

# Swiss Medtech Day 2021

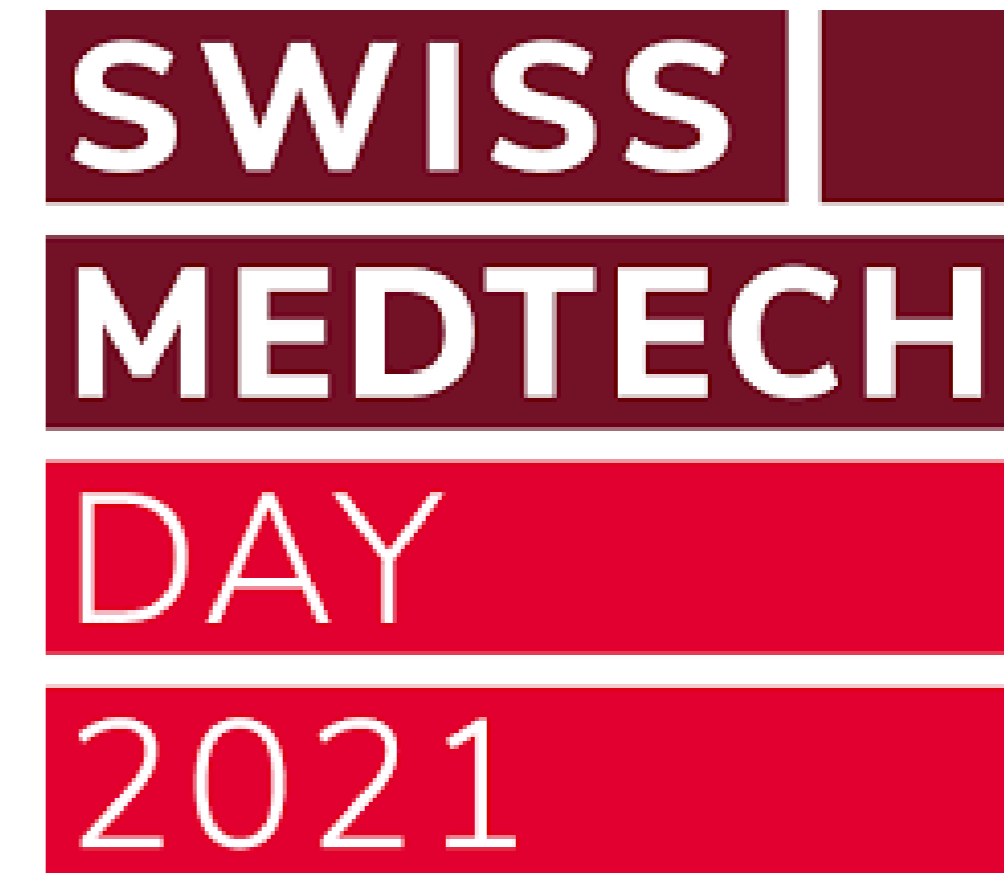
## Digital health applications (DiGA) in Germany

