

The Digital Health Care Act



#DiGA

#hih



health
innovation
hub



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 Healthcare
Mission ends 31.12.2021.





The hih-Team: Sparring Partner & Think Tank



Nataliya Bogdanova-Dochev
Events



Julia Hagen
Regulatory & political affairs



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Managing Director, DiGA



Jan B. Brönneke
HTA, Medical Devices, MedLaw



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Interoperability



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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

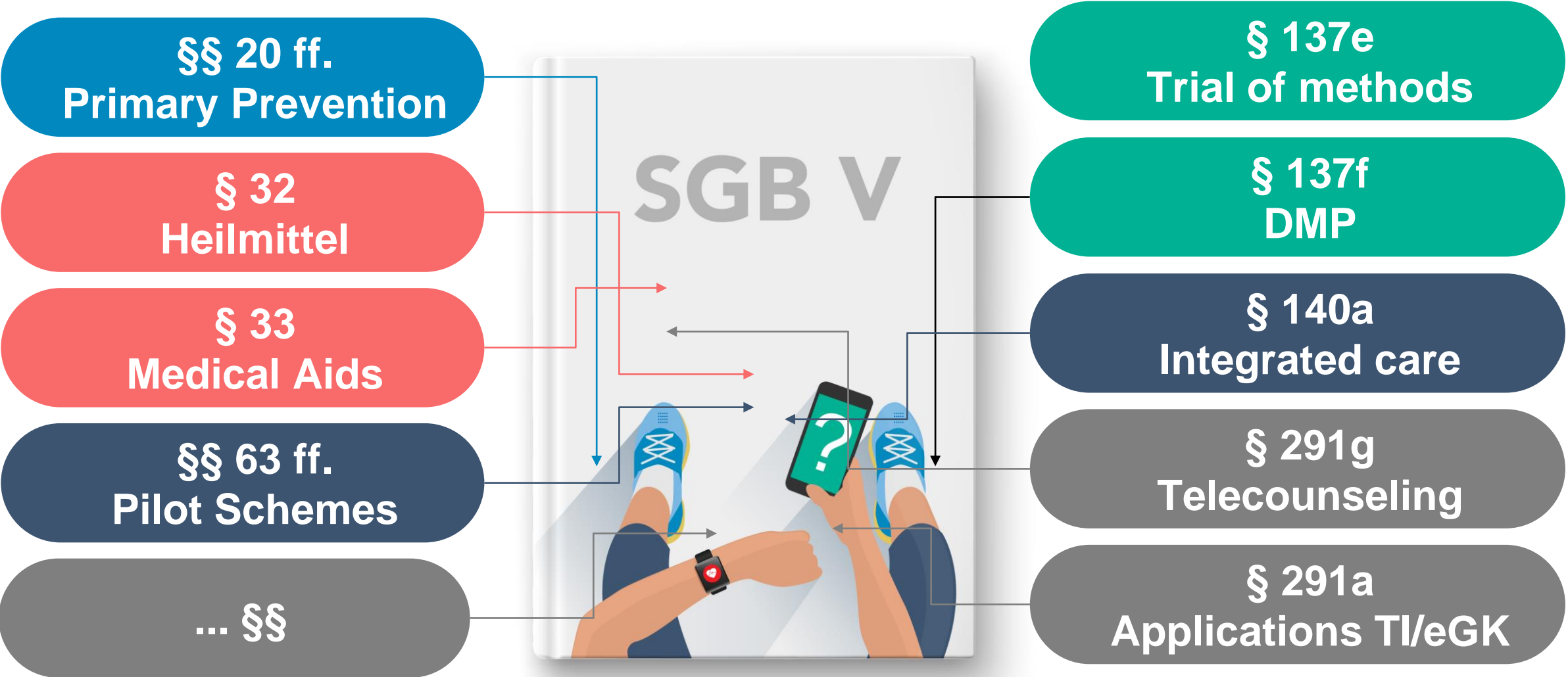
Electronic Health Record

AI Regulation

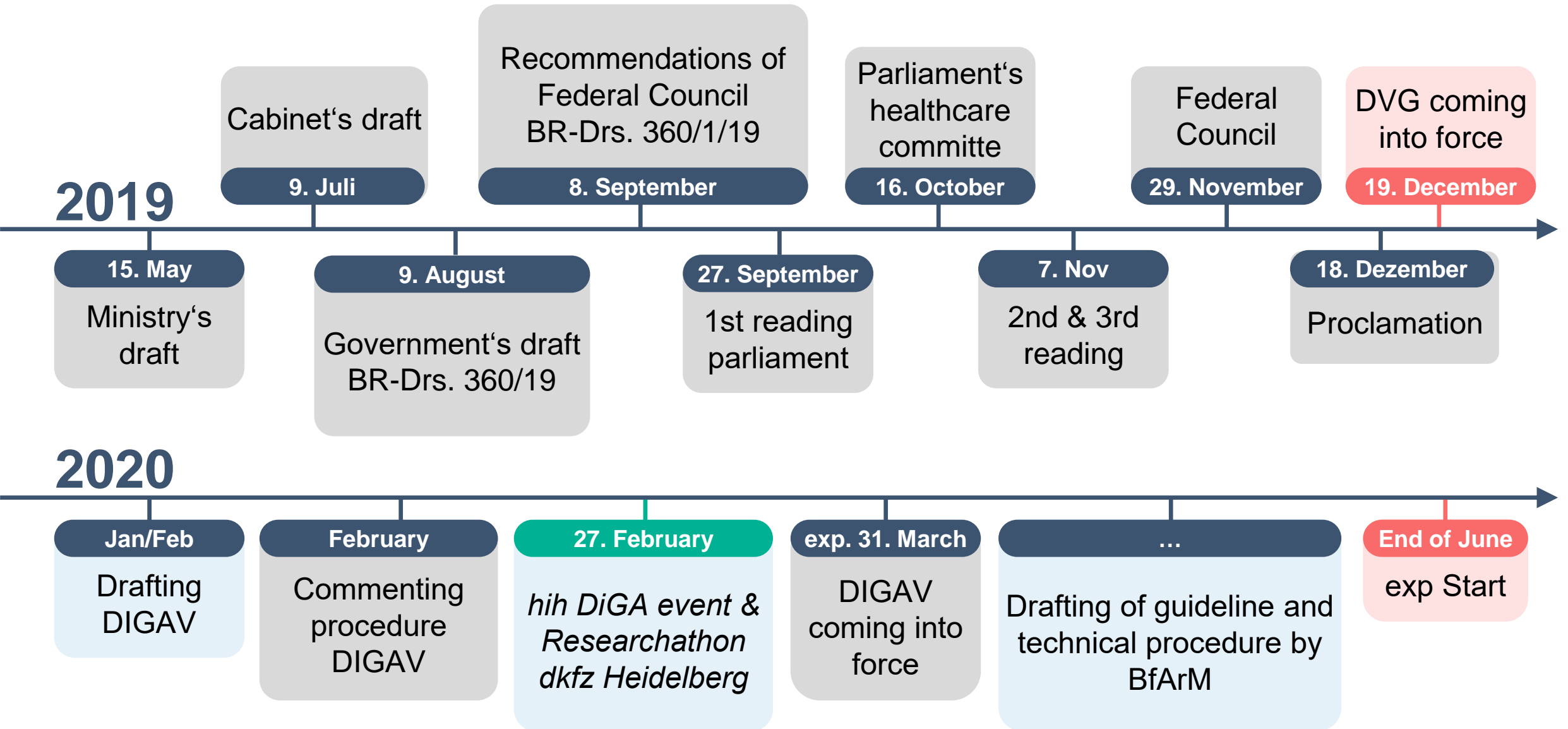
National Healthcare Portal

Value-Based-Medicine

Until 2020: No specific pathway into GKV for digital solutions



Timeline



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**

