

Digital Health in Germany – the DiGA Fast Track



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:

Think Tank, Idea Scout, Catalyst



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Our topics

Health data ecosystem

DiGA-Fast-Track

Digitization Hospitals

Digitization Long Term Care

Electronic Health Record

Health AI Regulation

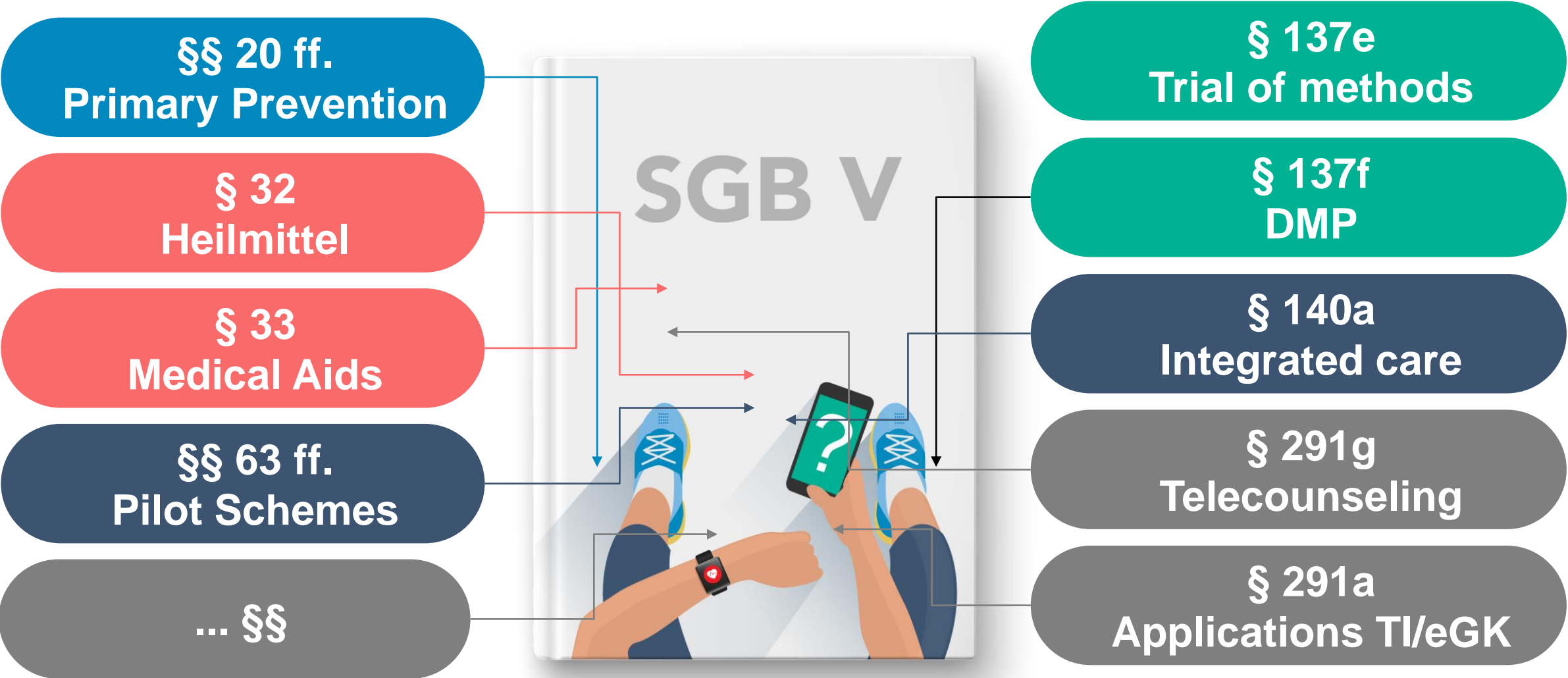
National Healthcare Portal

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

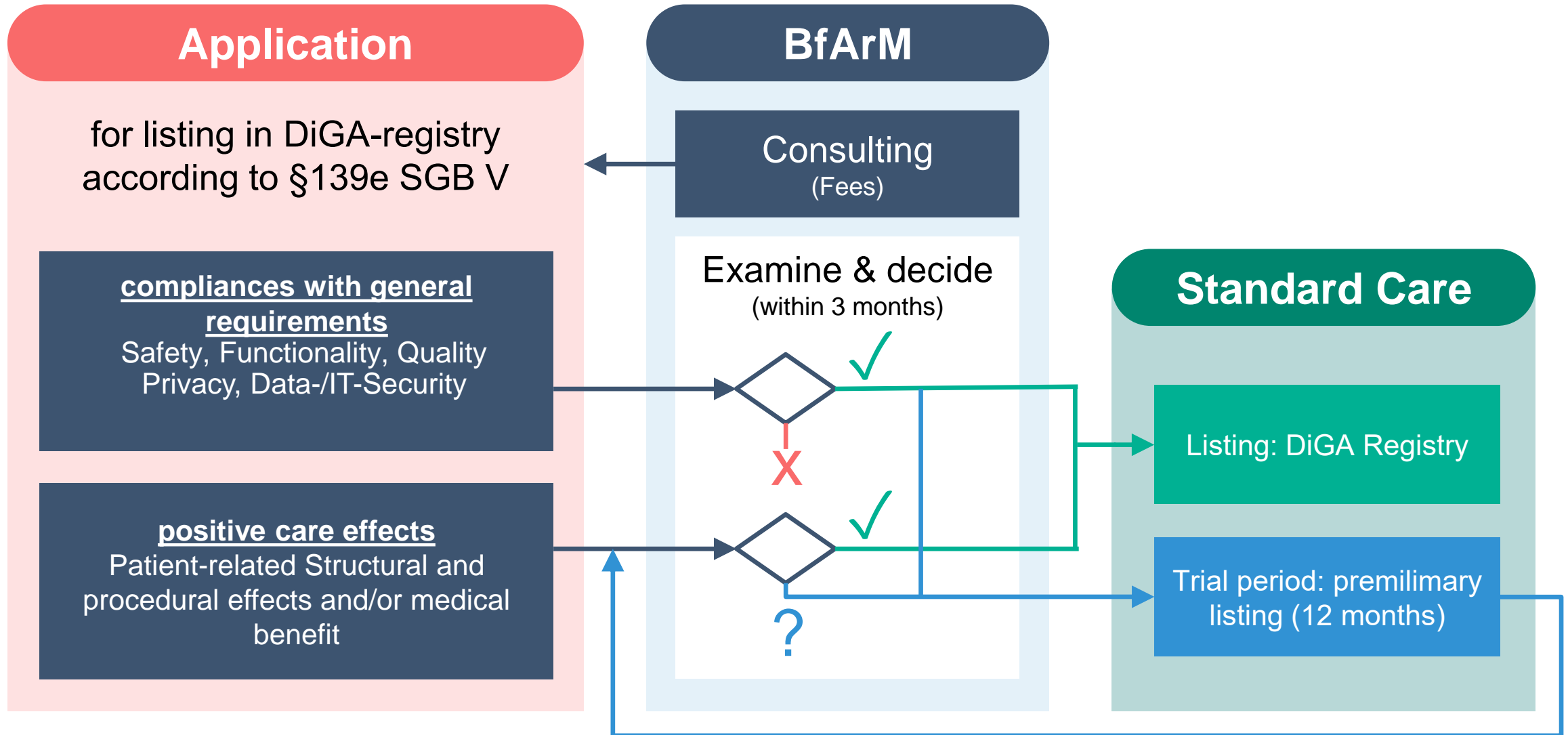
Main function

Relies on digital technologies

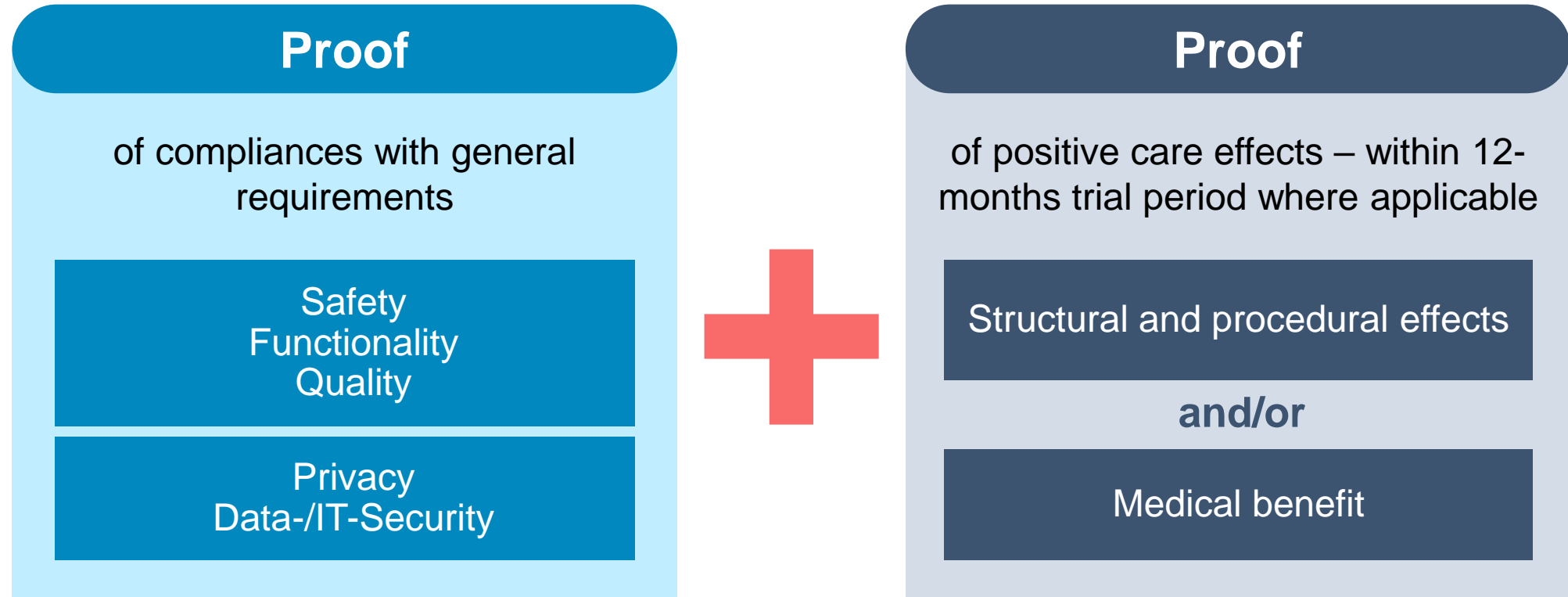
Functionalities

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

