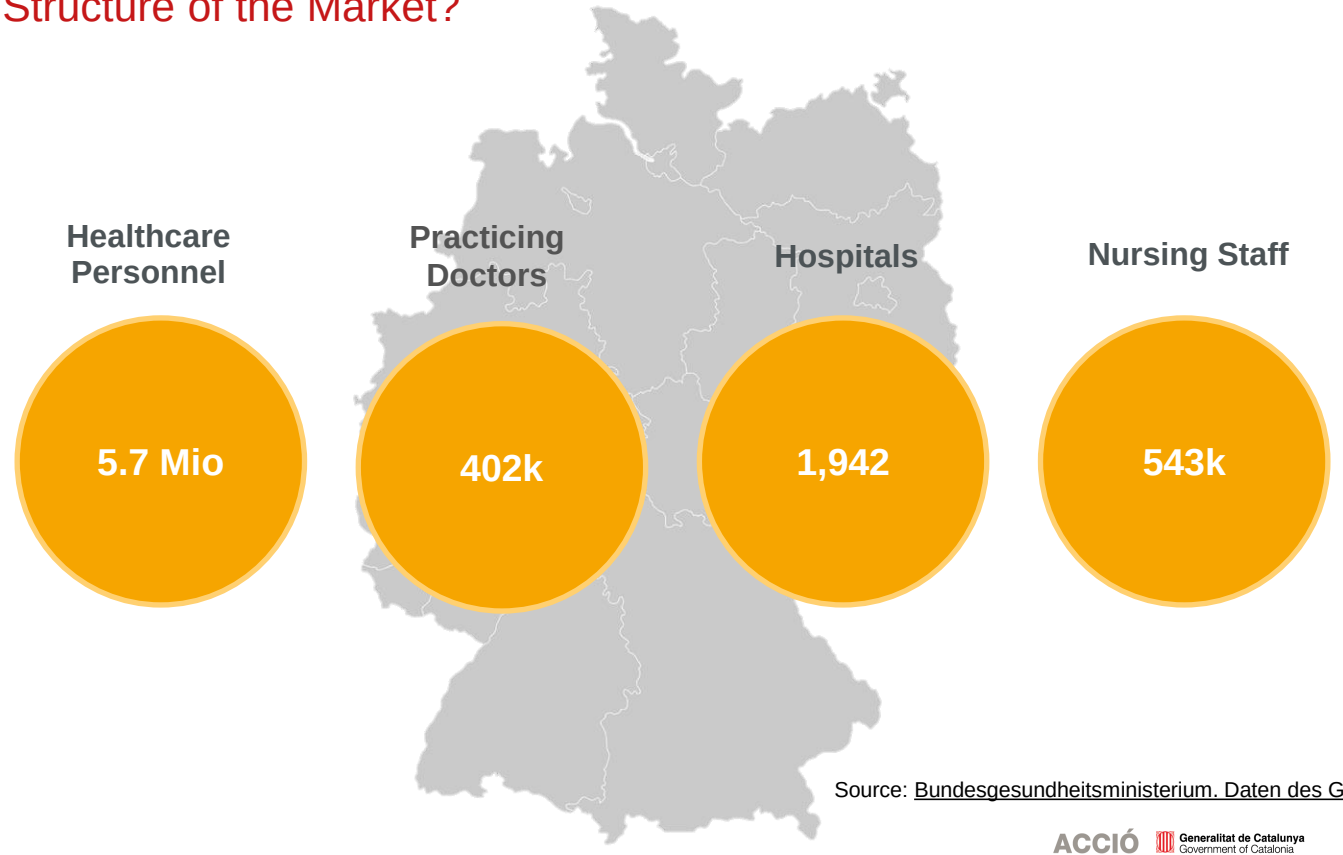
German Healthcare Market

What Is the Structure of the Market?



Source: Bundesgesundheitsministerium. Daten des Gesundheitswesens 2020

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Healthcare Providers

Who Is Providing Care?

Healthcare Providers
Public, free non-profit and private organisations

Healthcare providers according to SGB V and SGB XI

SHI-accredited doctors

Hospitals

Therapists & midwives

Aid providers

Pharmacies

Patient transports

Nursing staff

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General Division into Sectors

Where Is the Care Provided?

Outpatient care

Inpatient care (Hospitals)

Nursing care (inpatient & outpatient)

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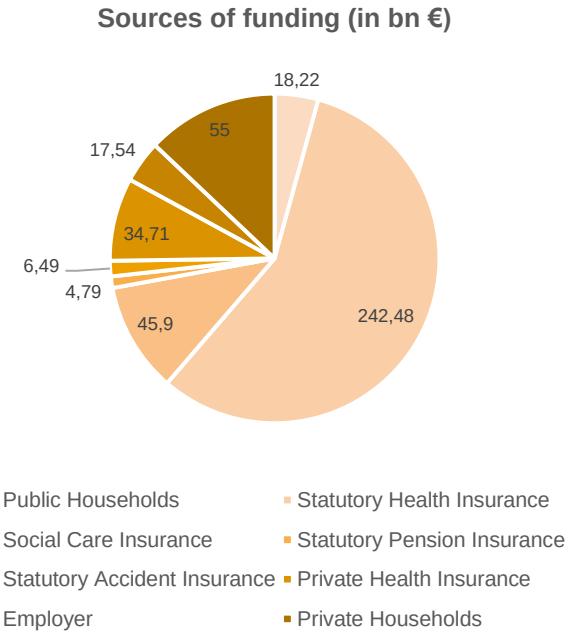
Organisational Relationship between Different Stakeholders

Who Is Paying for the Services?

Inpatient **VS.** Outpatient

SHI **VS.** PHI



Source: Destatis. Health expenditure by sources of funding 2021

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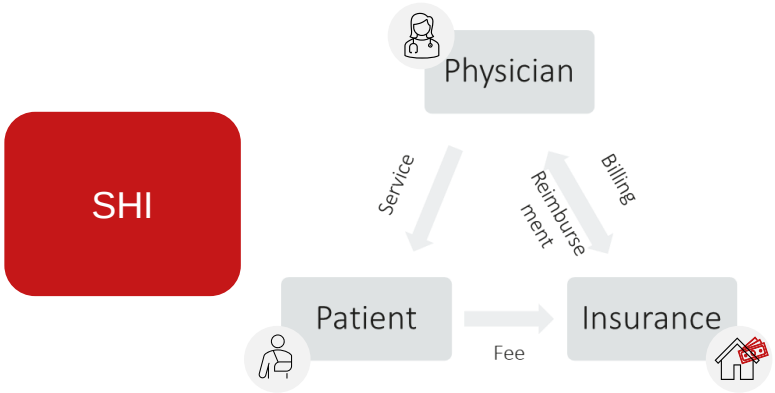
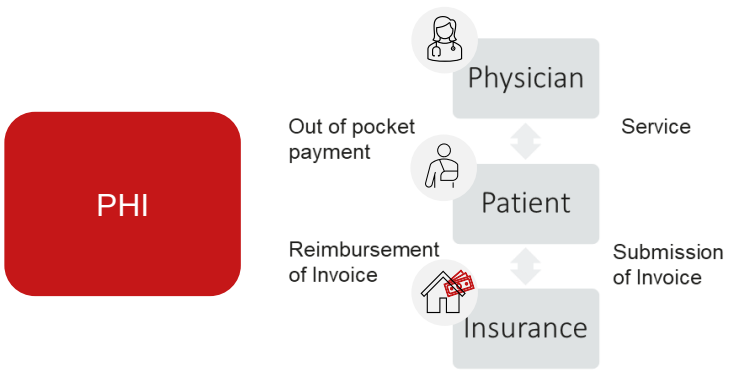
Reimbursement and Service Logic

How Is the Payment Organized?