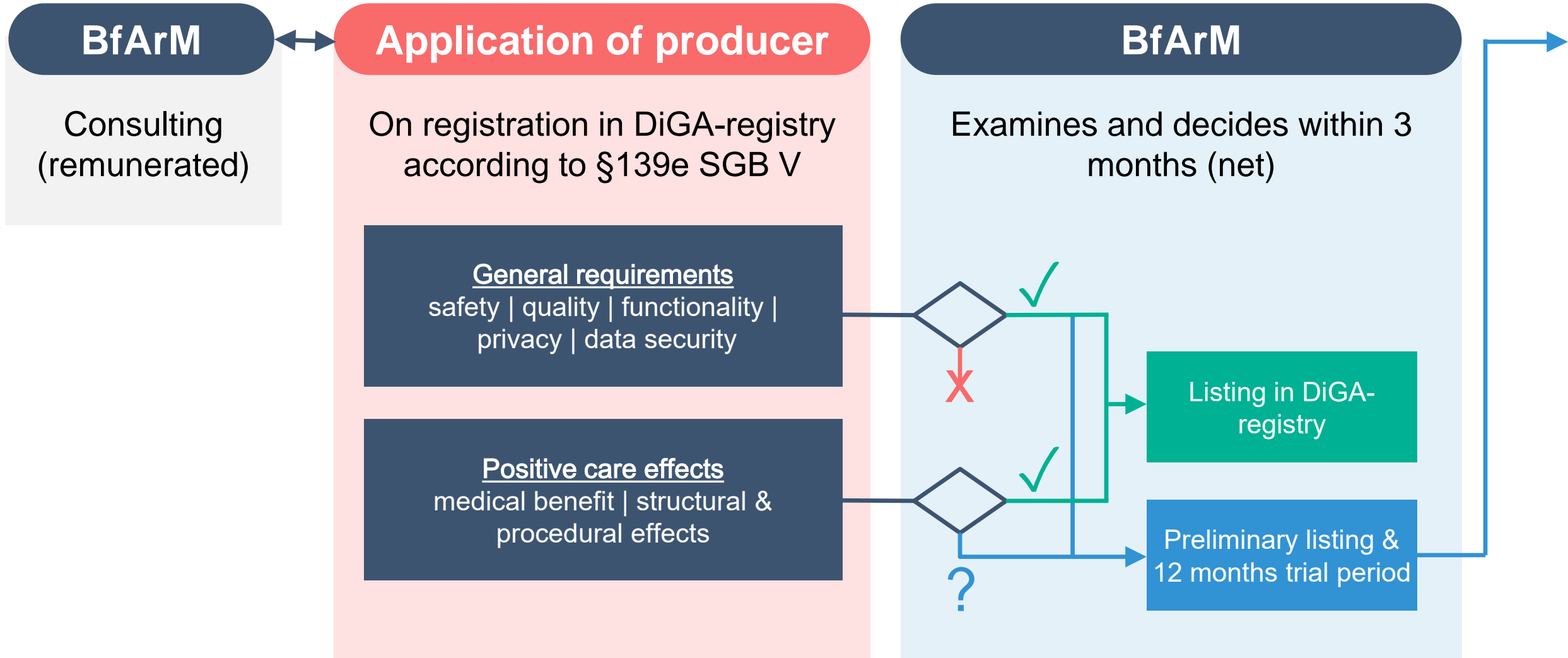
Main function

relies on digital technologies

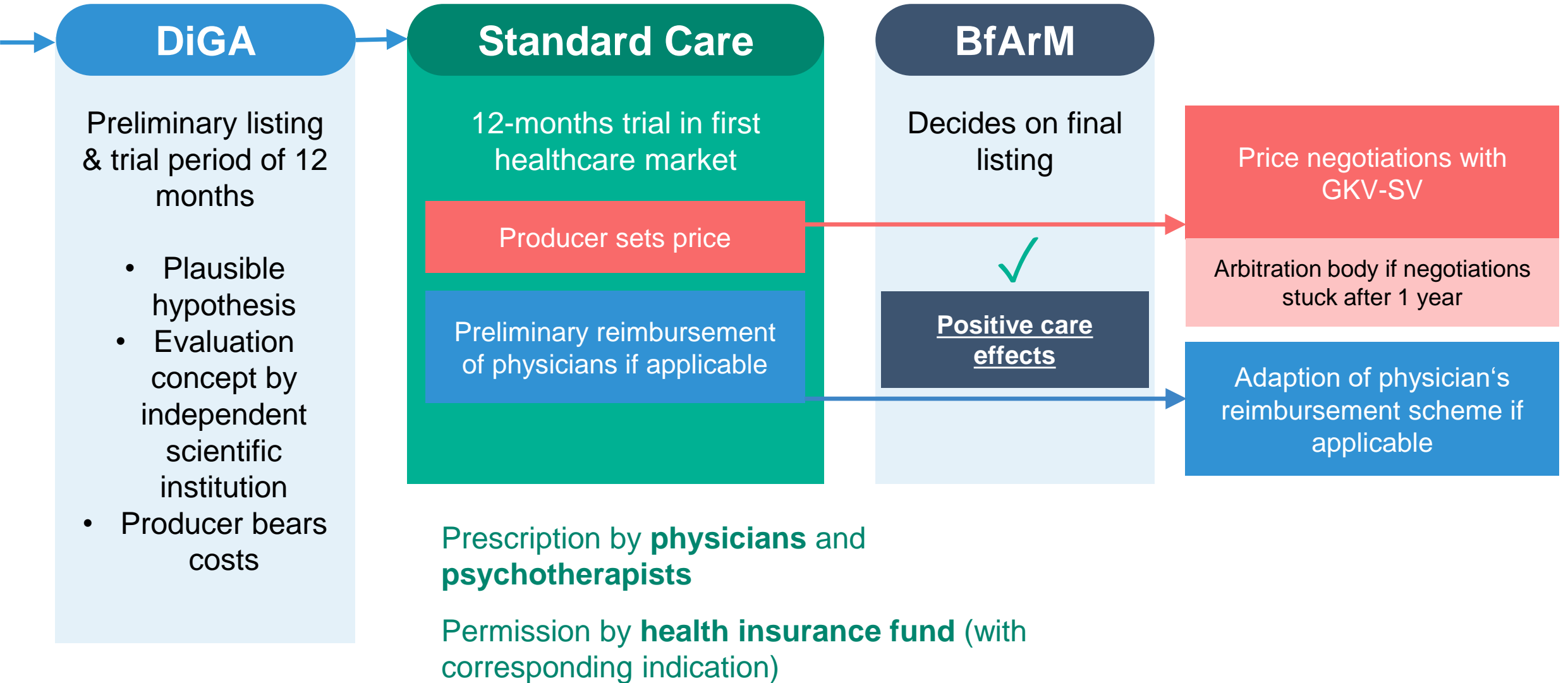
Functionalities

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

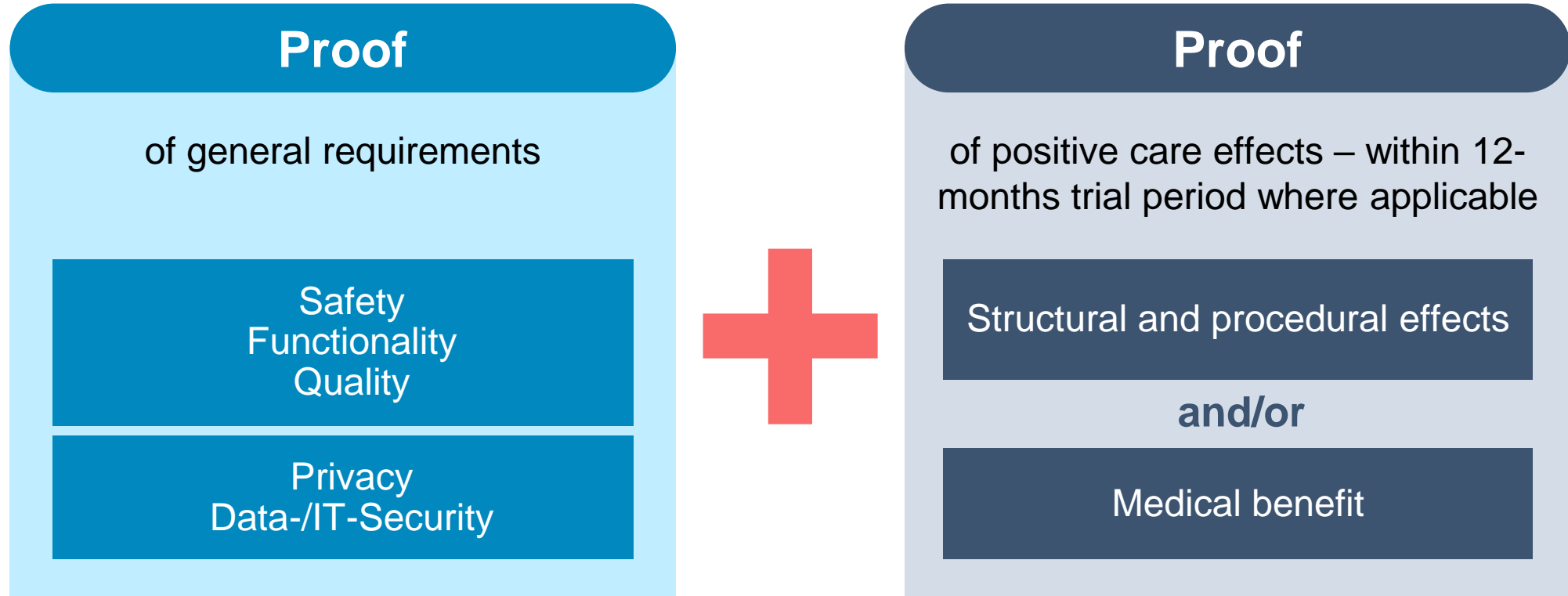
The Fast Track according to DVG (1/2)