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08.09.2021

### Healthcare Heads GmbH

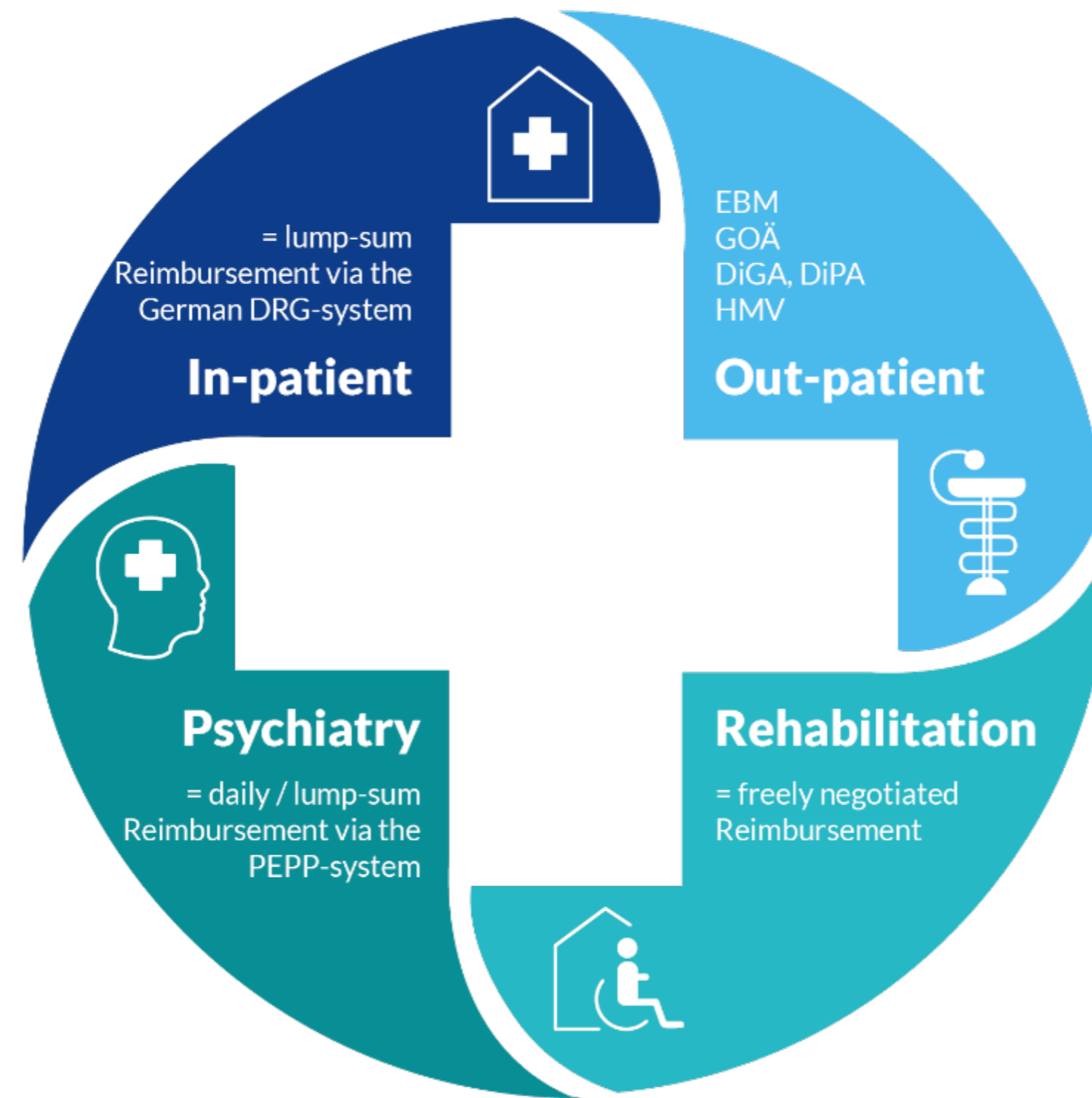
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# DiGAs – the youngest part of the German healthcare system

## German Reimbursement Overview (covered by health insurance)



Primary healthcare market

## No Reimbursement (not covered by health insurance)



Secondary healthcare market

## DiGAs – healthcare digitalization on the rise?

2010

- Study commission „internet and digital society“ of the German parliament

2014

- „Digital Agenda 2014 to 2017“ providing many digital basic principles

2019

- Introduction of the Digital Supply Act (DVG)
- Introduction of the Digital Health Application Ordinance (DiGAV)

2020

- May: Opening of the DiGA Fast Track process at BfArM
- October: First DiGA included to DiGA catalogue