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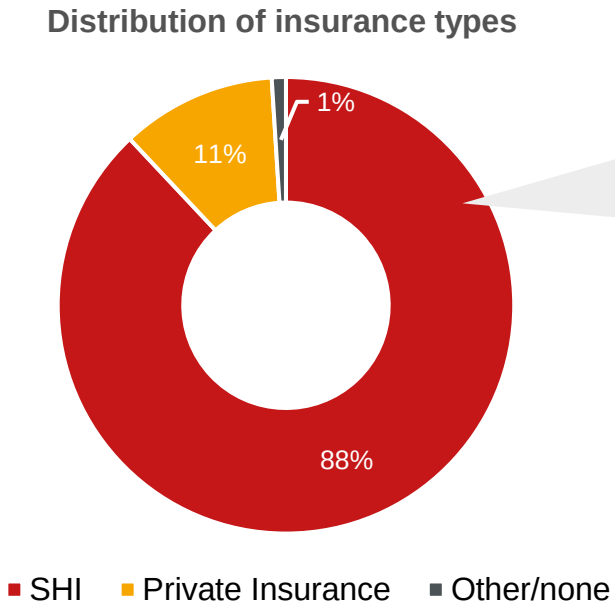
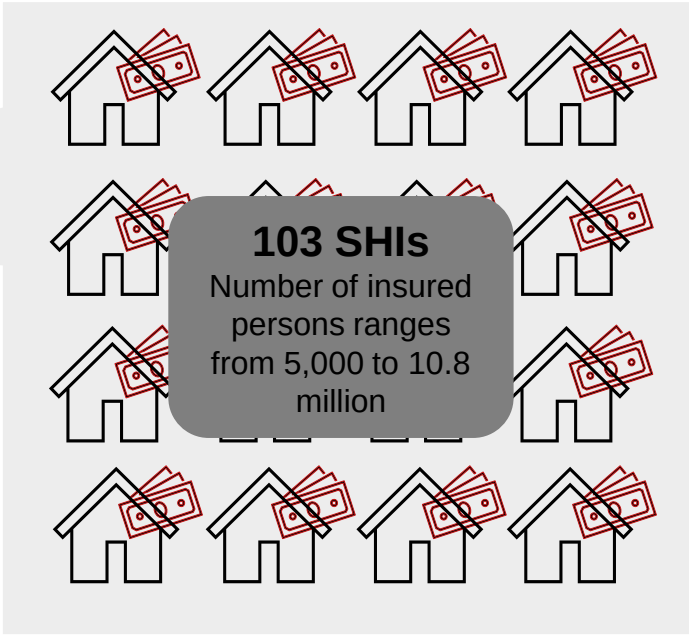
Statutory Health Insurance (SHI)

How Are the Payers Organized?





Source: Daten zum Gesundheitswesen: Versicherte (vdek.com) Versichertenzahlen: Die größten Krankenkassen in Deutschland, Alle gesetzlichen Krankenkassen - GKV-Spitzenverband

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Reimbursement Inpatient Sector

How Are Hospitals Financed?

Inpatient sector

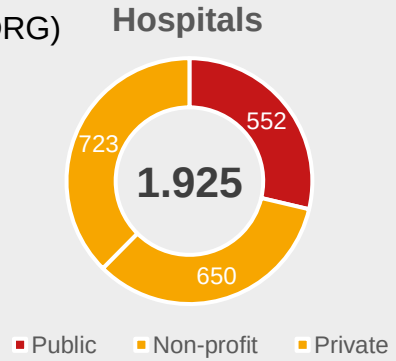
Outpatient sector

Dual reimbursement system

I. Investment costs – State governments
II. Running costs – Diagnosis Related Groups (DRG)

New treatment methods
(Neue Untersuchungs- und Behandlungsmethoden)

Reservation of prohibition
(Verbotsvorbehalt)



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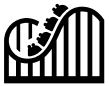
Hospital Future Act (Krankenhauszukunftsgesetz)

Investment Program for Hospitals

Aim

Improvement of digitalization of hospitals with 4.3 billion € (Sept. 2020)



Motivation

If hospitals can not fullfill digital „stage of maturity“, loss of income (2% of DRG) in 2025

How to?

Hospitals apply for financial support at Bundesamt für Soziale Sicherung

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Hospital Future Act (Krankenhauszukunftsgesetz)

Investment Program for Hospitals

- (Information) Technical equipment of the emergency room
- Patient portals for digital admission and discharge management
- Electronic documentation of care and treatment services
- Automated clinical decision support systems
- Digital medication management
- Internal digital process for requesting services
- Provision of secure IT infrastructures
- Online-based care record system
- Technical systems for setting up telemedical network structures
- Technical systems to prevent disruptions to the availability or confidentiality of information technology systems
- Adapt patient rooms to the special treatment requirements in the event of an epidemic

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Reimbursement Outpatient Sector – Standard Care

How Are Ambulatory Services Financed?

Inpatient sector

Outpatient sector

Catalogue of services and prices
(Uniform standard factor, Einheitlicher Bewertungsmaßstab)

Reservation of permission
(Erlaubnisvorbehalt)

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Reimbursement Pathways

Ask Yourself the Following Questions

Do you already have good **contacts** with health insurance companies (SHI, PHI) or service providers?

In which **sector** should the product be used? Outpatient, inpatient, nursing care, rehab, at home...

Appropriate reimbursement pathways for your medical device

What **type** is your product? Aid, medical device, risk class, patient-centered...

How much **time** may pass until market access?

Should the reimbursement be **permanent**?

Is market access planned to the **entire** SHI market or should market access start "**smaller**", e.g. to collect data first?