The Fast Track according to DVG (2/2)



Further specification



→ 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 Abs. 9 SGB V

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

§ 16 Abs. 1 DiGAV

**Allowed trials to
prove positive care effects**

*Controlled trials, showing that the use of
DiGA is superior to care without DiGA.*

§ 17 DiGAV

Allowed trials for diagnostic devices

*Trials, proving that sensitivity and specificity
of DiGA is non-inferior to established
diagnostic tools.*

Positive care effects (2/3)

Structural and procedural effects

Medical benefit

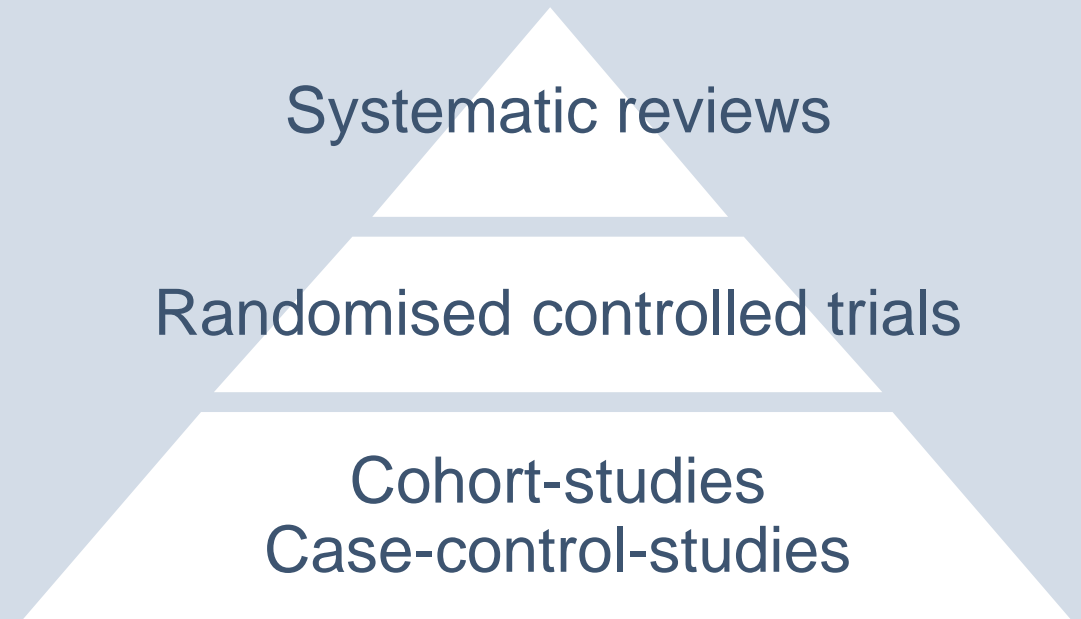


Positive care effects (3/3)