2021

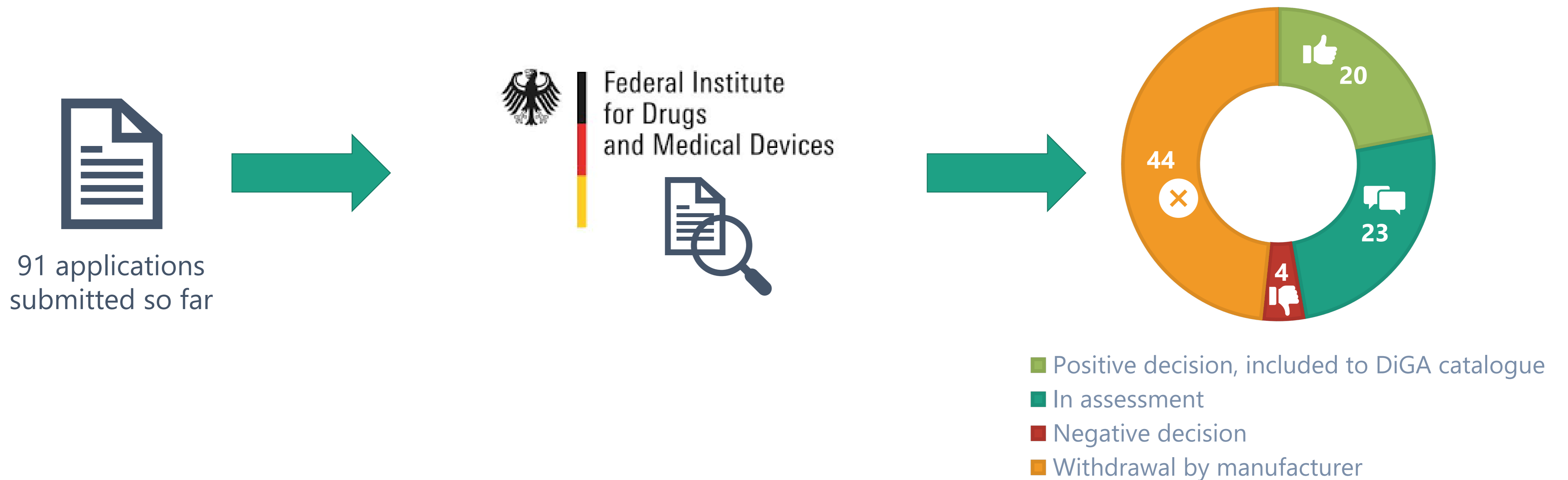
- 20 DiGAs included in the DiGA catalogue so far