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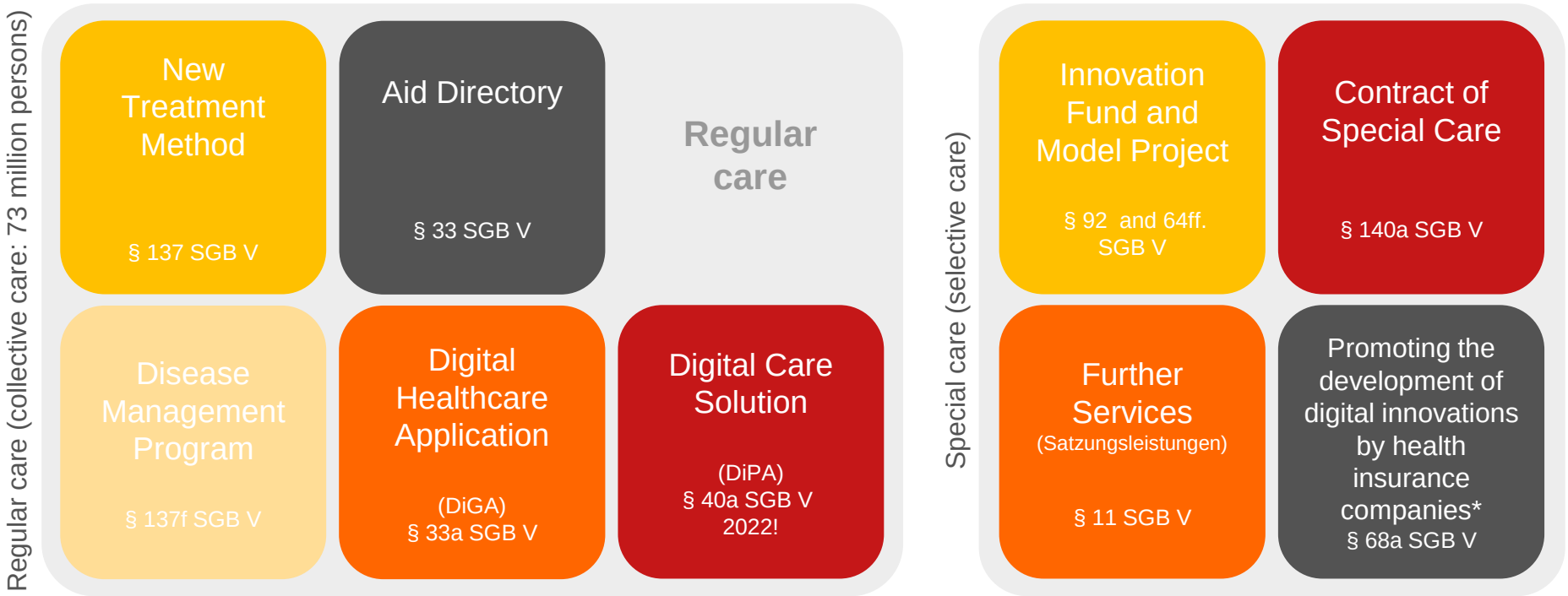
Reimbursement Pathways

Overview of Possibilities



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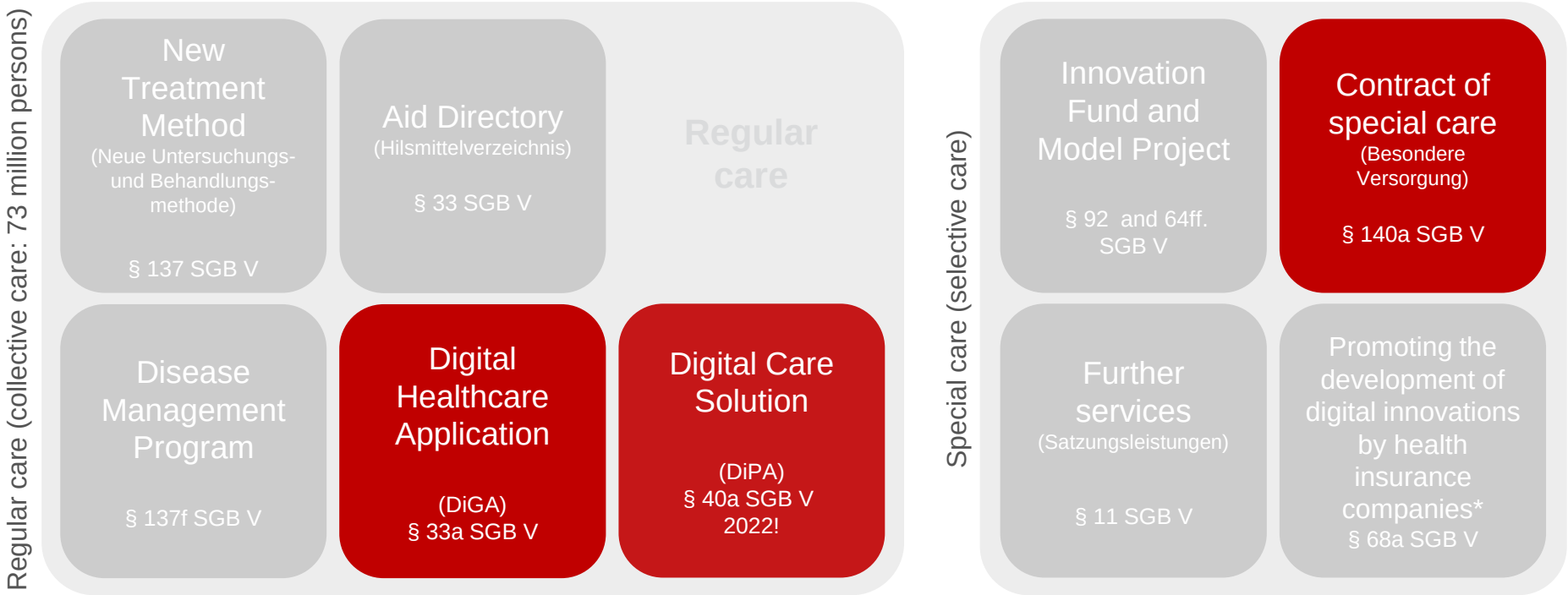
Reimbursement Pathways

Possibilities for Digital Applications



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Contract of Special Care (Selektivvertrag)

Legal Basis - § 140a SGB V

Aim

Improvement of medical care, for example intersectoral treatment pathways, integrated care

Partner

Health insurance company, health care professional, manufacturer

Also manufacturers of digital health products

Challenge

- Mainly regional contracts
- Benefit for all partners
- Find (longterm) partners

Possibility

- More contractual freedom
- Extension on regular care structures
- Scientific evaluation

Good to know

Agreements with collaborations of health insurance companies

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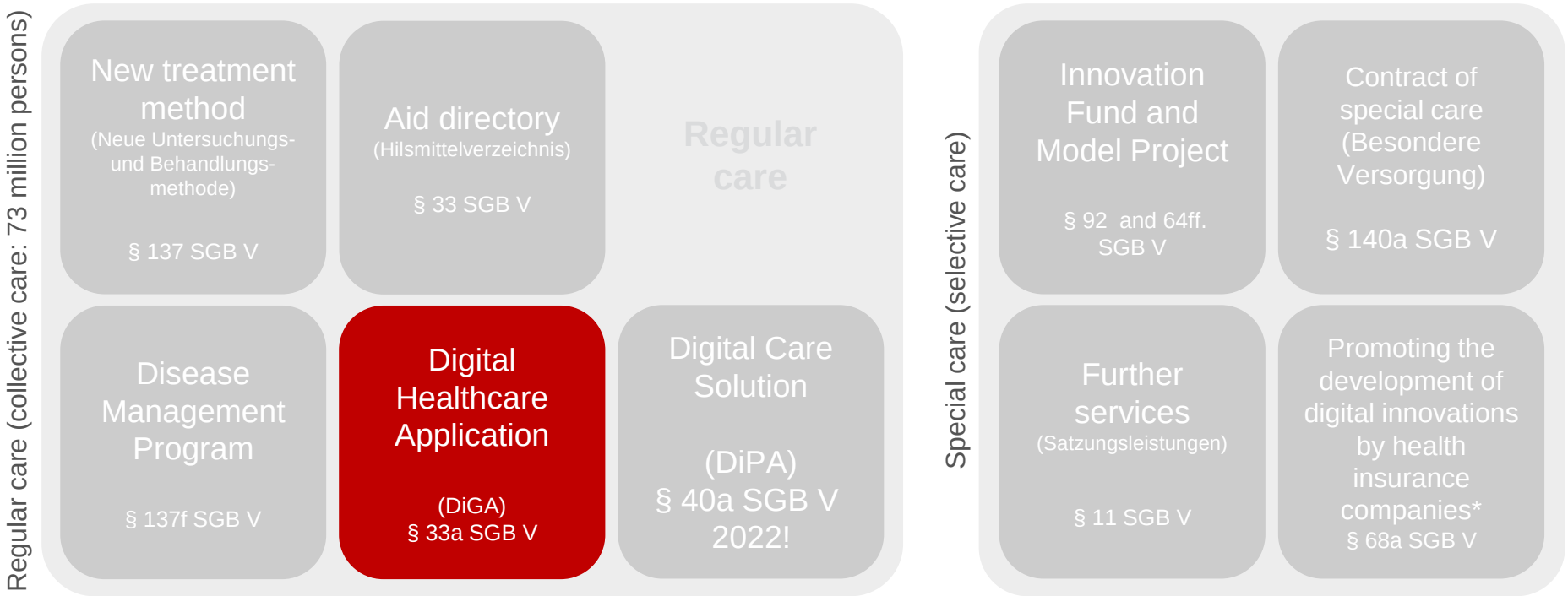
Reimbursement Pathways

