

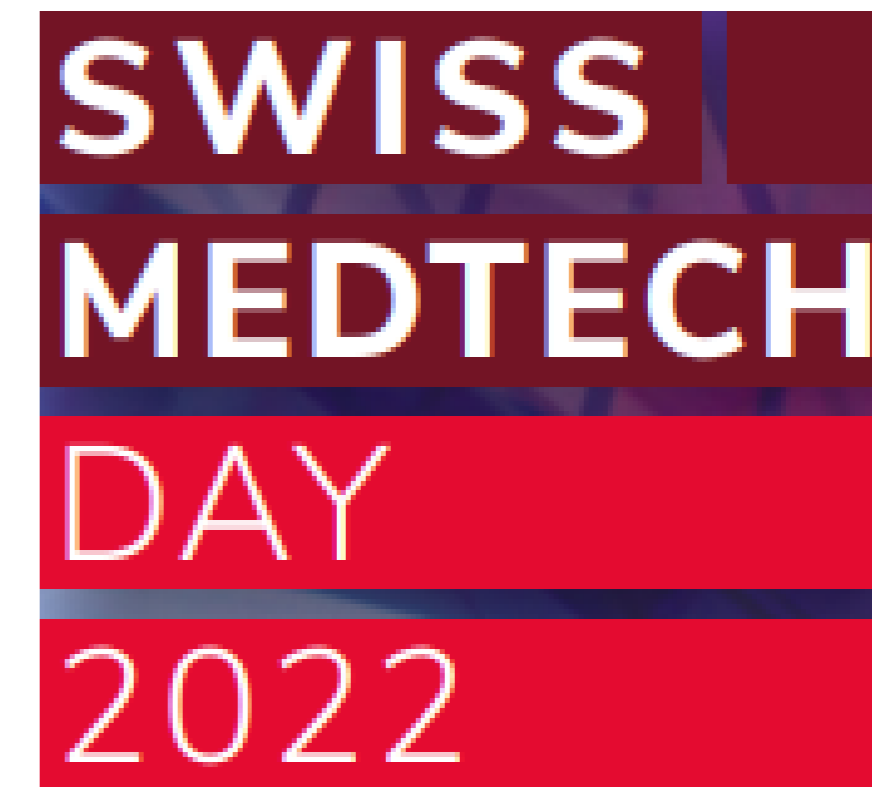
Swiss Medtech Day 2022

Digital health applications (DiGA) in Germany

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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

