



health  
innovation  
hub

**Digital Health Innovation for the German Healthcare system**

# DVG Fast Track



## hih at a glance

12 experienced experts  
in the fields of:

In- & Outpatient Medicine |  
Big Data | A.I. | Digital Health |  
Interoperability | HTA | MedLaw

**Our goal:**

Realising benefits of digital  
health care for patients

Financed by Federal Ministry of Health  
Mission ends 31.12.2021.





## The hih-Team: Sparring Partner & Think Tank



**Nataliya Bogdanova-Dochev**  
Events



**Julia Hagen**  
Regulatory & political  
affairs



**Dr. Henrik Matthies**  
Managing Director, DiGA



**Jan B. Brönneke**  
HTA, Medical Devices,  
MedLaw



**Dr. med. Kai  
Heitmann**  
Interoperability



**Ecky Oesterhoff**  
Hospital



**Prof. Dr. med. Jörg Debatin**  
Chairman



**Dr. Philipp Kircher**  
Privacy, IT-security,  
MedLaw



**Lars Roemheld**  
AI & Data



**Claudia Dirks**  
Communications



**Ralf König**  
Pharmacy



**Dr. med. Philipp Stachwitz**  
Outpatient care

## Our topics

Data-“donation“

DiGA-Fast-Track

Digitalization Hospitals

Digitalization Long Term Care

Electronic Health Record

AI Regulation

National Healthcare Portal

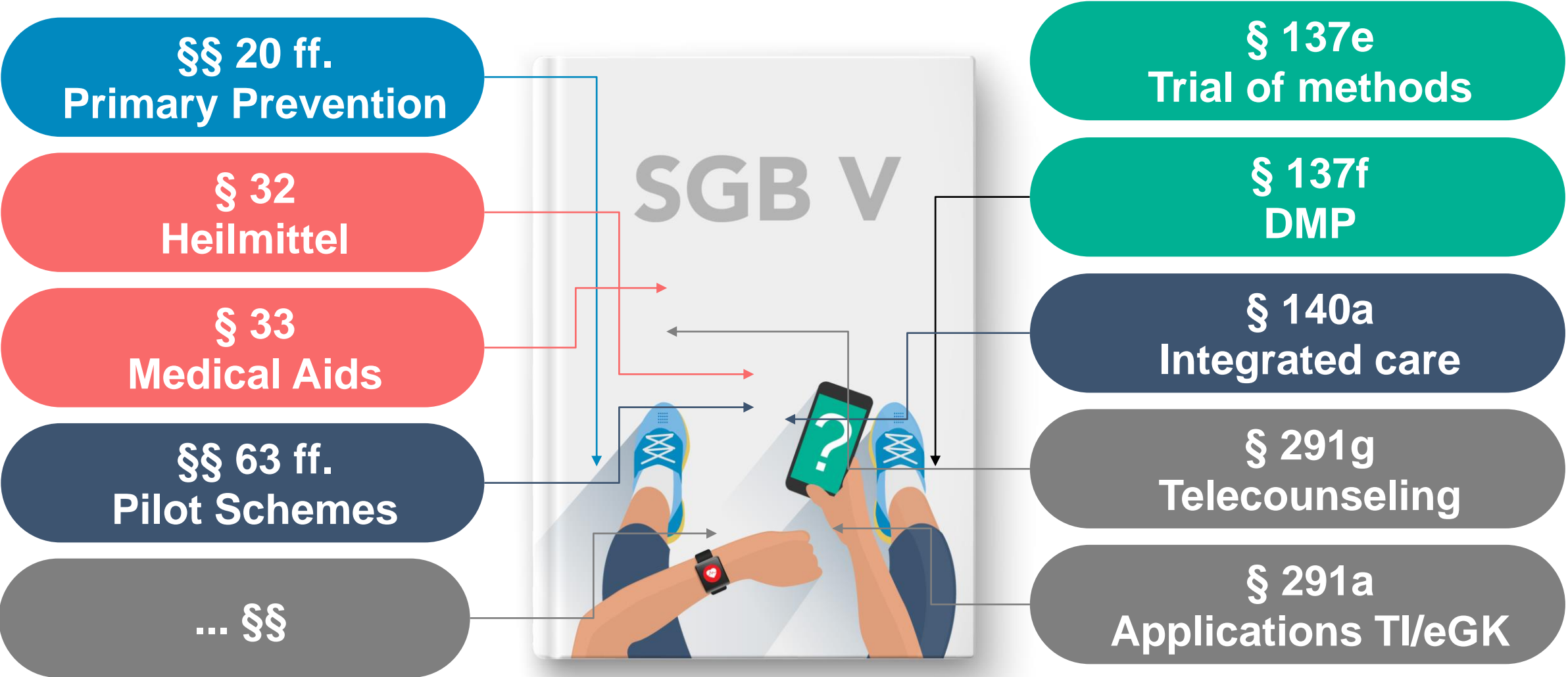
Value-Based-Medicine

## Digital Health Applications (DiGA)

# DVG FastTrack



# Until 2020: No specific pathway into GKV for digital solutions



# Definition: DiGA (digital health application)

## Medical Device

Classes I and IIa MDR  
(+ provisional rules MDR)