DiGA Fast Track Process



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 – what's inside?

Structural and procedural effects

Medical benefit

Reduction of therapy related efforts/strains

Securing standard of care

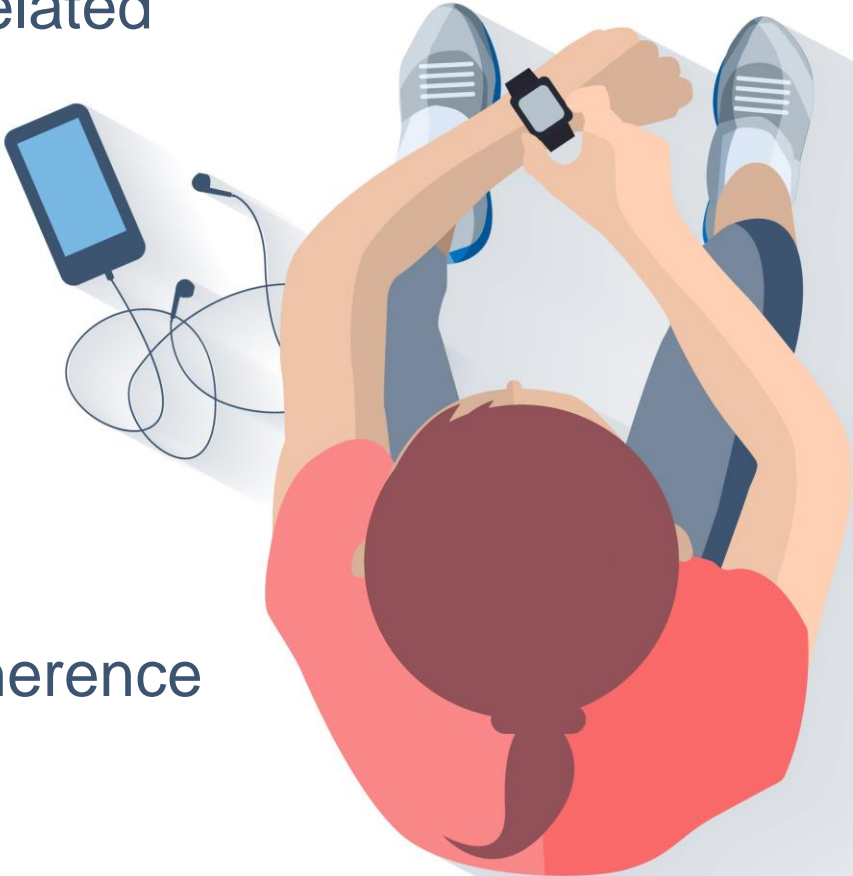
Coordination of care

Access to care

Health literacy

Adherence

Patient safety...