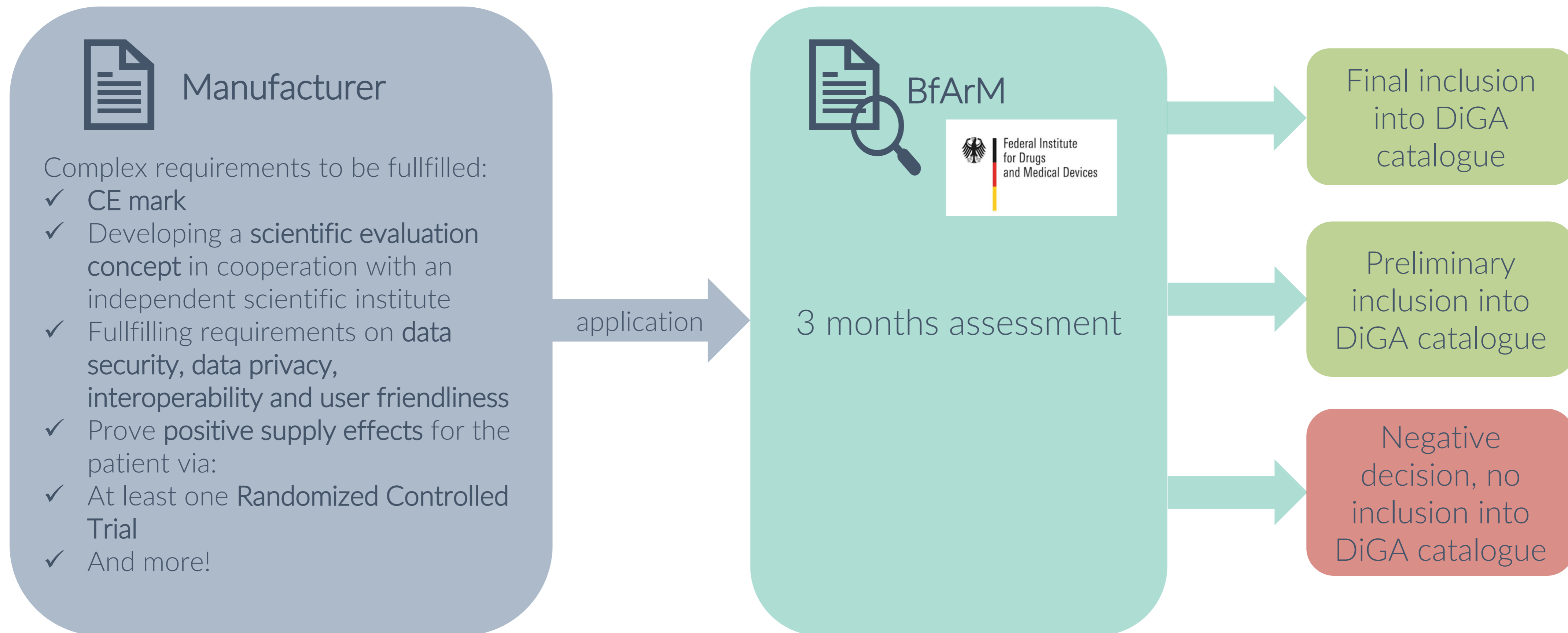
- KOL Mapping from Reimbursement and Market Access perspective
- Stakeholder channel management
- Use of our network of contact persons from payers, associations, politics and the self-governmental body, clinical users and administrations

What is a DiGA?