DiGA as an Example



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Digital Health Applications (DiGA)

Legal Basis – Digital Healthcare Act (Digitale-Versorgung-Gesetz)

- Digital Healthcare Act enabled „app on pre-scription“
- Entry into force: December 2019
- Beginning of the procedure: May 2020
- Reimbursement by health insurance

- 73 million insured persons (statutory health insurance)
- DiGAs can be prescribed by physicians and psychotherapists

- DiGAs must successfully pass a process at BfArM
- Reimbursable DiGAs are listed in the DiGA directory

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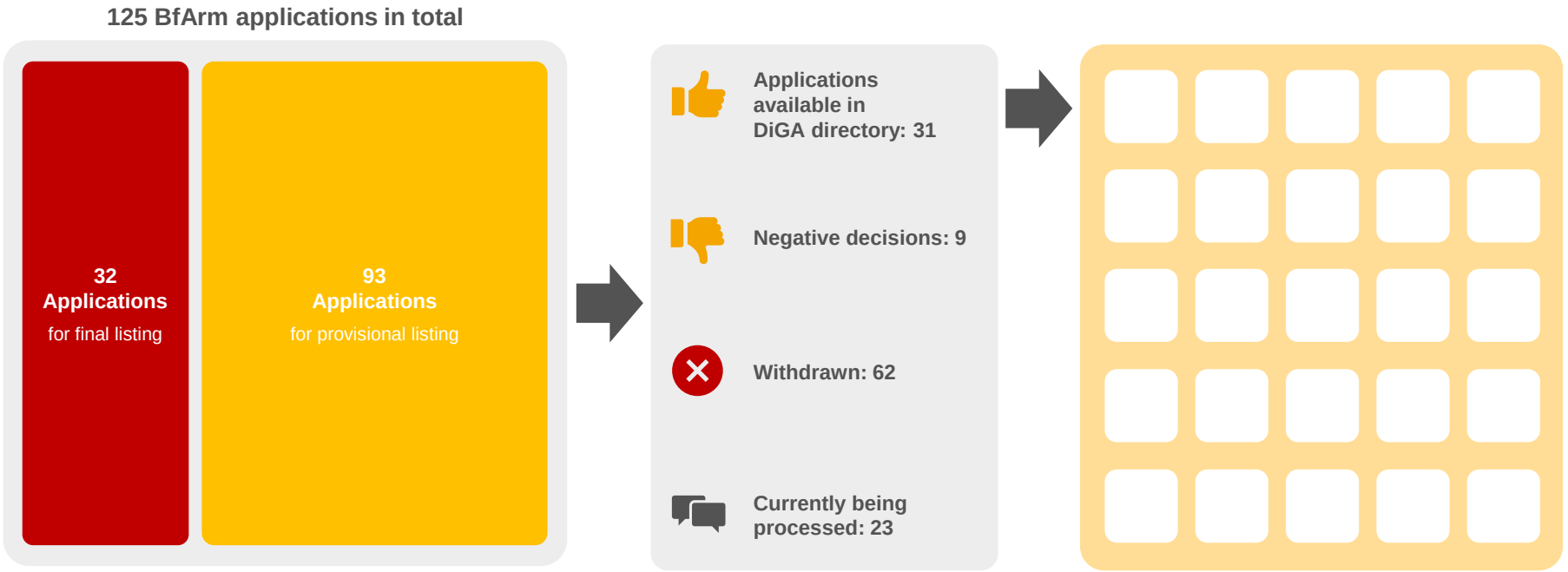
Digital Health Applications (DiGA)

Number of Applications and Successfully Listed DiGA



Source: BfArM, 23.03.2022

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Digital Health Applications (DiGA)

Way to Reimbursement

Prescription by physician **OR** direct request to insurance company by patients with diagnosis

Health insurance company creates activation code

Activation and confirmation of the app by entering the code

Reimbursement of the activation code with the insurance company

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Digital Health Applications (DiGA)

DiGA Characteristics

Medical device of the risk class I or IIa according to MDR (or MDD)

Main function is based on digital technologies

Not a digital application that serves only for the collection of data from a device or for controlling a device. Medical purpose must be achieved through the main digital functions.

Supports the recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment or alleviation or compensation of injuries or disabilities