## What is a DiGA?

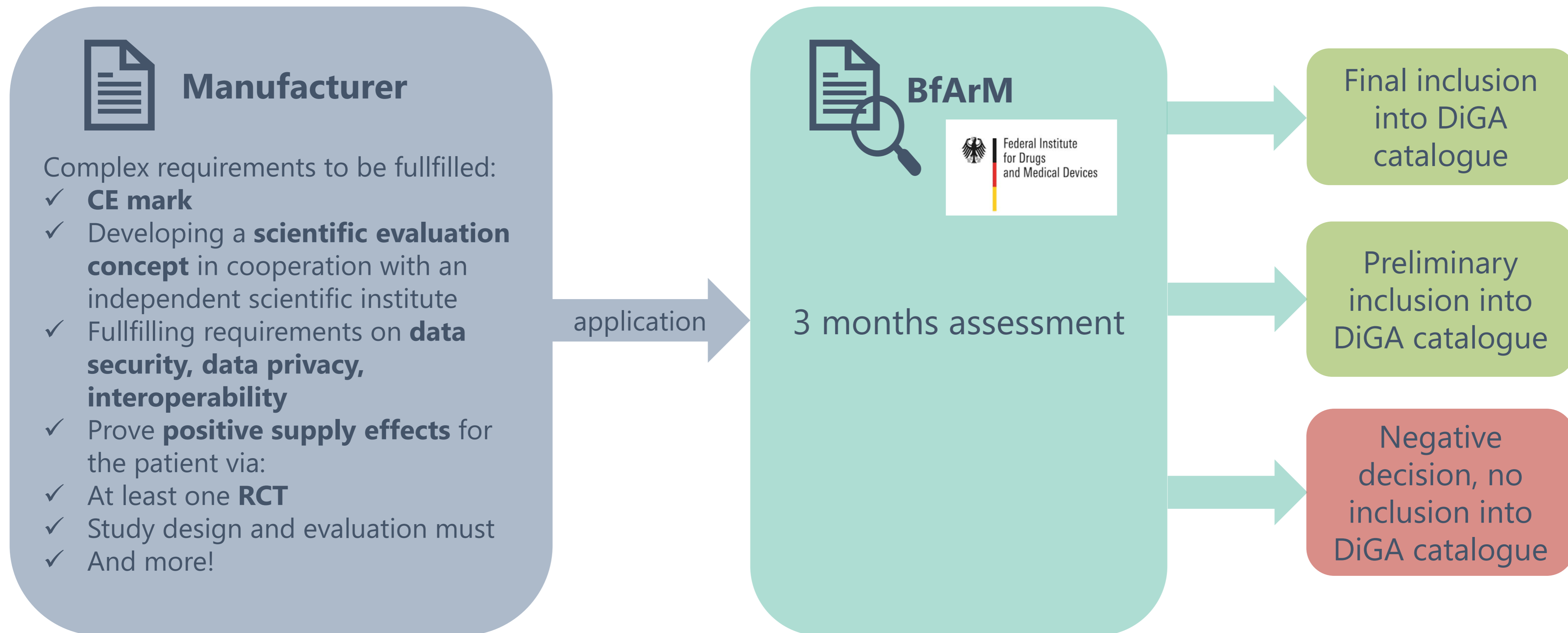
A DiGA is a **digital medical device**

- ✓ It must belong to medical device **risk class I or IIa** (according to MDR or under the transitional provisions according to MDD)
- ✓ The main function is based on **digital technologies**.
  - ✓ It is not a digital application that is only used to read or control a device.
- ✓ DiGAs support the **detection, monitoring, treatment and alleviation of diseases** or support the **detection, treatment, relief or compensation** of injuries or disabilities.
- ✓ DiGAs are not used for primary prevention.
- ✓ The DiGA is **used by the patient or by the service provider and the patient jointly**.
- ✓ It **can be an app**, but it does not have to be.

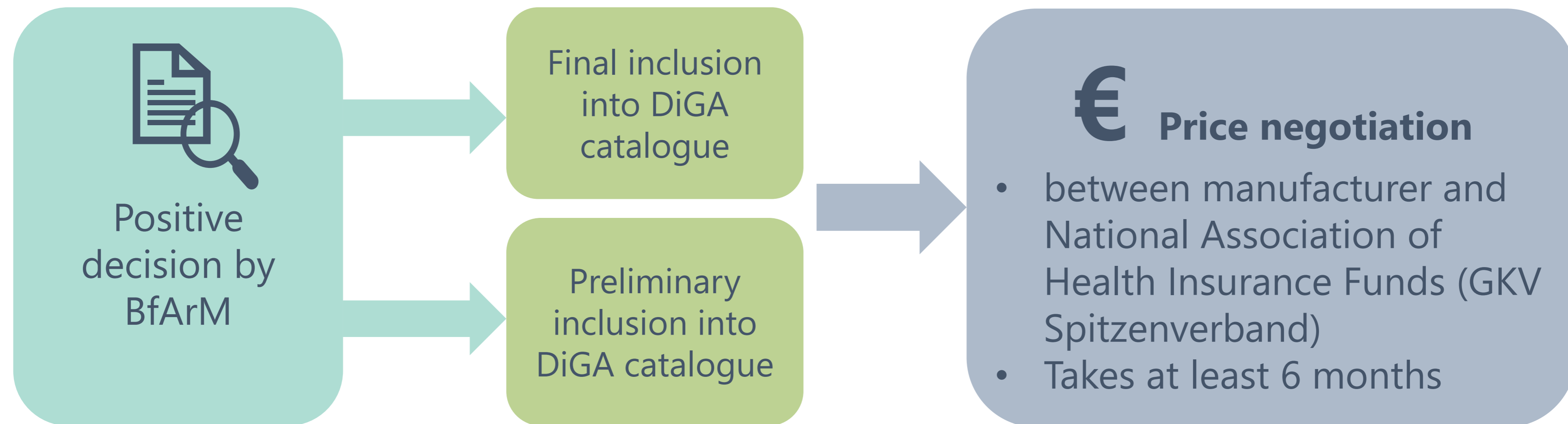
## DiGA assessment at BfArM – status quo