## Intended use

Centered on patients,  
possibly including treating  
doctors

**SGB V**

**DiGA acc.  
§ 33a SGB V**

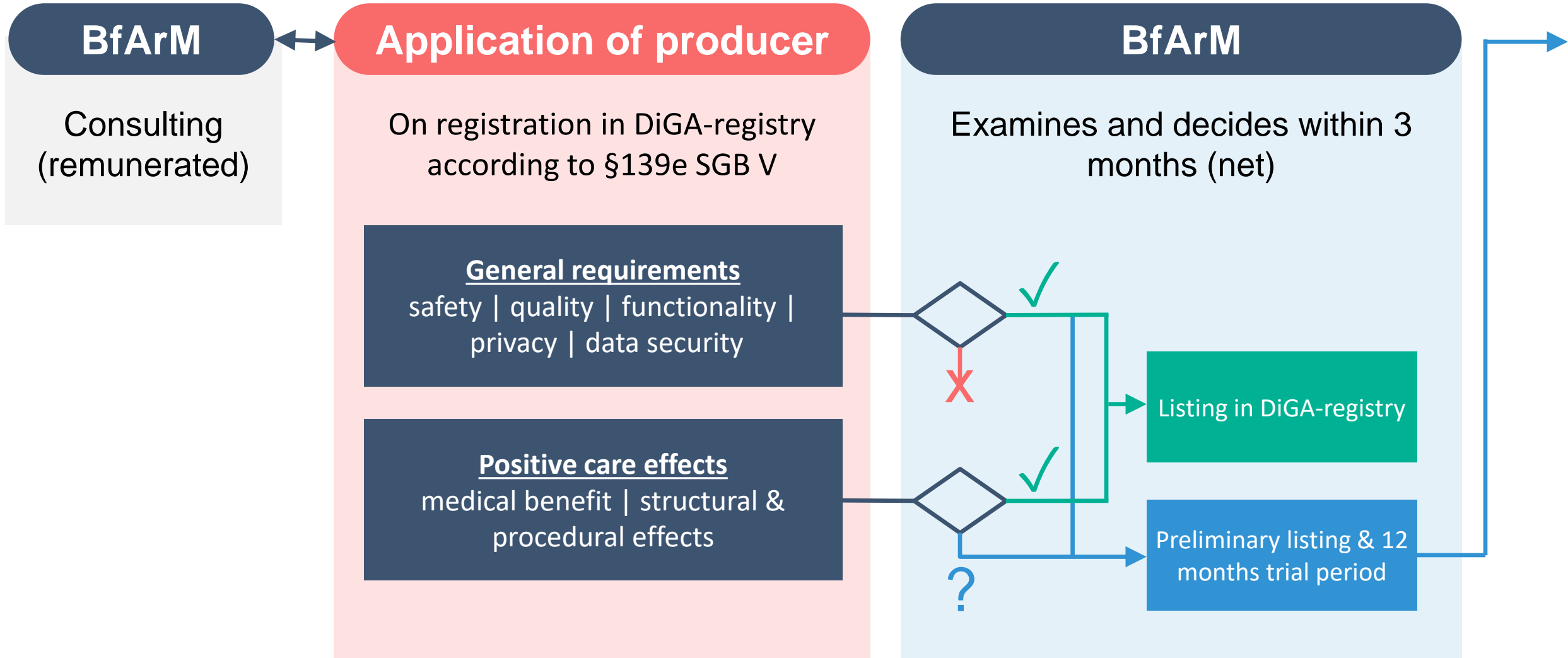
## Main function

Relies on digital technologies