Does not serve primary prevention

Is used only by the patient or by the patient and the healthcare provider

DiGA are therefore “digital assistants” in the hands of patients

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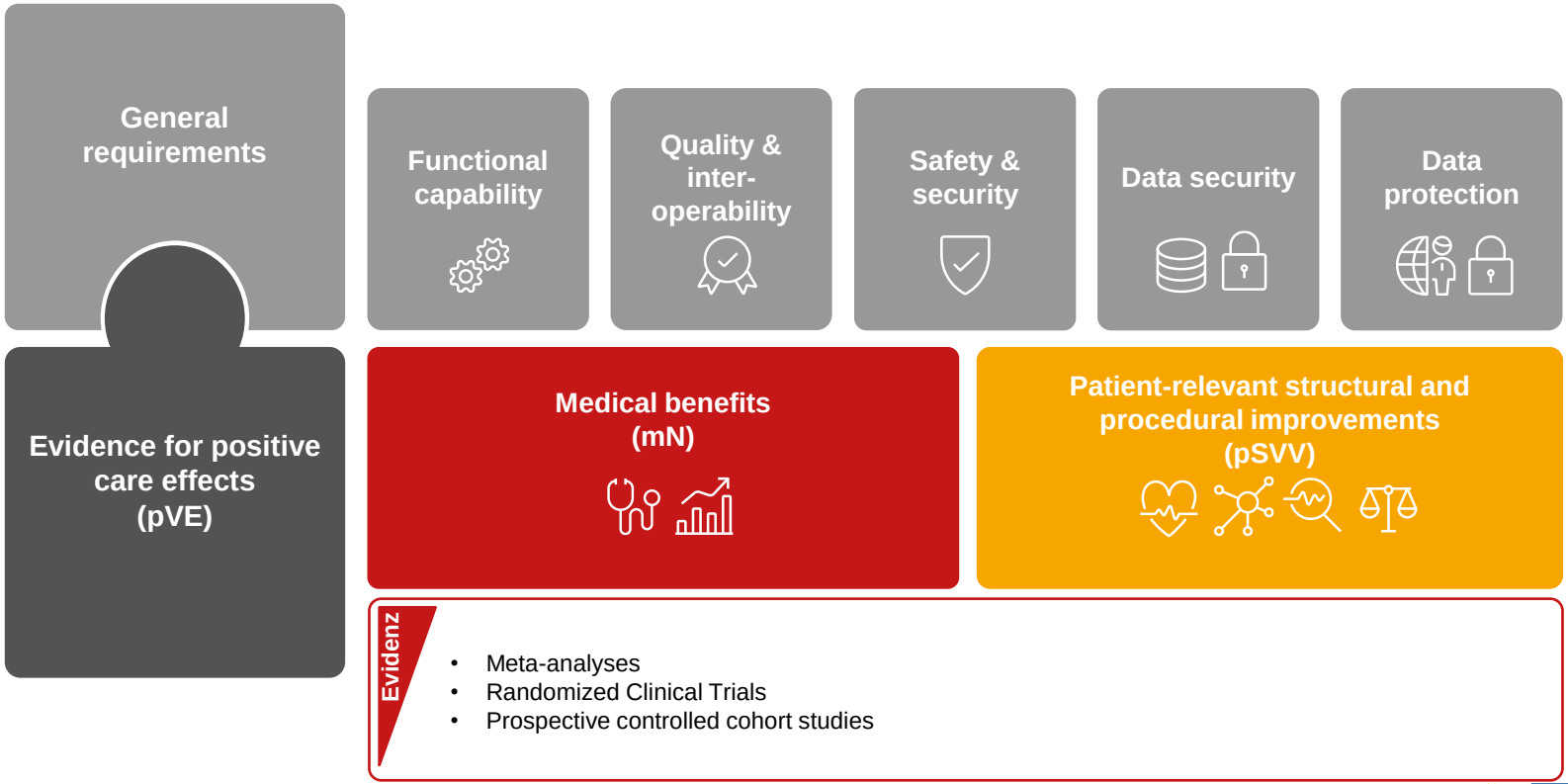
Digital Health Application

Requirements (Verified by BfArM)



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Telematik Infrastruktur (TI)

Definition

- The TI networks all players in the healthcare system in the area of statutory health insurance and ensures the cross-sectoral, cross-system and secure exchange of information.

- It is a closed network to which only registered users (persons or institutions) with an electronic health professional and practice card have access.

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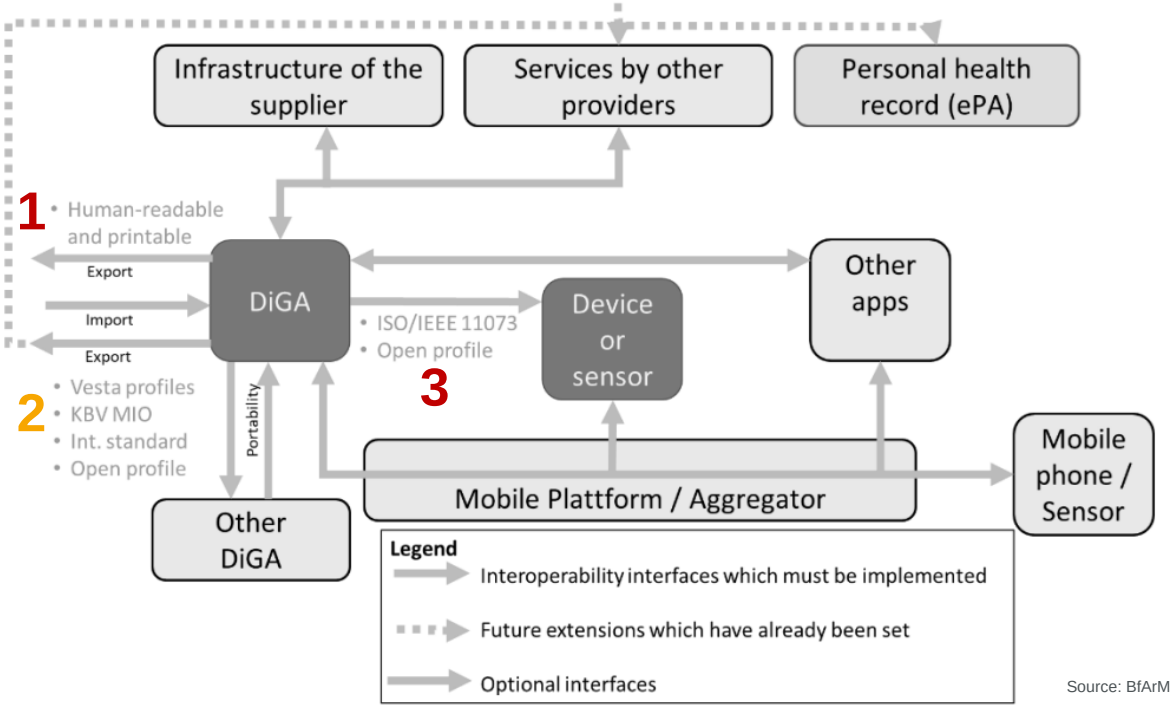
Interoperability Requirements for DiGA

Interoperability for DiGA (ePA and Digital Health Applications)



Source: BfArM DiGA Guide

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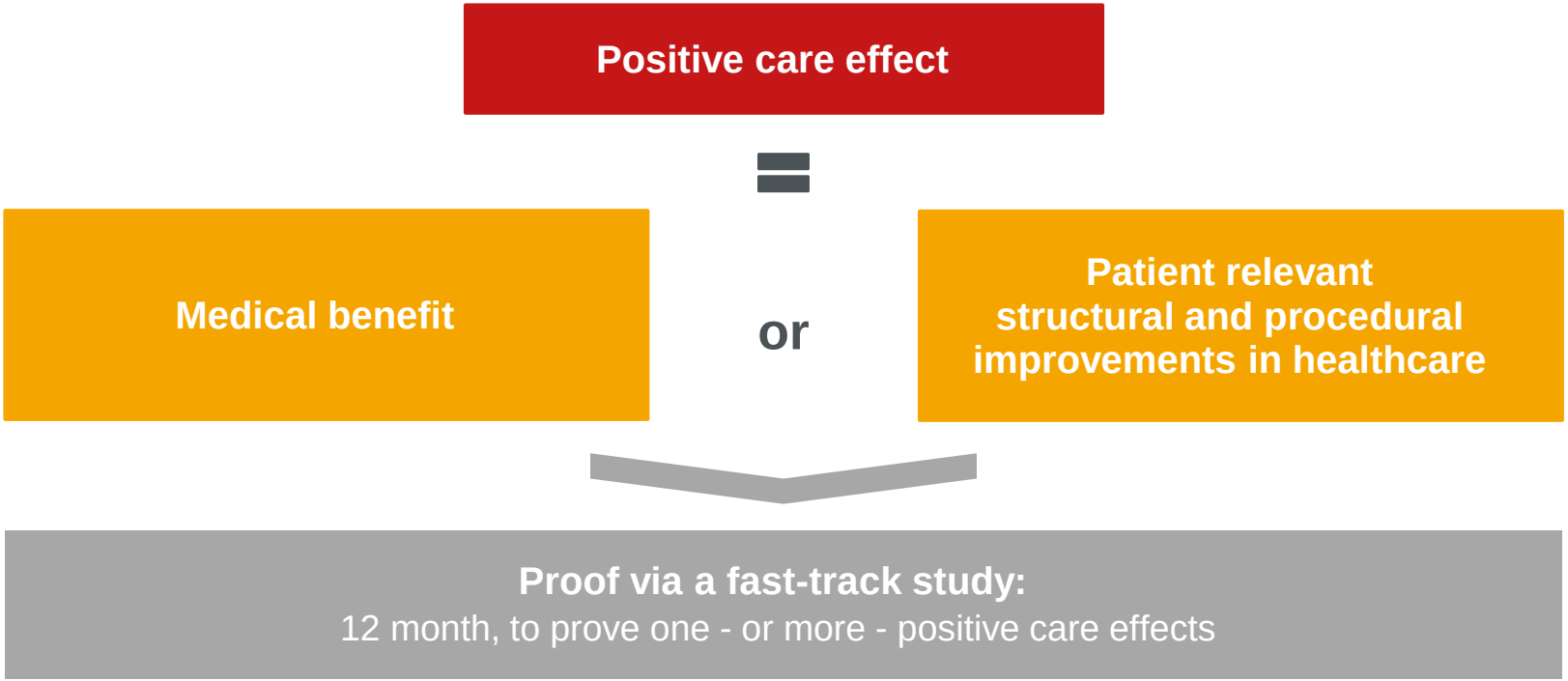
Digitale Health Applications (DiGA)