A DiGA is a **digital medical device**

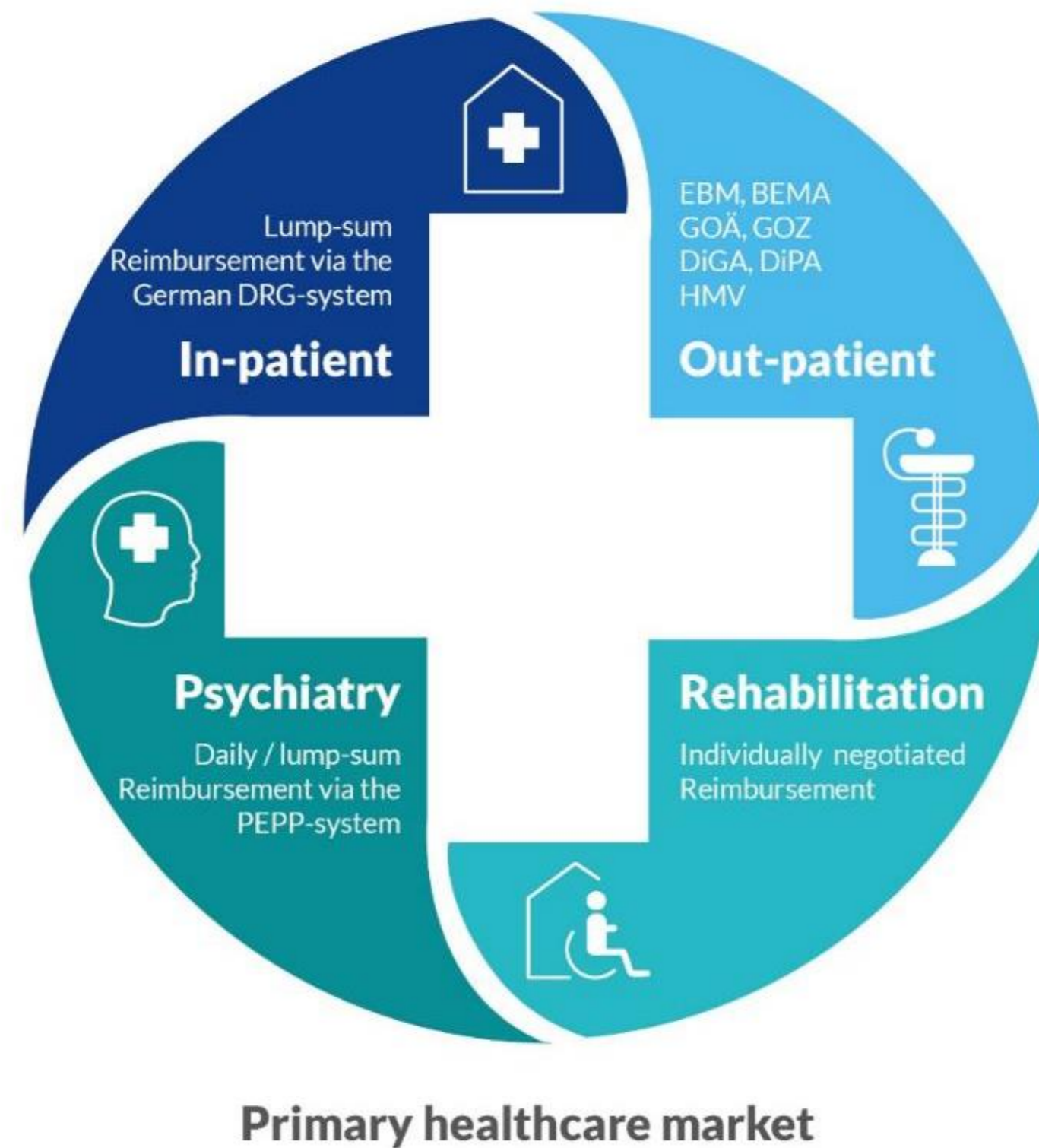
- ✓ It must belong to medical device **risk class I or IIa** (according to MDR or under the transitional provisions according to MDD)
- ✓ The main function is based on **digital technologies**.
 - ✓ It is not a digital application that is only used to read or control a device.
- ✓ DiGAs support the **detection, 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.

The DiGA application process – unbreachable?



DiGAs – the youngest part of the German healthcare system

German Reimbursement Overview (covered by health insurance)



No Reimbursement (not covered by health insurance)



DiGAs – healthcare digitalization on the rise?