## Functionalities

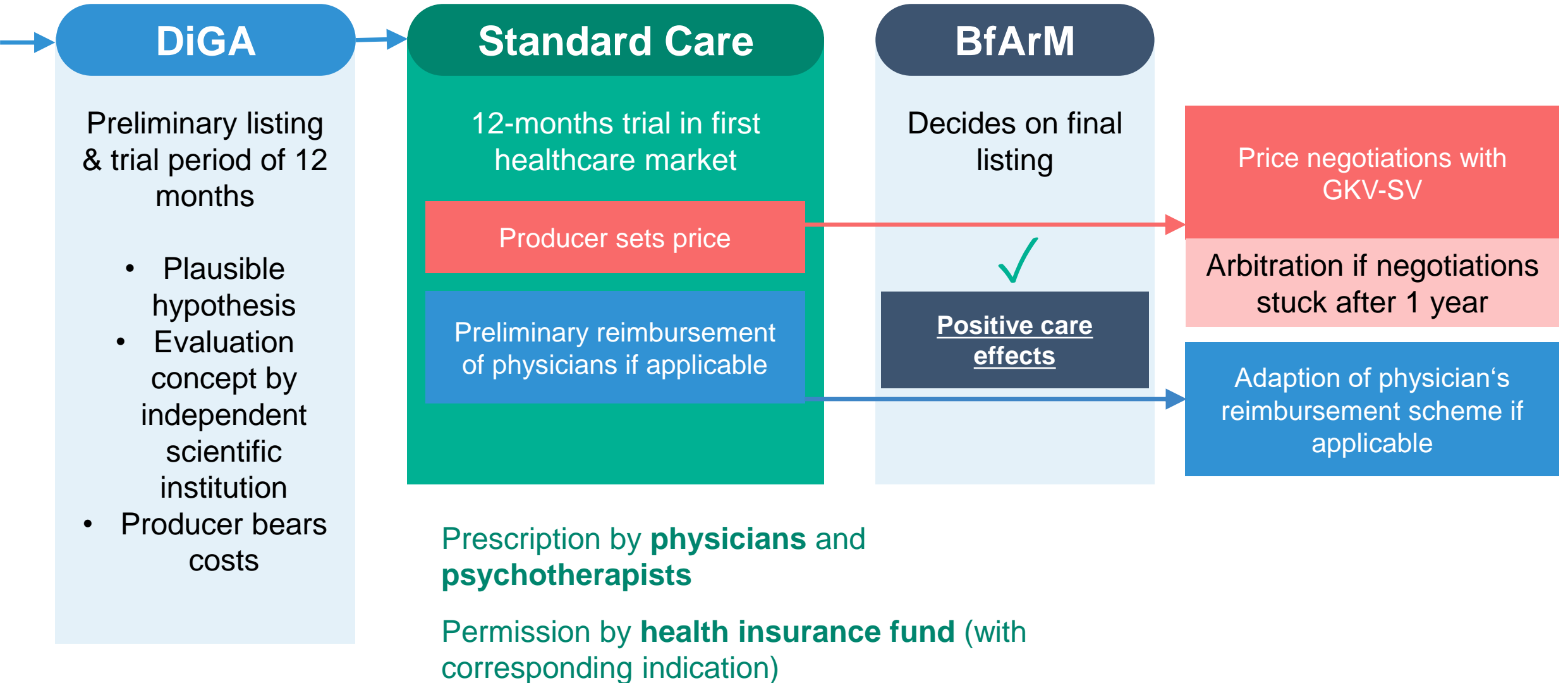
Detection (monitoring),  
treatment, palliation /  
abatement of pain,  
compensation of diseases,  
injuries, disabilities