Types of Positive Care Effects (pVE)



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Digitale Health Applications (DiGA)

Positive Care Effects (pVE)

Medical benefit (mN)

1 Improvement of the state of health	**2** Reduction of the duration of a disease
3 Prolongation of survival	**4** improvement in the quality of life

Patient-relevant improvement of structure and processes (pSVV)

1 Coordination of the treatment procedures	**2** Alignment of treatment with guidelines and recognized standards	**3** Adherence	**4** Facilitating access to care	**5** Patient safety
6 Health literacy	**7** Patient autonomy	**8** Coping with illness-related difficulties in everyday life	**9** Reduction of the therapy-related efforts and strains for patients & their relatives	

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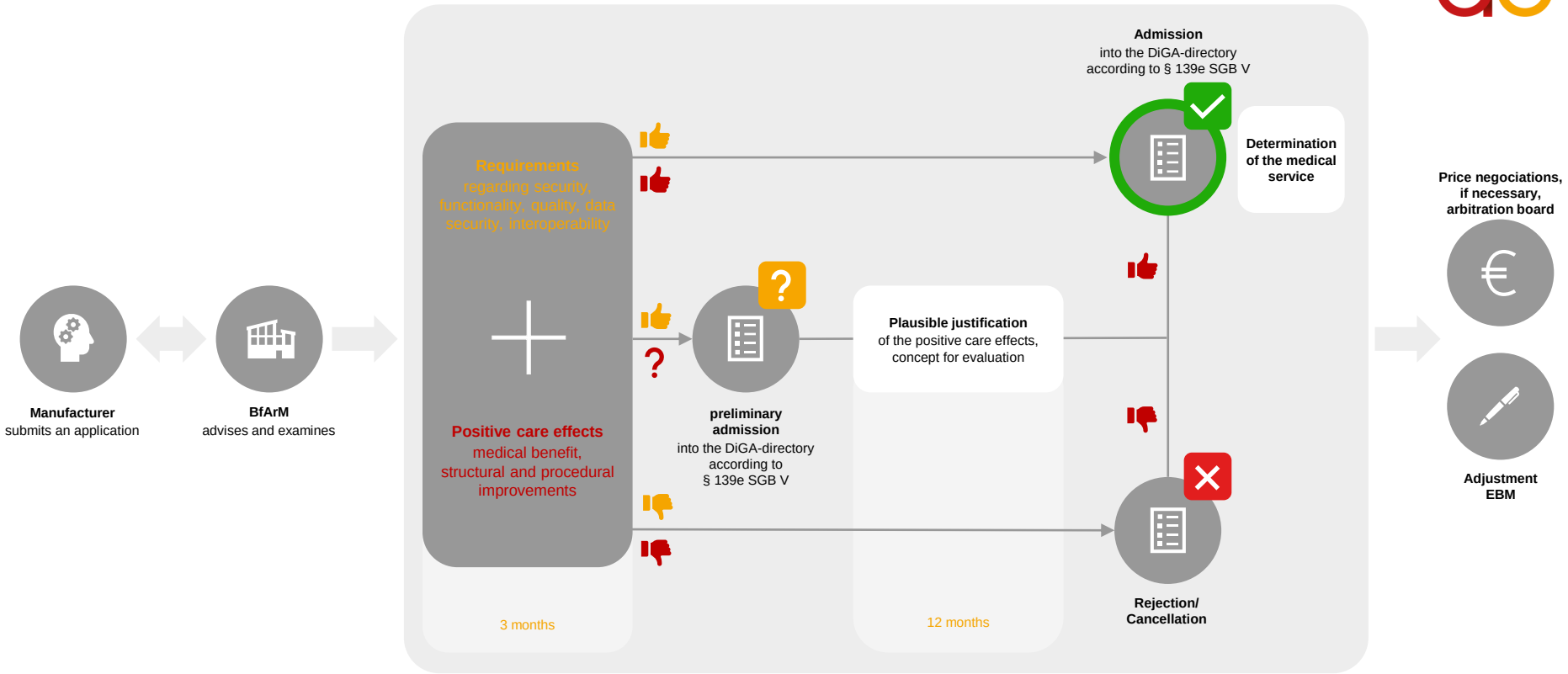
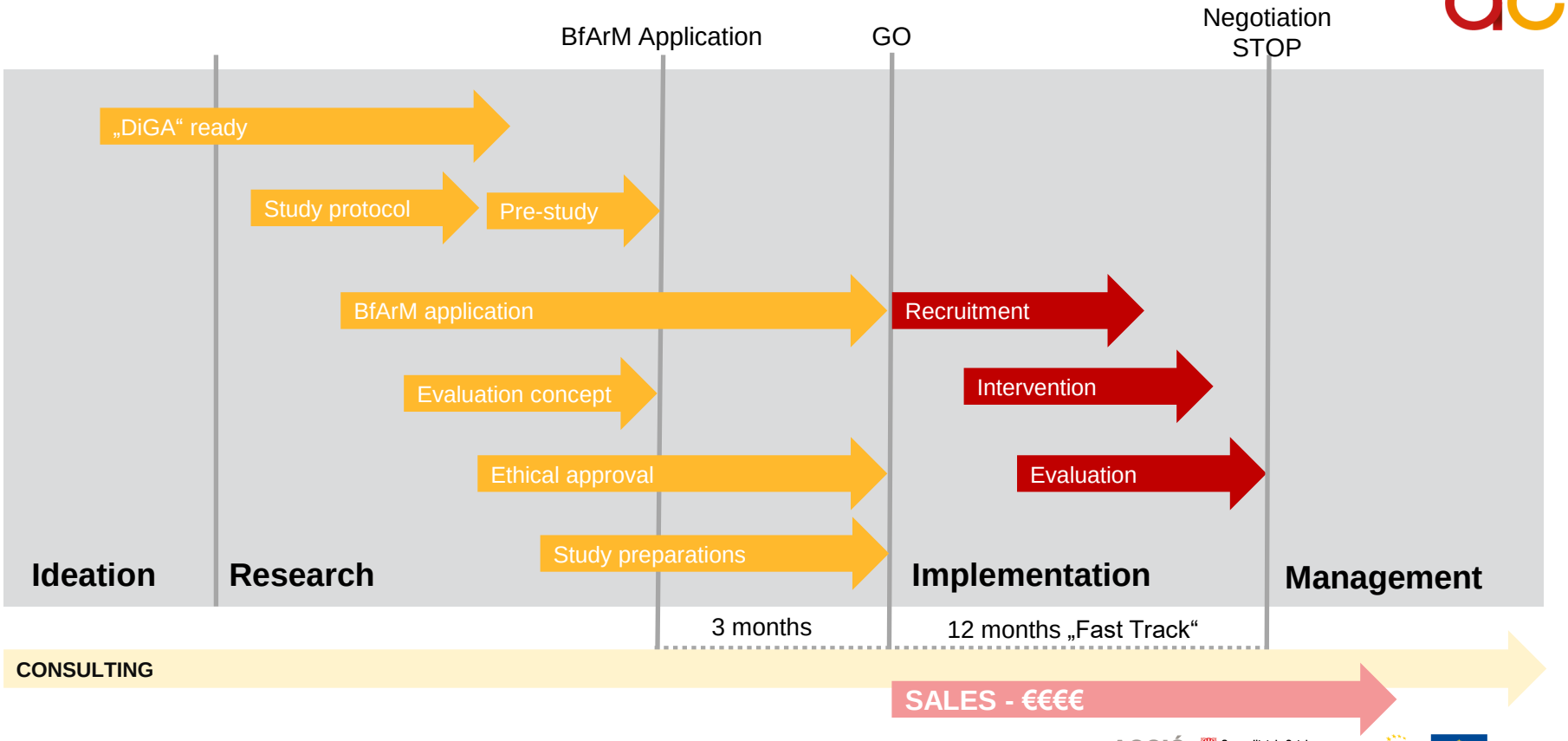
The DiGA Fast Track Procedure