Morbidity

Quality of Life

Mortality

Positive care effects – specific assessment requirements

§ 139e para. 9 SGB V

Further regulation shall be based on principles of evidence based medicine

<p>§ 10 para 1 & 2 DiGAV</p>	<ul style="list-style-type: none"> • <i>Retrospective study</i> • <i>(Prospective allowed)</i> • <i>Comparative (incl. intraindividual)</i> 	<p>§ 10 para 1 & 5</p>
<p>§ 11 para 1 DiGAV</p>	<ul style="list-style-type: none"> • <i>Prospective study mandatory when lack of significant data or comparability</i> 	<p>Application of DiGA better than non-application = • <i>Absence of treatment</i> • <i>Treatment without DiGA</i> • <i>Treatment with other DiGA</i> + <i>Comparator = realities of care</i></p>
<p>§ 10 para 3 DiGAV</p>	<ul style="list-style-type: none"> • <i>Quantitative methods</i> • <i>Methods of clinical sciences or other disciplines</i> 	
<p>§ 12 DiGAV</p>	<p>+ <i>Determination of Sensitivity & Specificity</i></p>	

Positive care effects – what else to consider?

Application for 12 months trial period requires

§ 14 DiGAV

1. *plausible justification of positive care effect
(min. systematic review of usage data)*