Structural and procedural effects



Medical benefit



Possible Data Sources

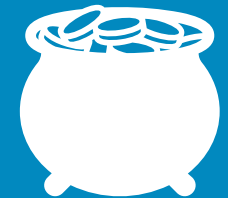
RWD:

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



**That's
new!**

- Trial-Data



Examples: Evidence for structural and procedural effects

Clinical trials

**Pilot-DiGA
Structures Treatment-Pathways for
Patients and Doctors**

(prospective) Cohort Study

(retrospective) Case-Control-Study

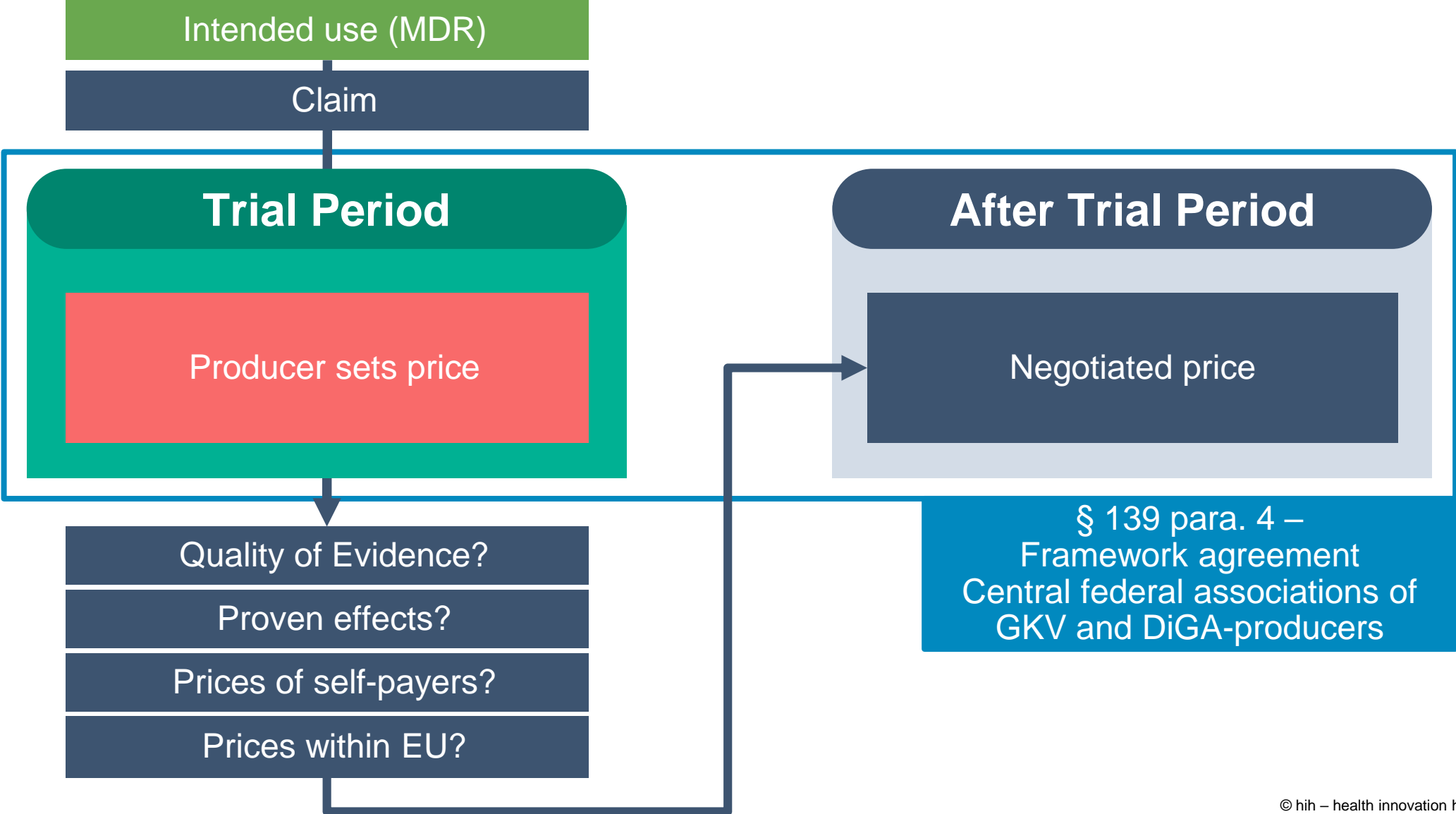
Or...