Source: own illustration based on BfArM

At a Glance: dmac Services along the DiGA Roadmap



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Digital Health Applications (DiGA)

10 Learnings

1. DiGA can achieve **considerable prices**
2. **High requirements,** especially concerning evidence
3. Partially still **hesitant prescribers**
4. Overall **number of prescriptions** still manageable, yet already considerable for single DiGA
5. Manufacturers should deal with the **proof of PCE** at an early stage
6. **Time and financial expenditure** of the DiGA process should not be underestimated
7. Structured and **focused approach** as well as **complexity reduction** expedient in most cases
8. **Intensive exchange** necessary even after application has been submitted
9. **Marketing and sales** of DiGA should also be considered at an early stage
10. DiGA as a **potential success model for Europe**

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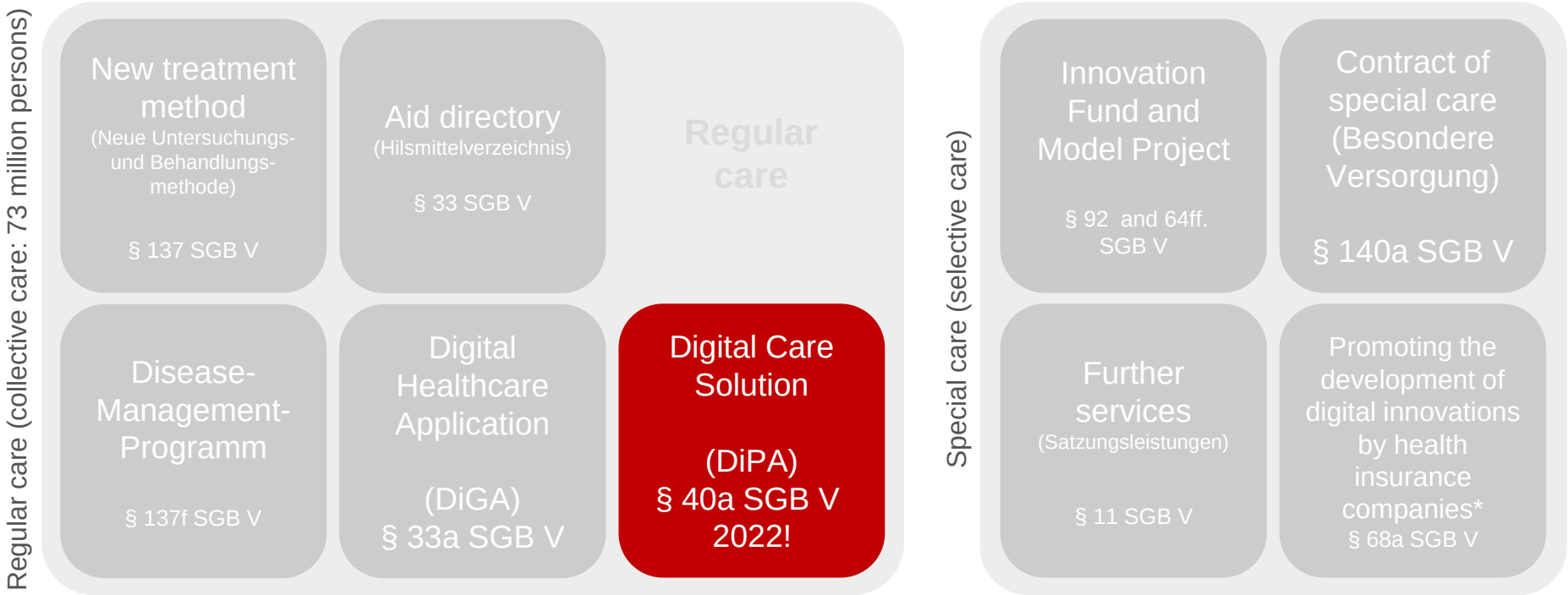
ABOUT

DiPA

Reimbursement Pathways

DiPA as an Example



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Digital Care Solutions (DiPA)

The Digital Healthcare and Nursing Care Modernisation Act (DVPMG)

- DVPMG launched digital care solutions
- Entry into force: June 2021
- Beginning estimated for summer 2022
- Reimbursement by social care insurance

- Adresses care receivers in the outpatient sector
- DiPA will not be prescribed
- Cost coverage by social care insurance has to be applied for

- DiPA must successfully pass a process at BfArM
- DiPA will be listed in the DiPA directory

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Digital Care Solutions (DiPA)

Definition According to §40a SGB XI

In contrast to DiGA, DiPA do not have to be medical devices

Main function essentially based on digital technology

The existence of a care level is required

Purpose:

Reducing impairments of the independence/abilities of the person in need of care

Preventing a worsening of the need of care

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Digital Care Solutions (DiPA)

Target Group

Use by the person in need of care only

Use in interaction of the person in need of care with relatives and ambulatory care facilities

Targeted only at the person in need of care

Can only be used in ambulatory/home care

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Digital Care Solutions (DiPA)

Requirements (According to §78a SGB XI)

General requirements

Functional capability, safety and security

Quality
(e. g. barrier-free, age-appropriate usability, etc.)

Data security

Data protection

Evidence for nursing benefits

Management of special nursing situations (e.g. falls, dementia)

Organization and management of daily nursing routines

Evidence

- Requirements for level of evidence still unclear
- Evaluation of the organization and management of daily nursing routines seems complex
- Evidence will be regulated in a framework agreement

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Digital Care Solutions (DiPA)

Admission Process

Requirement:

Application based on digital technologies

Application to BfArM

Evidence of:
- Safety
- Functionality
- Quality
- Data security
- Data protection
- Nursing benefit

Evidence of nursing benefit **must already be proven**

Preliminary listing in contrast to DiGA not possible!