Political situation

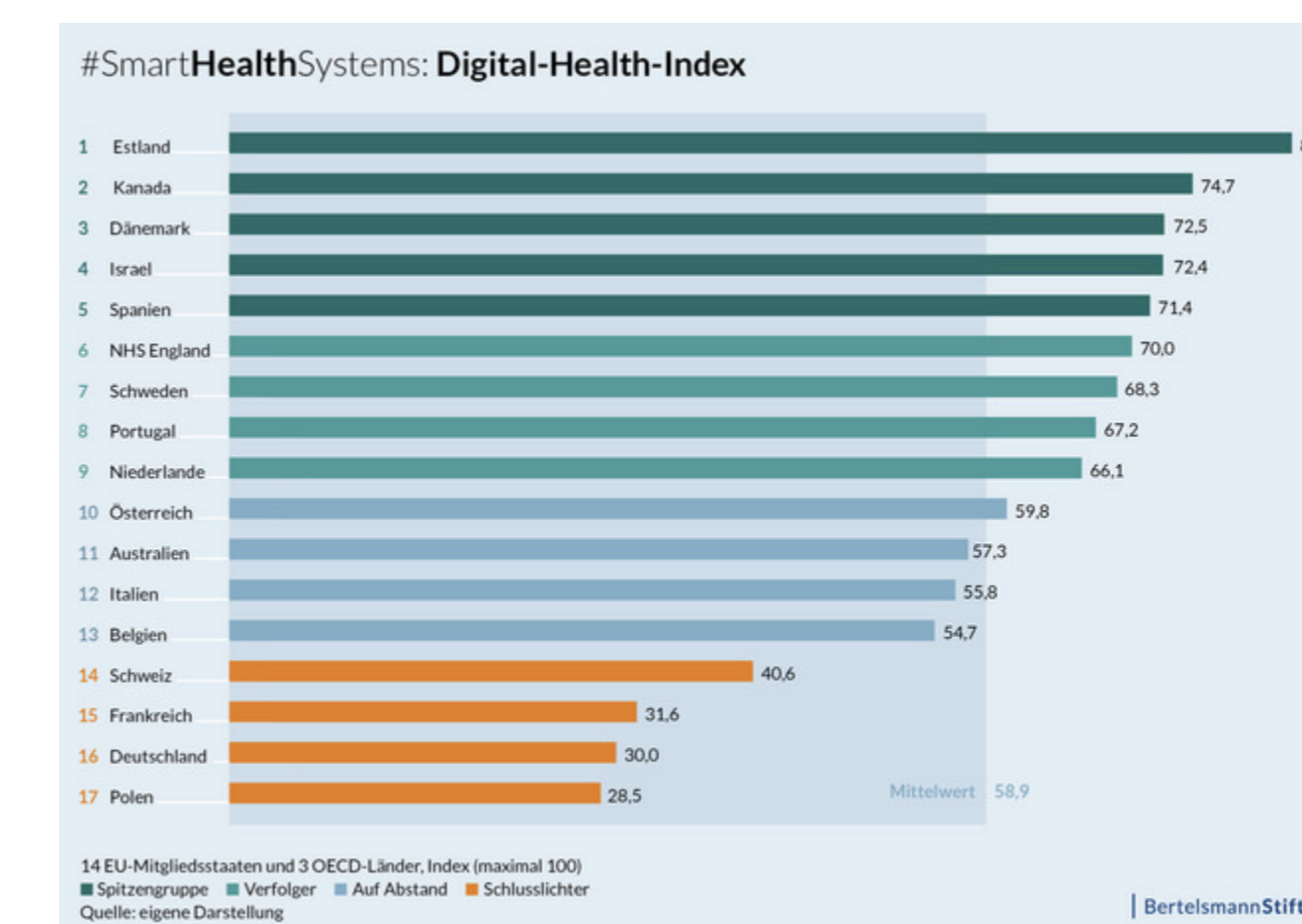