§ 15 DiGAV

2. *scientific study concept
provided by manufacturer-independent institute*

Other aspects

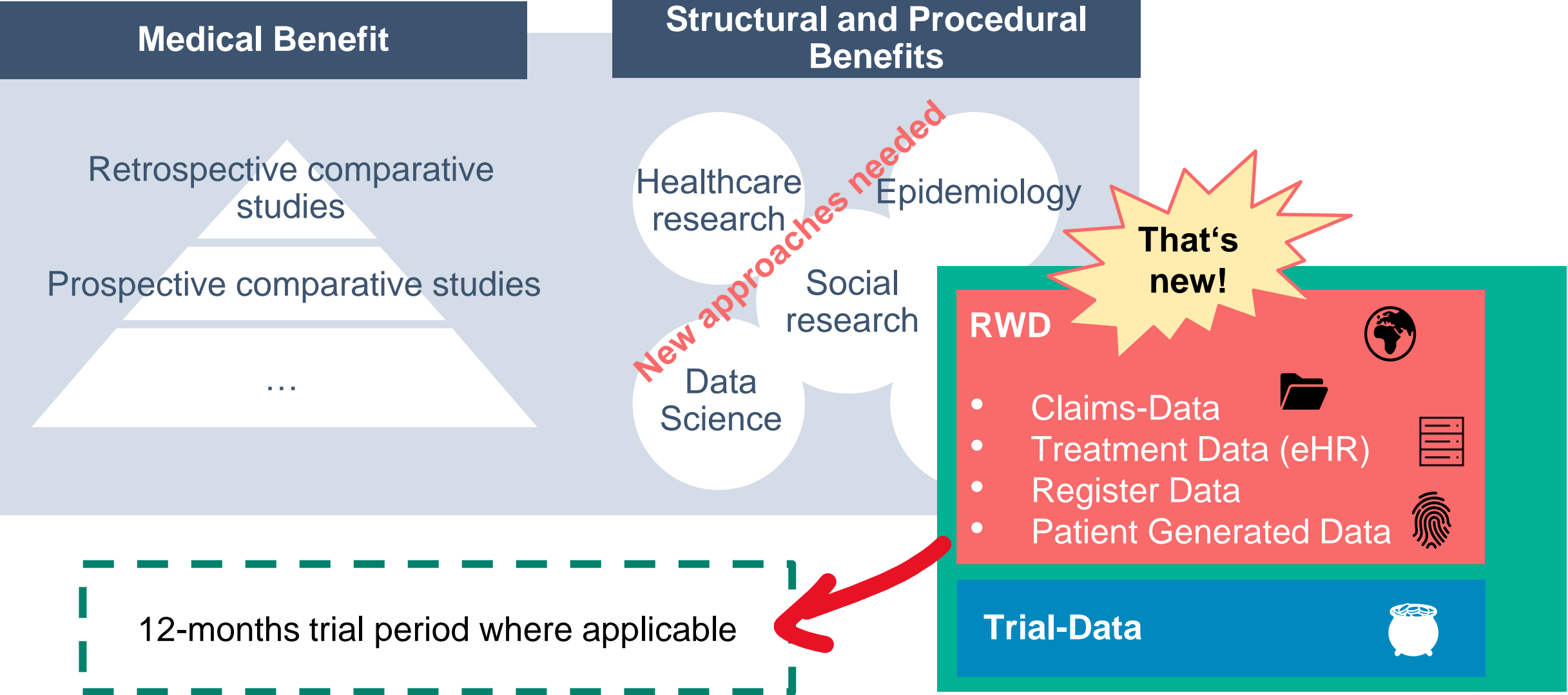
§ 10 para. 6
DiGAV

*Obligation to publish results online and studies in registries
(primary or partner registry or data provider of WHO ICTRP)*

§ 10 para. 5
DiGAV

*Studies must be conducted in Germany!
Otherwise: Proof of transferability to German healthcare realities!*

Scientific approaches and data sources





BfArM Guideline helps (English version available)