# The DiGA application process – unbreachable?



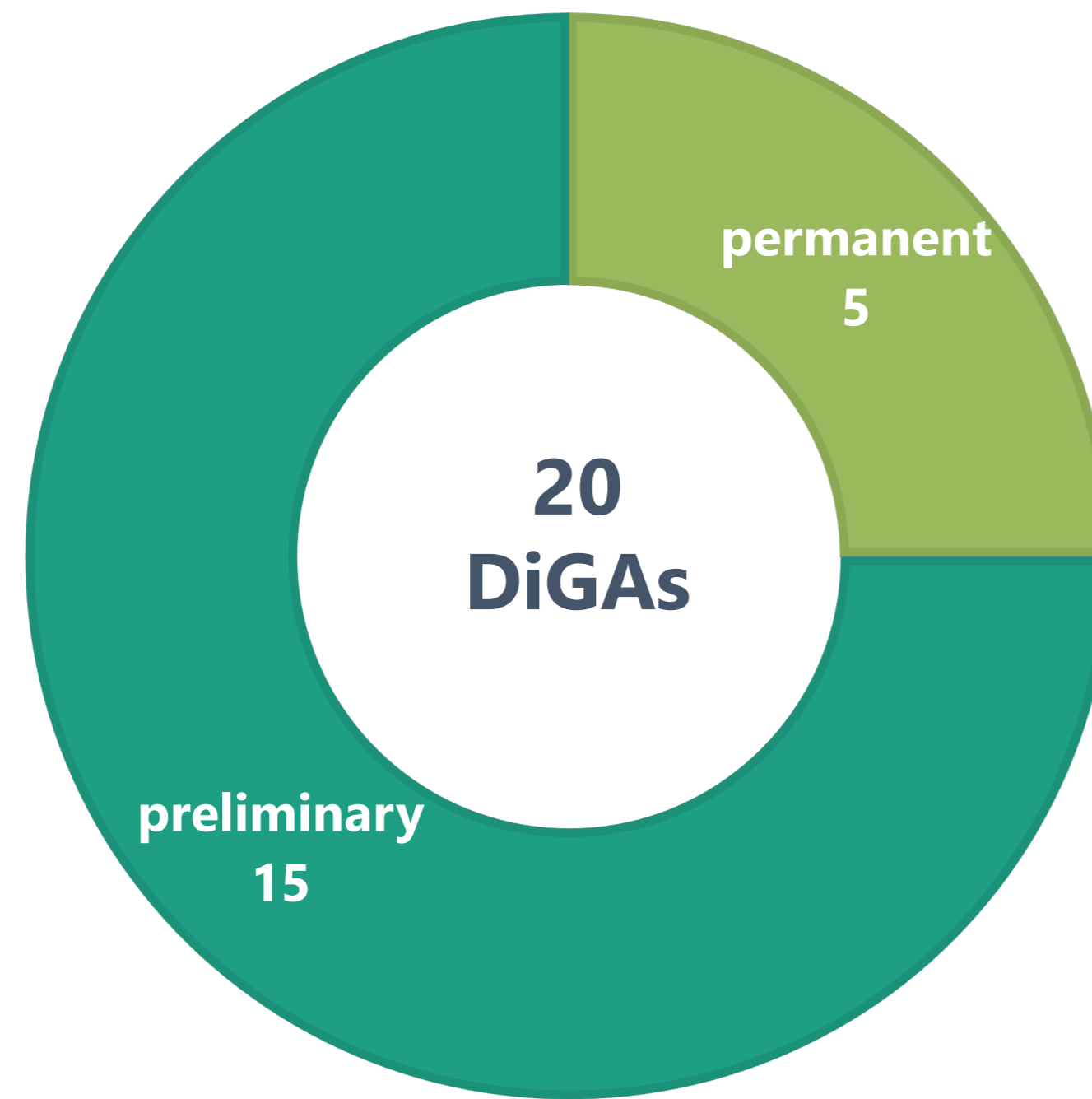
## The DiGA application process – worthwhile?