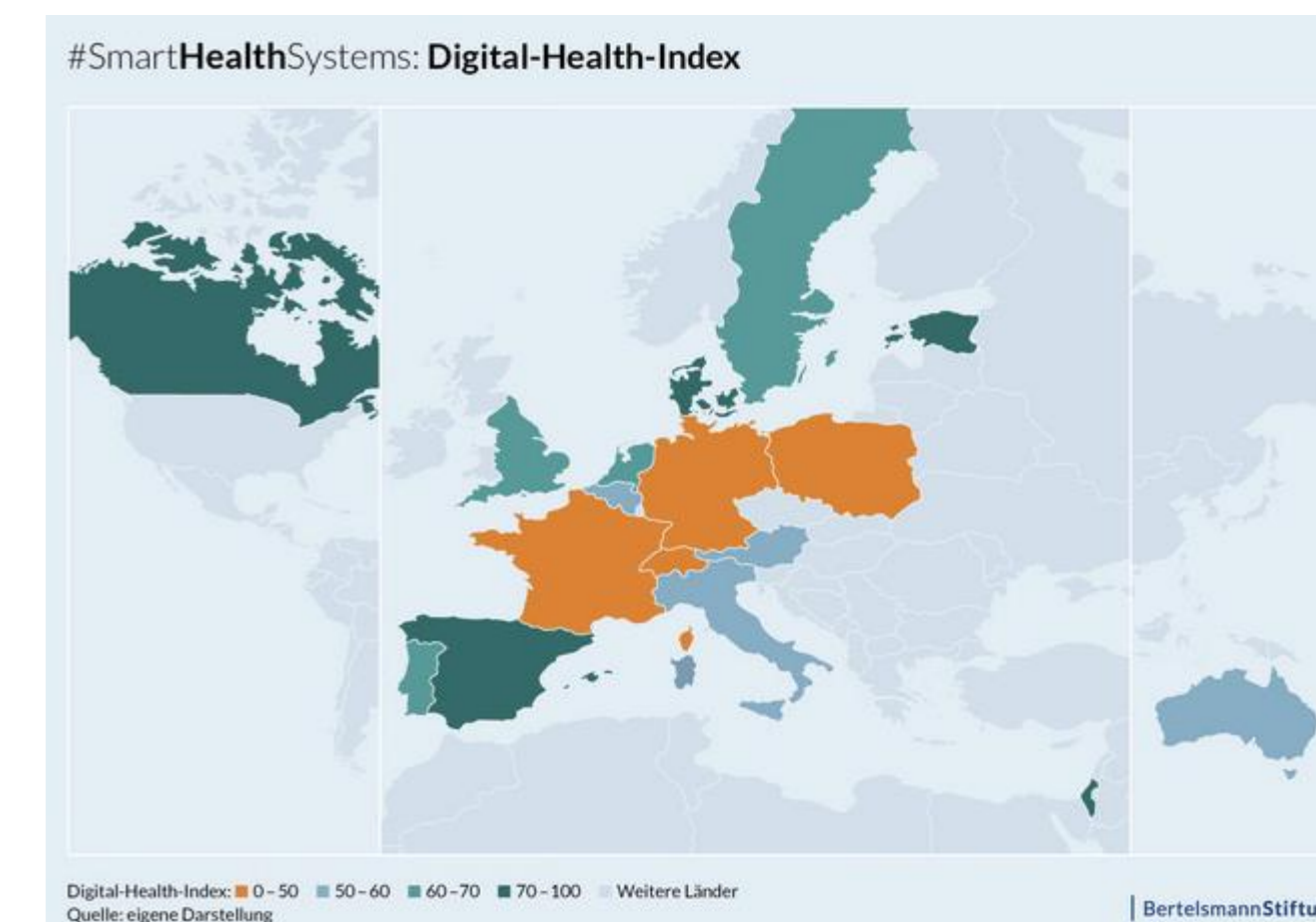