Details requirements

Details DiGA-definition

Software-Hardware-combo

Software-Service-combo

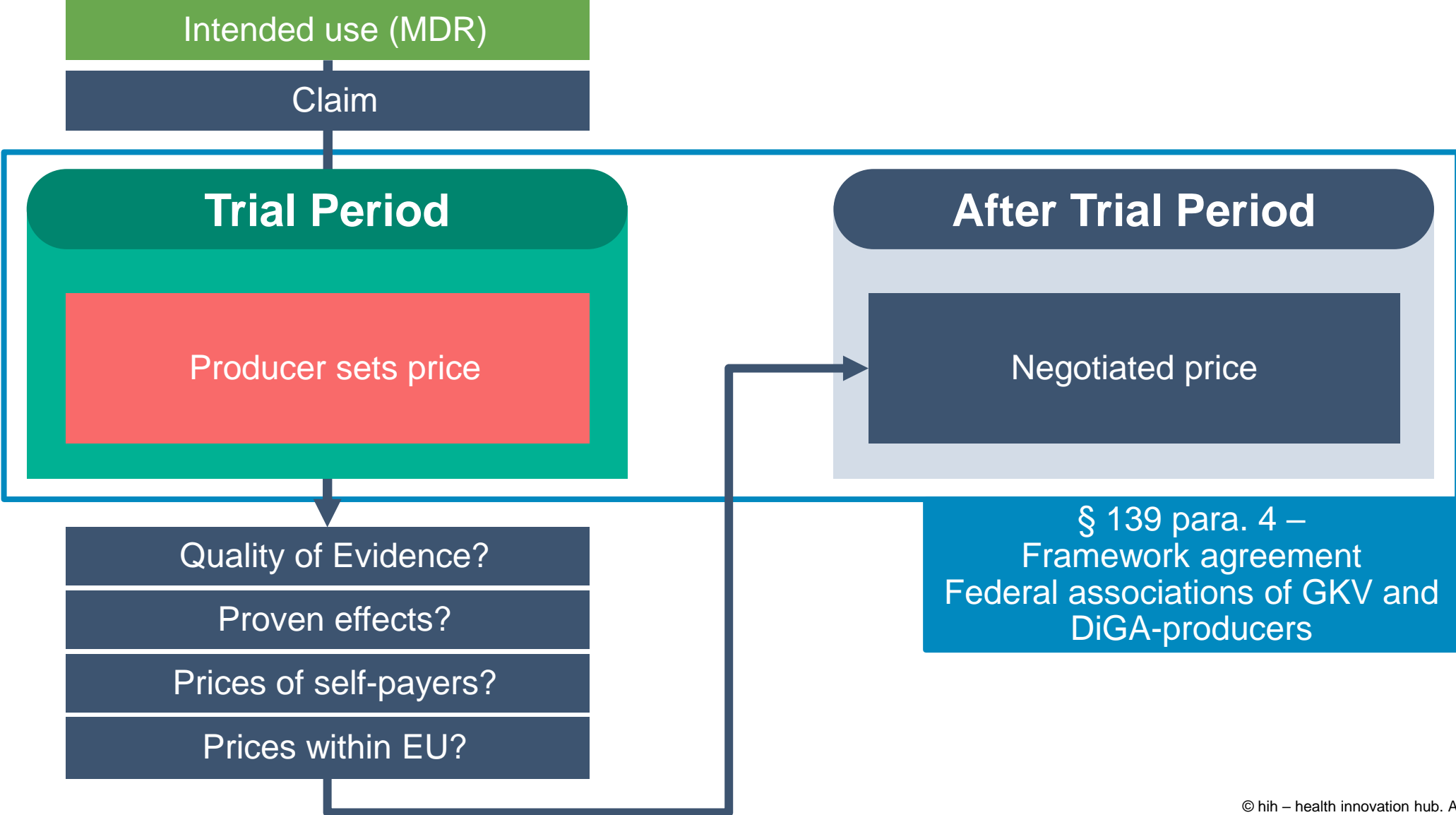
Further obligations

Procedural questions

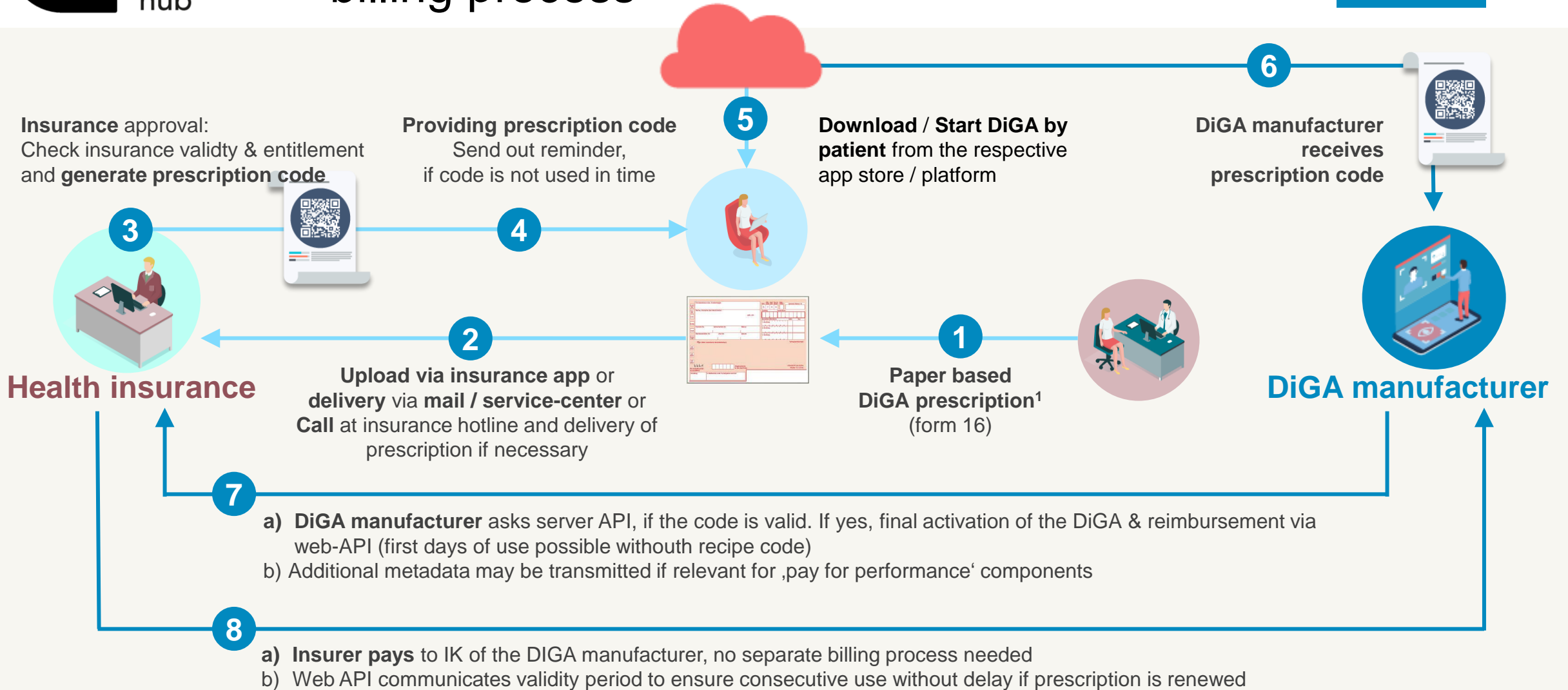
Content of registry

Details consulting

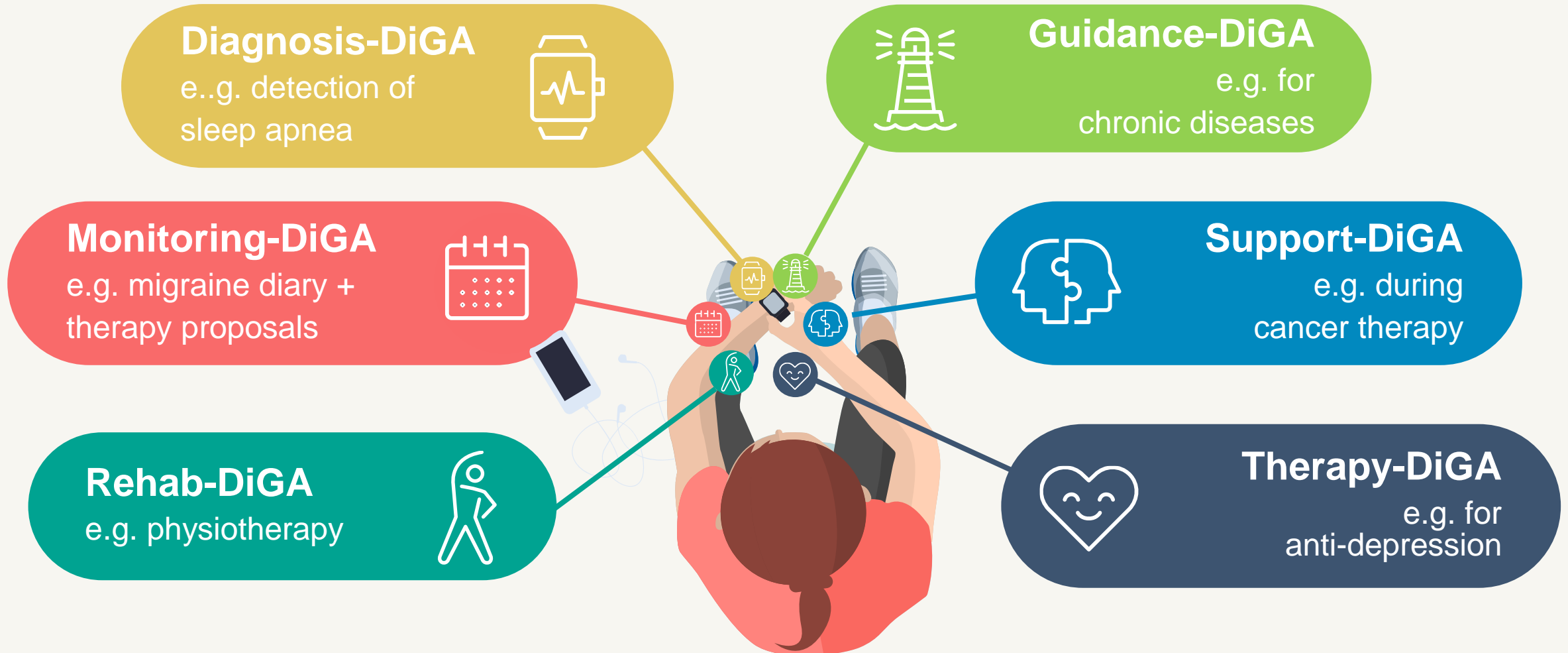
Pricing



Detailed DiGA prescription & billing process



DiGA – Various healthcare use cases



DiGA – high expectation and global interest



- First prescriptions started on Oct. 6th 2020
- Structured way into standard care (GKV: 73 mio Germans)
 - ✓ Improves medical practice
 - ✓ Promotes innovations
 - ✓ Increases attractiveness for startups, VCs etc.

First book on the process (and other important things) – available only in German for now

Dankeschön.

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health innovation hub (hih)



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