Being listed as a DiGA gives access to:

- ✓ All (103 at the moment) statutory health insurances
- ✓ 73 million insurants (88% of the German population)
- ✓ 170,000 contracted physicians, dentists, psychotherapists

## DiGA catalogue – status quo



### Average price for

DiGAs with preliminary inclusion

**410 €**

DiGAs with permanent inclusion

**491 €**



**20,000 prescriptions since October 2020**



## Our recommendation for a successful DiGA application

- Check requirements and their deadlines and time schedules.
- Get support of (external) experts for DiGA and Market Access pathways to the German healthcare system
- Decide on next reasonable steps.
- Become a member of a manufacturer's organization which participates in the negotiation of DiGA pricing (e. g. BVMed)



**Thank you!**

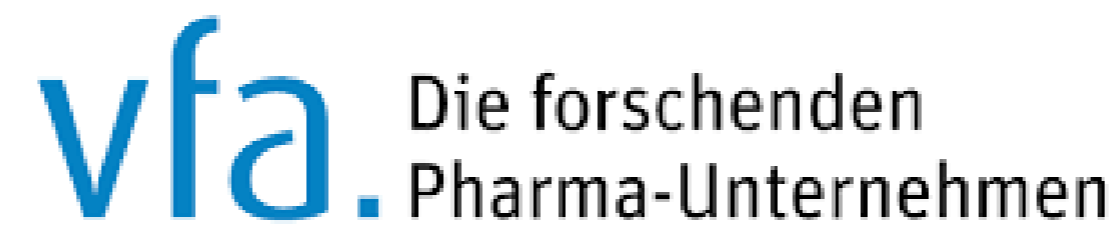
# Back-up



HEALTHCARE HEADS  
MARKET ACCESS NAVIGATORS



# Relevant associations in the process of DiGA pricing





**Healthcare Heads CEOs**  
Dr. med. Susanne Habetha  
Sven Sauermann

- Healthcare Heads GmbH (HcH) offers consulting services in the healthcare business for medical device companies.
- We focus on Reimbursement and Market Access solutions.
- It is our aim to deliver highest quality solutions and exceed customers' expectations.
- We are driven by the motivation to use our expertise to grant access for patient to innovative Medical Devices.
- Our USP is the multidisciplinary expertise – allowing a multidisciplinary unique approach that spans between the poles of medicine, public health, economics and medical industry interests.

## Market Access

- Market analyses
- Strategy development
- Pricing
- Training on the German healthcare system

## Reimbursement

- Reimbursement status analyses
- DRG/ZE/OPS/NUB proposals
- Development and accompaniment of special forms of Reimbursement and projects with payers
- Reimbursement information (brochures)
- Support in achieving out-patient Reimbursement
- Support with DiGA catalogue listing

## Economics

- Cost and benefit calculations and profitability analyses for medical devices and therapies
- InEK data analyses
- Dynamic tools to present economic results
- Execution of calculation projects with InEK reference hospitals
- CaseStudies und Value messaging

## Evidence

- Identification of evidence gaps
- Preparation of evidence and value dossiers
- Consultancy on clinical and economic evidence generation
- Safeguarding of the clinical compensation by quality assurance projects (e.g. clinical indication pathway KIP)

## External Affairs

- KOL Mapping from Reimbursement and Market Access perspective
- Stakeholder channel management
- Use of our network of contact persons from payers, associations, politics and the self-governmental body, clinical users and administrations



# HEALTHCARE HEADS

MARKET ACCESS NAVIGATORS

Specialized in Market Access for Medical Devices

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