- 2010 • Study commission „internet and digital society“ of the German parliament
- 2014 • „Digital Agenda 2014 to 2017“ providing many digital basic principles
- 2019 • Introduction of the Digital Supply Act (DVG)
• Introduction of the Digital Health Application Ordinance (DiGAV)
- 2020 • May: Opening of the DiGA Fast Track process at BfArM
• October: First DiGA included to DiGA catalogue
- 2021 • 20 DiGAs included into the catalogue
- 2022 • 31 DiGAs included in the DiGA catalogue

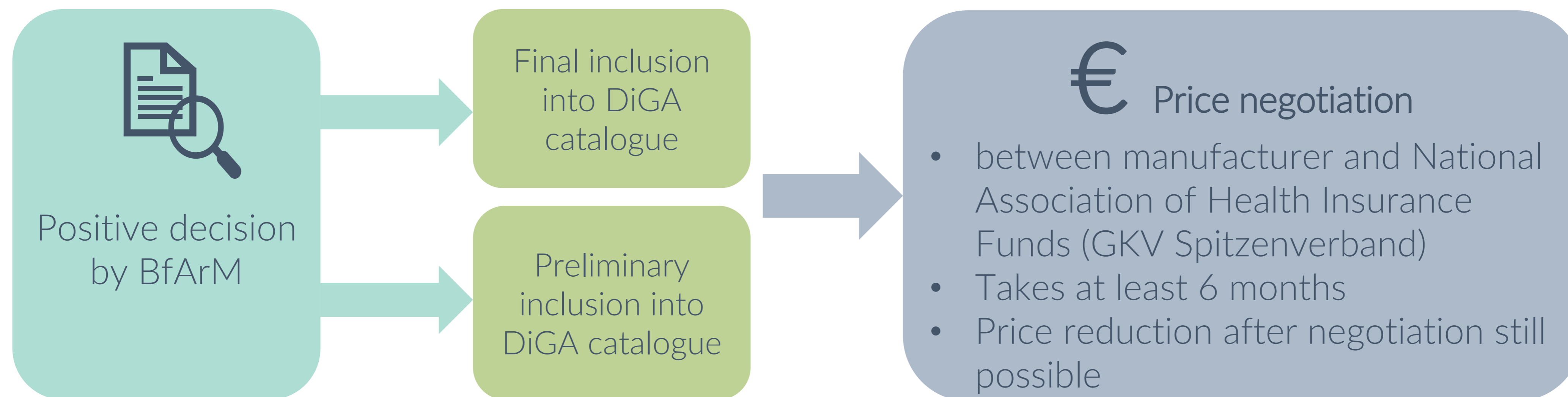


Physicians do not see potential

- Germany ranks position #16 out of 17 countries surveyed in terms of healthcare digitalization
- Physicians blame the Telematik-Infrastruktur and a missing digitalization strategy
- Lack of maturity of components