# The Fast Track according to DVG (1/2)

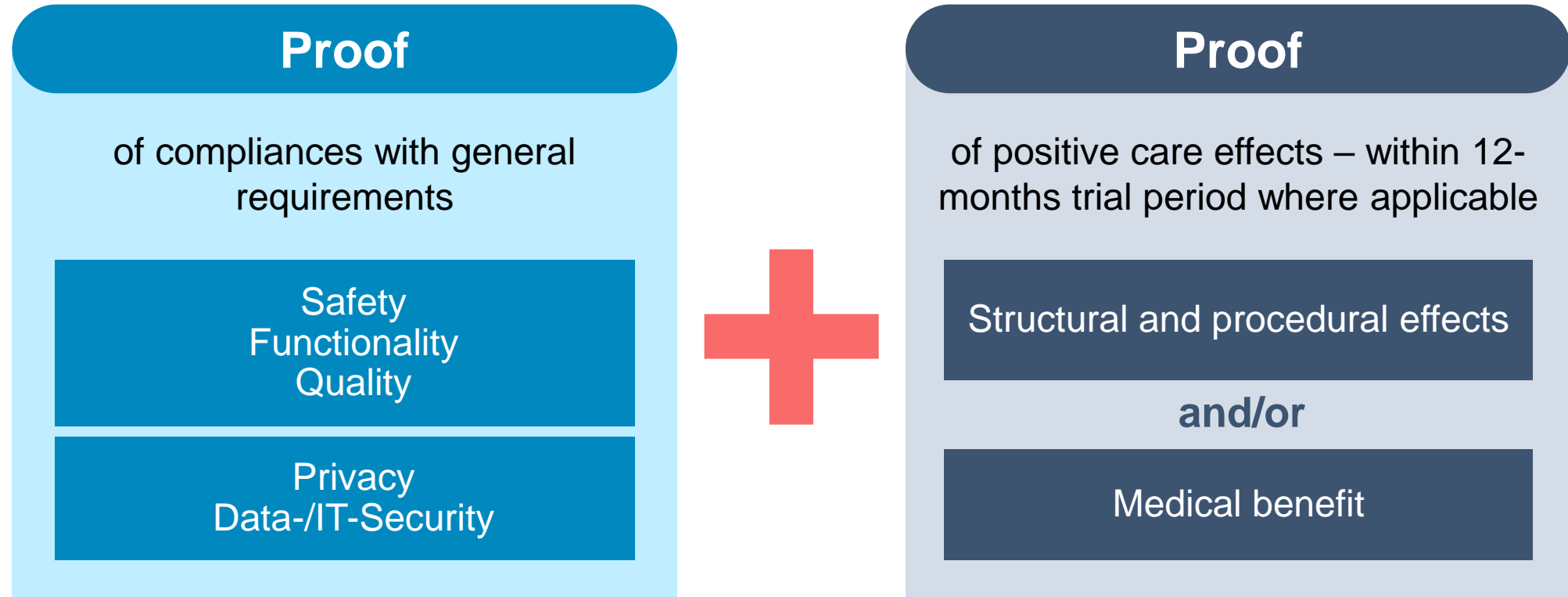




# The Fast Track according to DVG (2/2)



# Further specification of requirements



→ Further specification by DIGAV by BMG and guideline by BfArM

# General requirements

## Proof of

CE-Marking

Consumer protection

Privacy & Data-Security

Patient safety

Robustness

Interoperability

User friendliness  
(Patients & Physicians)