**Medication-DiGA with Voice-Control
Allows verbal diary with medication-
alarm**

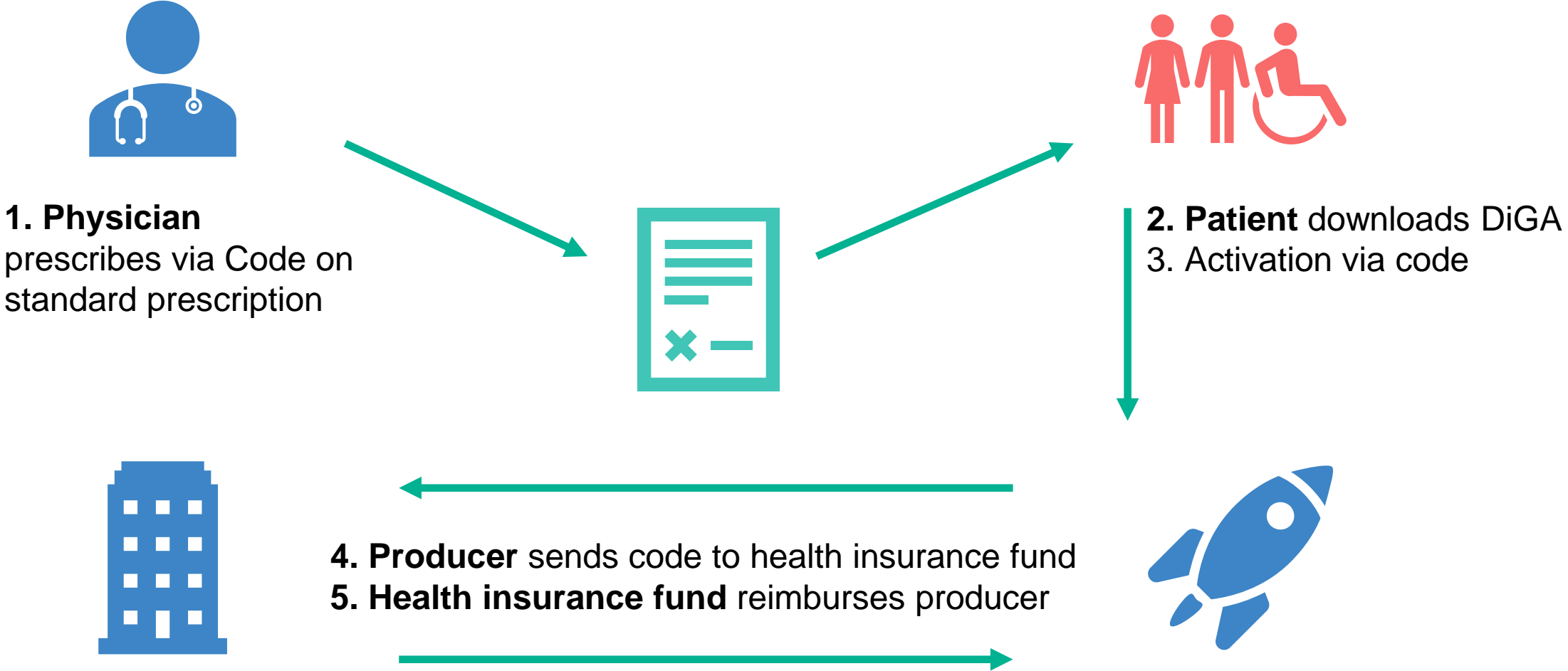
Comparative Social
Psychological Study

A/B Testing

Pricing



Potential prescription and reimbursement procedure



What's next?





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November

International
DiGA
Researchathon



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

Thank you!

www.hih-2025.de/magazin



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