BfArM decision within 3 months:

Rejection or admission to DiPA directory

Agreement of the amount of remuneration
Within 3 months after admission

Between German National Association of Social Care Insurance Funds and manufacturer

Up to 50 € per month

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Digital Care Solutions (DiPA)

…Waiting for the Framework Agreement

Clarification in the framework agreement

Definition of nursing benefit

Definition of possible nursing benefit categories

Requirements for proof of nursing benefits

Pricing of supporting services

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Digital Care Solutions (DiPA)

Comparison to Digital Health Applications (DiGA)

	DiPA	DiGA
Purpose	- Reduction of impairments in the independence or abilities of the person in need of care - Counteracting a worsening of the need for care (§40a SGB XI)	Detection, monitoring, treatment, alleviation of diseases, injuries and disabilities (§33a SGB V)
Legal Basis	Digital Healthcare and Nursing Care Modernisation Act (2021)	Digital Care Act (2019)
Expected Benefit	Nursing Benefit	Positive Care Effect
Directory	Directory of Digital Care Solutions (DiPA directory)	Directory of digital health applications (DiGA directory)
Reimbursement	- Social Care Insurance - Start of reimbursement approximately in the summer of 2022 - Direct request to nursing care insurance company - Requirement: care level	- Statutory Health Insurance - Reimbursement already possible - Prescription **OR** direct request to insurance company - Requirement: indication

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Program

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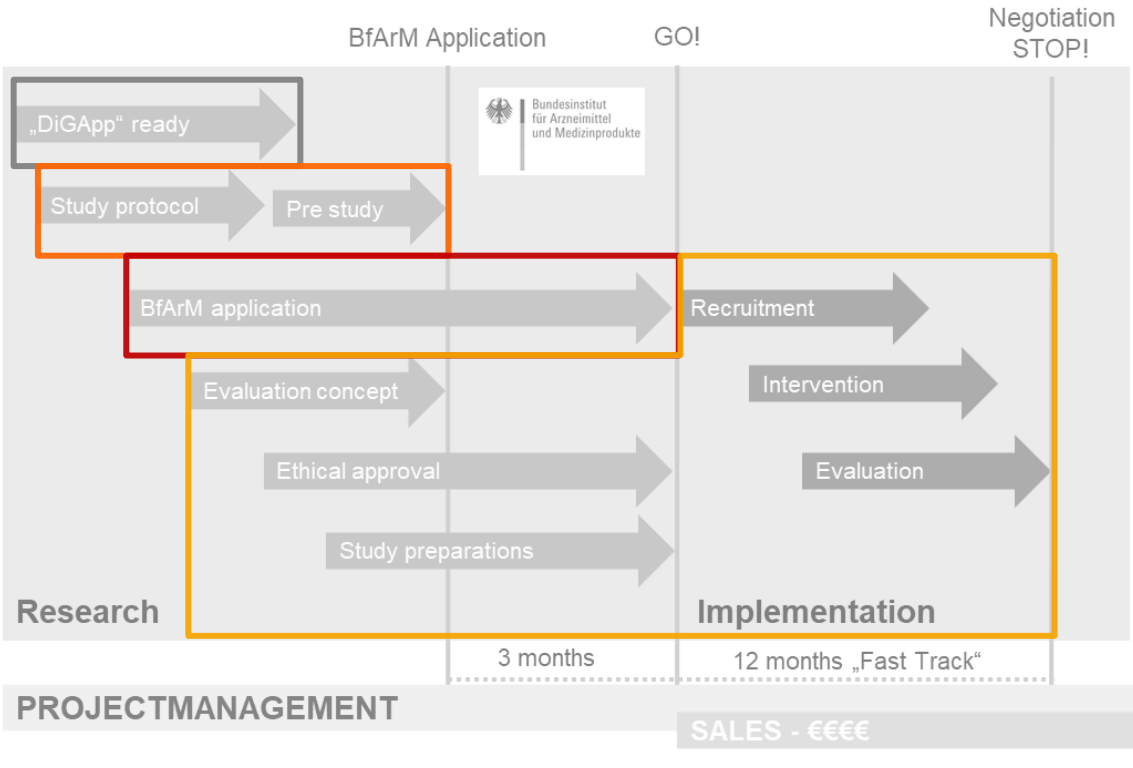
Wrap-Up

dmac Services



Requirement analysis
e.g. shaping the digital main function, patient centered visualisation concepts, development pathways

Pre-study
e.g. study design, protocol, ethics approval, conduction, data analysis

Application
e.g. writing the DiGA application, interaction with BfArM

Evaluation study
e.g. evaluation concept, study center recruitment, contracting, conduction, data analysis, medical writing and publication

Additional services
e.g. project management, BfArM advice support, pricing, marketing

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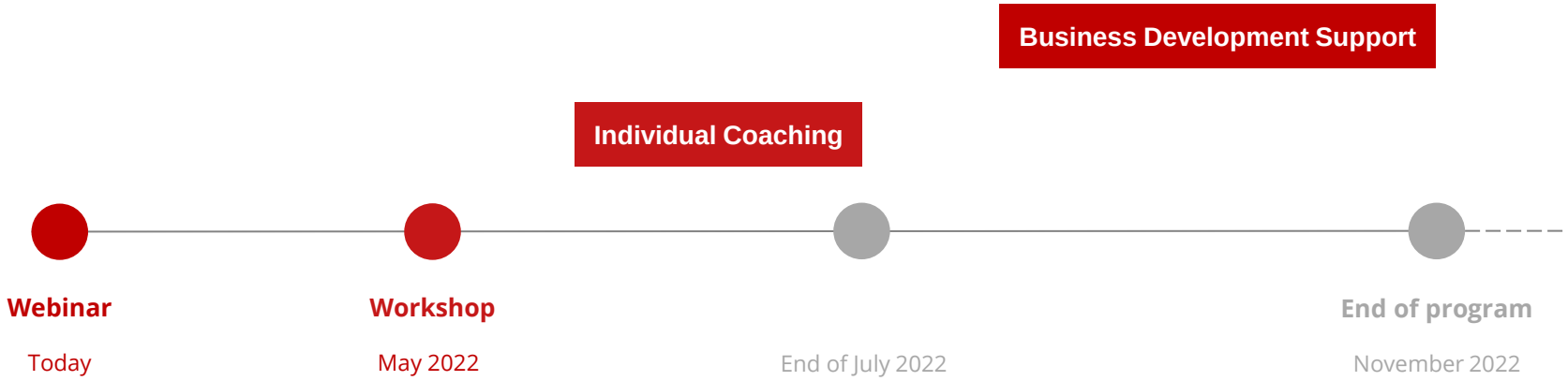
Program Timeline



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Matthias Rass

Head of Strategy & Innovation

matthias.rass@mv-dmac.de

Elisa Bott

Project Manager Innovation

elisa.bott@mv-dmac.de

Cordula Forster

Project Manager Health Economics

cordula.forster@mv-dmac.de

Sophie Terheyden

Project Manager DiGA

sophie.terheyden@mv-dmac.de

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https://www.mv-dmac.com/

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