Quality of  
medical content

# Positive care effects (1/3)

## SGB V and DiGAV

### § 139e para. 9 SGB V

*Proof of positive care effects is based on the principles of evidence based medicine.*

### § 10 para. 1 & 2 DiGAV

*Retrospective controlled trials, showing that the use of DiGA is superior to care without DiGA.  
Prospective controlled trials possible.*

### § 11 para. 1 DiGAV

*Prospective controlled trials mandatory when lack of significant data or comparability.*

### § 12 DiGAV

#### **Trials for diagnostic devices**

*Trials, showing sensitivity and specificity of DiGA.*

# Positive care effects (2/3)

## Structural and procedural effects

## Medical benefit

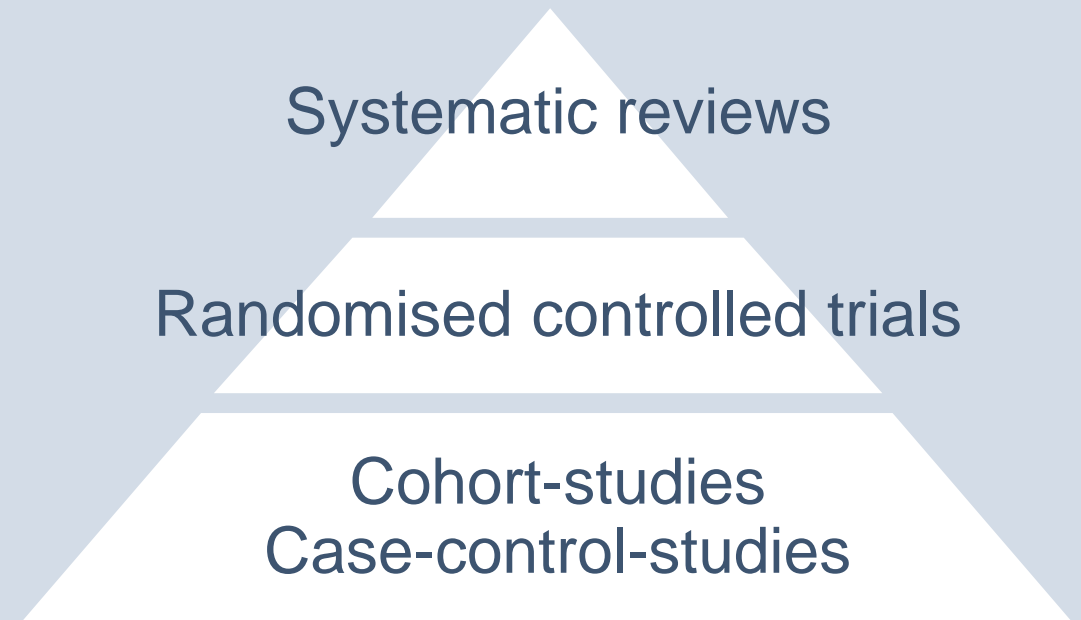