- Outdated infrastructure in physician practices
- Reading health insurance cards leads to system crashes
- Sick leaver certificates do not reach the correct recipients
- Rolling out E-prescriptions has been stopped politically
- The digital patient record is supposed to be center of the healthcare digitalization – but every payer has an own patient record, patients need to actively request it
- As a consequence the main communication tool between physicians, hospitals and payer is a fax



The DiGA application process – worthwhile?



Being listed as a DiGA gives access to:

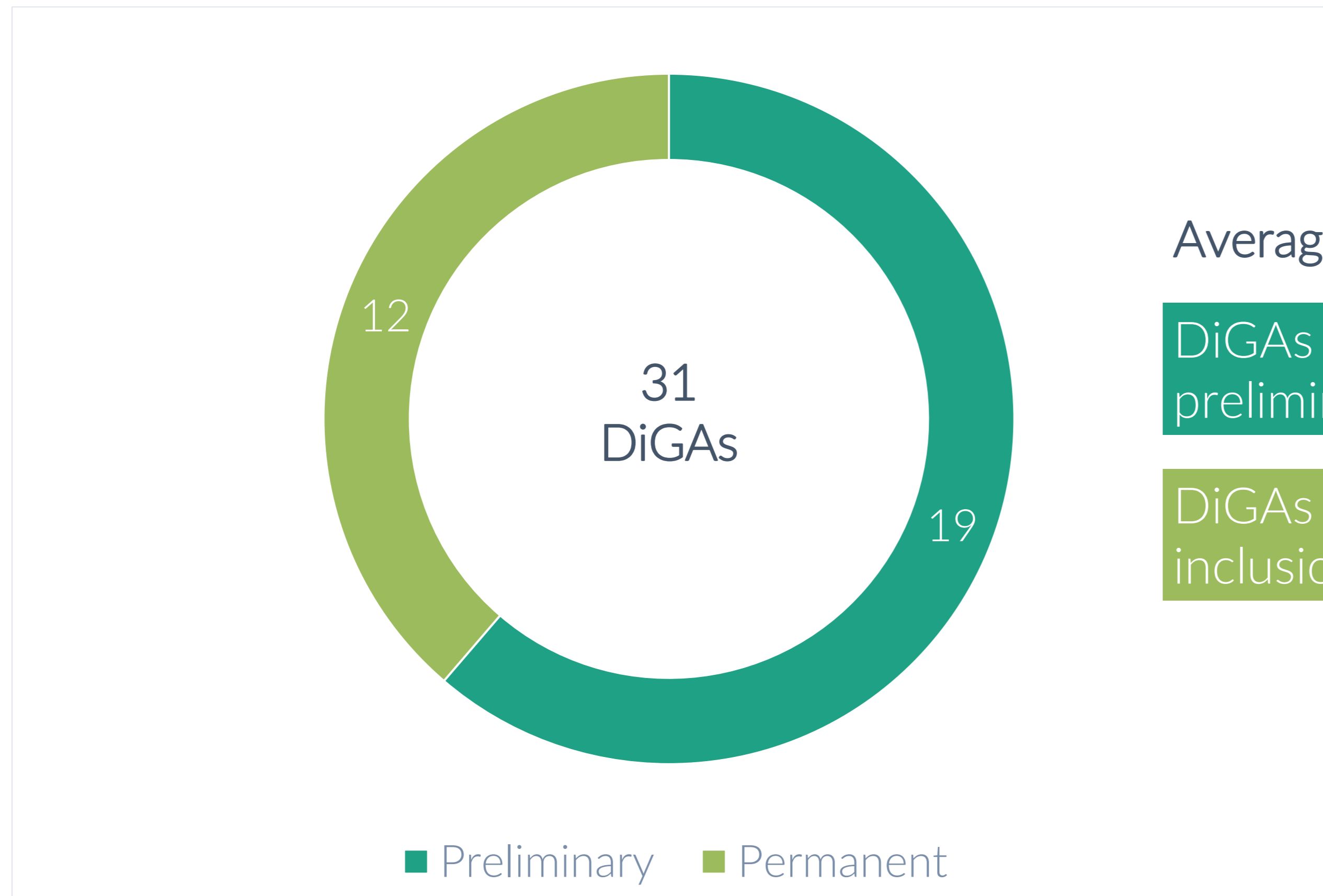
- ✓ All (97 at the moment) statutory health insurances
- ✓ 73 million insurants (88% of the German population)
- ✓ 170,000 contracted physicians, dentists, psychotherapists

