Digital Health Innovation for the German Healthcare system

DVG 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

The hih-Team: Sparring Partner & Think Tank

Nataliya Bogdanova-Dochev
Events

Jan B. Brönneke
HTA, Medical Devices, MedLaw

Prof. Dr. med. Jörg Debatin
Chairman

Claudia Dirks
Communications

Julia Hagen
Regulatory & political affairs

Dr. med. Kai Heitmann
Interoperability

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Dr. Philipp Kircher
Privacy, IT-security, MedLaw

Ralf König
Pharmacy

Dr. Henrik Matthies
Managing Director, DiGA

Ecky Oesterhoff
Hospital

Lars Roemheld
AI & Data

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Outpatient care

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## Our topics

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<tr>
<th>Data-“donation“</th>
<th>Electronic Health Record</th>
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<td>DiGA-Fast-Track</td>
<td>AI Regulation</td>
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<td>Digitalization Hospitals</td>
<td>National Healthcare Portal</td>
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<td>Digitalization Long Term Care</td>
<td>Value-Based-Medicine</td>
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Digital Health Applications (DiGA)

DVG FastTrack
Until 2020: No specific pathway into GKV for digital solutions

- §§ 20 ff. Primary Prevention
- § 32 Heilmittel
- § 33 Medical Aids
- §§ 63 ff. Pilot Schemes
- § 137e Trial of methods
- § 137f DMP
- § 140a Integrated care
- § 291g Telecounseling
- § 291a Applications TI/eGK
Definition: DiGA (digital health application)

**Medical Device**

Classes I and IIa MDR (+ provisional rules MDR)

**Intended use**

Centered on patients, possibly including treating doctors

**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)

BfArM
Consulting (remunerated)

Application of producer
On registration in DiGA-registry according to §139e SGB V

General requirements
safety | quality | functionality | privacy | data security

Positive care effects
medical benefit | structural & procedural effects

BfArM
Examines and decides within 3 months (net)

Listing in DiGA-registry

Preliminary listing & 12 months trial period

Positive care effects
✓

Positive care effects
✗
The Fast Track according to DVG (2/2)

**DiGA**
- Preliminary listing & trial period of 12 months
  - Plausible hypothesis
  - Evaluation concept by independent scientific institution
  - Producer bears costs

**Standard Care**
- 12-months trial in first healthcare market
  - Producer sets price
  - Preliminary reimbursement of physicians if applicable

**BfArM**
- Decides on final listing

- Price negotiations with GKV-SV
- Arbitration if negotiations stuck after 1 year
- Adaption of physician's reimbursement scheme if applicable

Prescription by **physicians** and **psychotherapists**
Permission by **health insurance fund** (with corresponding indication)
Further specification of requirements

Proof of compliances with general requirements
- Safety
- Functionality
- Quality
- Privacy
- Data-/IT-Security

→ Further specification by DIGAV by BMG and guideline by BfArM

Proof of positive care effects – within 12-months trial period where applicable
- Structural and procedural effects
- and/or
- Medical benefit
**General requirements**

<table>
<thead>
<tr>
<th>Proof of</th>
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<tbody>
<tr>
<td>CE-Marking</td>
<td>Consumer protection</td>
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<tr>
<td>Privacy &amp; Data-Security</td>
<td>Patient safety</td>
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<tr>
<td>Robustness</td>
<td>Interoperability</td>
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<tr>
<td>User friendliness (Patients &amp; Physicians)</td>
<td>Quality of medical content</td>
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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**
- Reduction of BoI in daily life
- Securing standard of care
- Coordination of care
- Access to care
- Health literacy
- Adherence
- Patient safety...

**Medical benefit**
- Morbidity
- Quality of Life
- Mortality
- Adverse effects
Positive care effects (3/3)

Structural and procedural effects
- Healthcare research
- Behavioural research
- Data Science
- Epidemiology
- etc.

Medical benefit
- Systematic reviews
- Randomised controlled trials
- Cohort-studies
- Case-control-studies

New data pools
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
- Software-Hardware-combo
- Further obligations
- Content of registry

- Details DiGA-definition
- Software-Service-combo
- Procedural questions
- Details consulting
### Pricing

1. **Intended use (MDR)**
2. **Claim**
3. **Trial Period**
   - Producer sets price
   - Quality of Evidence?
   - Proven effects?
   - Prices of self-payers?
   - Prices within EU?
4. **After Trial Period**
   - Negotiated price
   - § 139 para. 4 – Framework agreement
   - Federal associations of GKV and DiGA-producers
Potential prescription and reimbursement procedure

1. Physician prescribes DiGA via standard prescription

2. Patient downloads DiGA
3. Uploads prescription in health insurance app / hotline / mail
3. Receives activation code

4. Provider sends code to health insurance fund
5. Health insurance fund reimburses provider
What’s next?

mid July, tba

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

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 (German)