# Positive care effects (3/3)

## Structural and procedural effects



## Medical benefit



# Possible Data Sources

## RWD:

- Claims-Data
- Treatment Data (eHR)
- Register Data
- Patient Generated Data



**That's  
new!**

- Prospective Trial-Data



## **BfArM Guideline** (English version in progress)

**Details requirements**

**Details DiGA-definition**

**Software-Hardware-combo**

**Software-Service-combo**

**Further obligations**

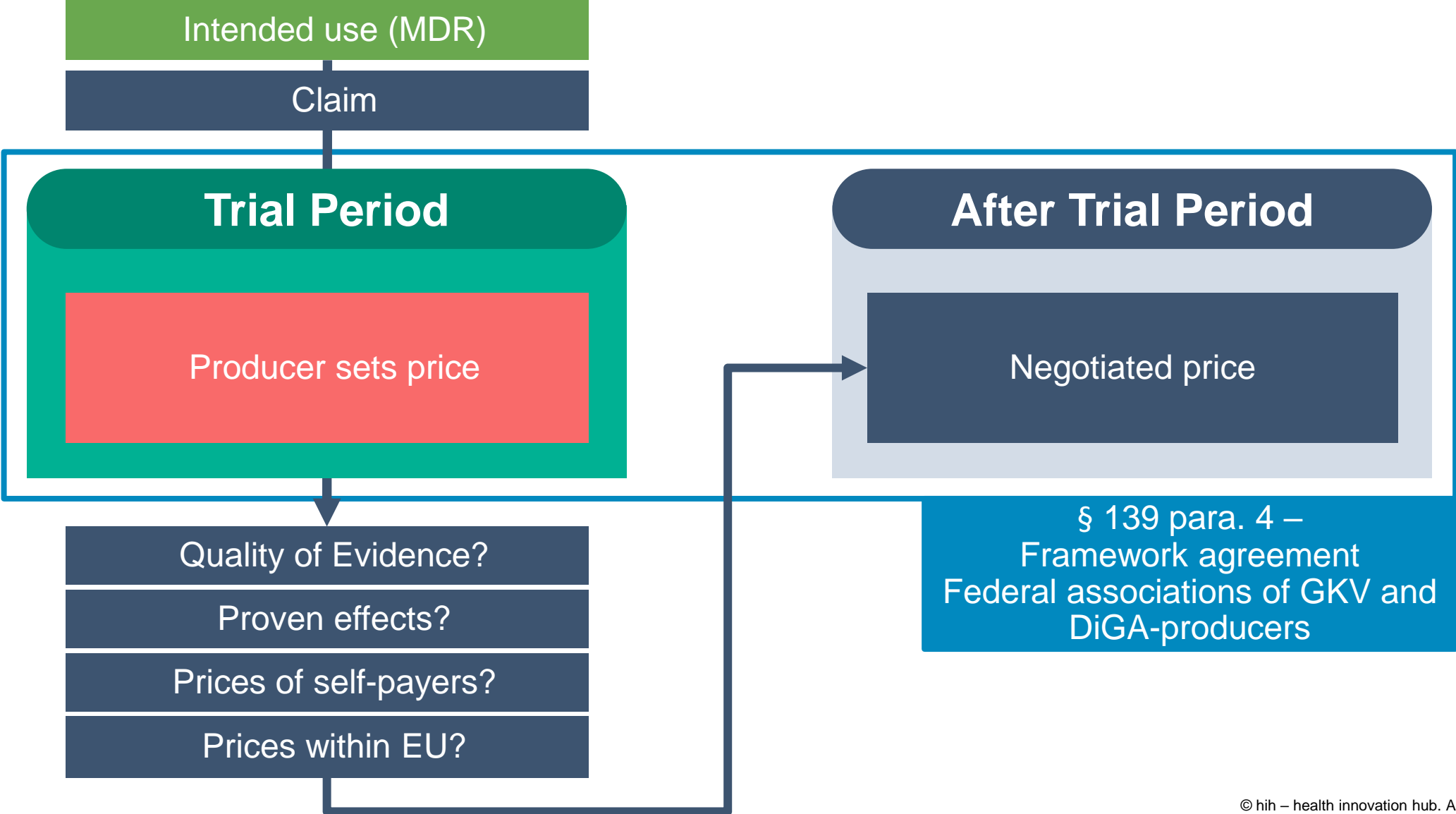
**Procedural questions**

**Content of registry**

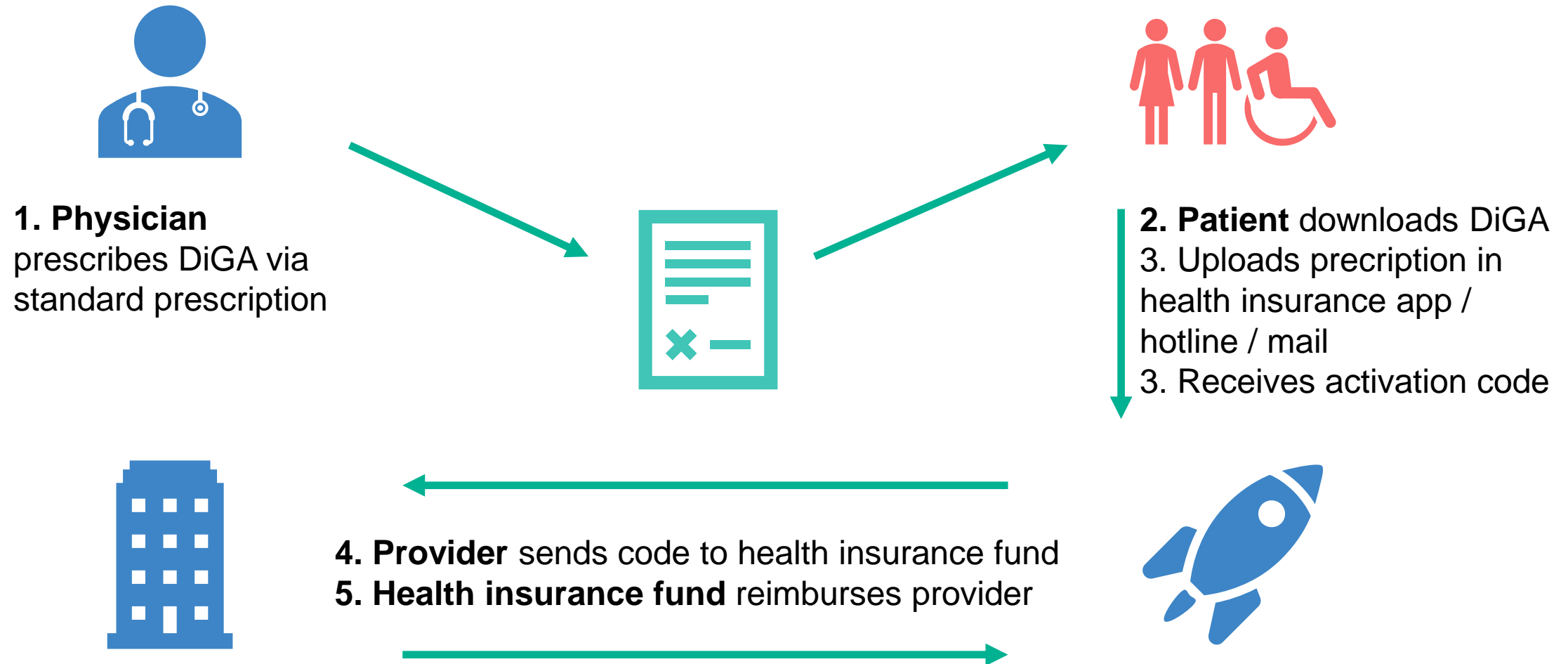
**Details consulting**



# Pricing



# Potential prescription and reimbursement procedure





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**What's next?**

**mid July, tba**

# **International DiGA Summit**





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November

International  
**DiGA**  
Researchathon



Full day, English-speaking event in Berlin  
More information soon at: [hih-2025.de/veranstaltungen](https://hih-2025.de/veranstaltungen)

See you soon.

[www.hih-2025.de](http://www.hih-2025.de)



hih2025



health innovation hub (hih)

Further information on DiGA-procedure including guideline and application-form on

[https://www.bfarm.de/DE/Medizinprodukte/DVG/\\_node.html](https://www.bfarm.de/DE/Medizinprodukte/DVG/_node.html) (German)