Payers don't like DiGAs



- Positive decision, included to DiGA catalogue
- Negative decision
- Withdrawal by manufacturer
- In assessment
- Deleted by BfArM (after inclusion)

DiGA catalogue – status quo



Average price for

DiGAs with preliminary inclusion	466€
DiGAs with permanent inclusion	397 €

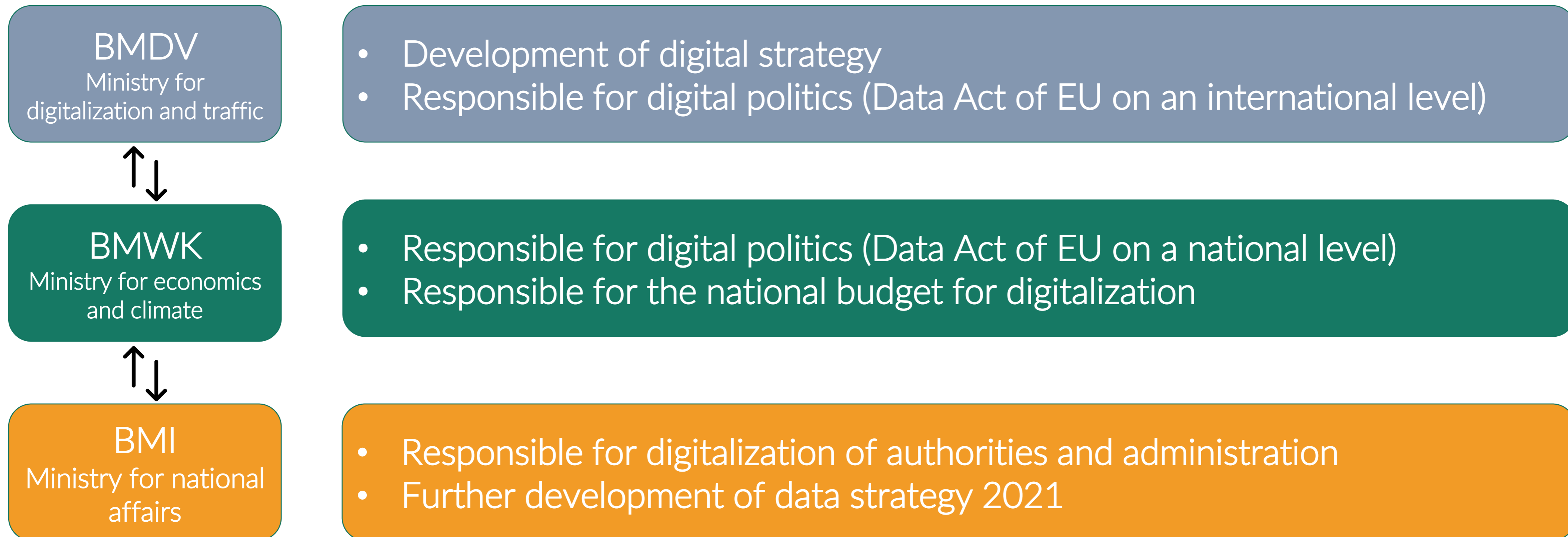


40,000 prescriptions since October 2020*

Source: <https://diga.bfarm.de/de/verzeichnis>; Status quo June 2022

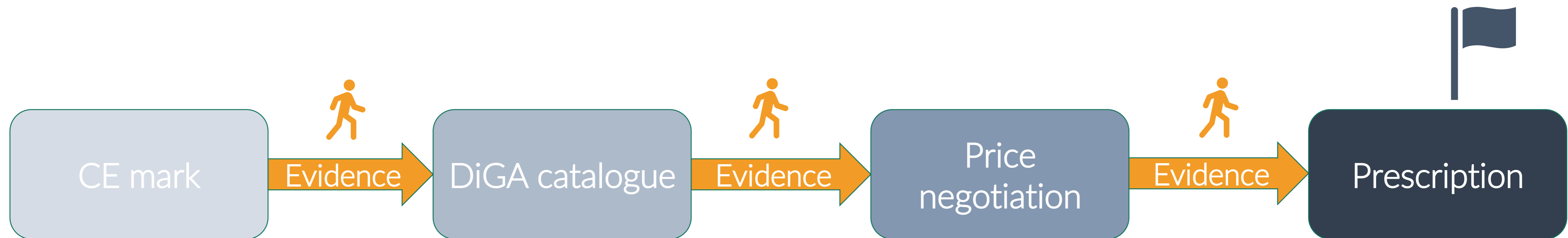
* Until January 2022; <https://www.aerztezeitung.de/Wirtschaft/40000-Mal-wurden-Apps-auf-Rezept-bislang-verordnet-425814.html>

Responsibilities of „digital ministry“ clarified



Cooperation and coordination between the different ministries is necessary for a successful German digitalization

Evidence as key for consistent pathway into physician practices

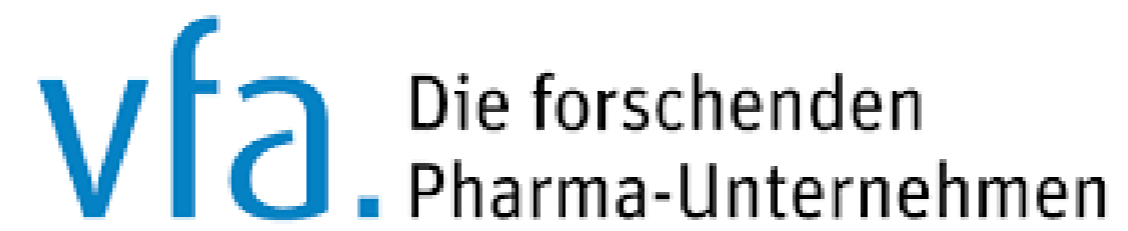


Our recommendation for a successful DiGA application

- 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 and other organizations of the following slide)



Relevant associations in the process of DiGA pricing





Thank you!



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