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

The hih-Team:
Think Tank, Idea Scout, Catalyst

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Our topics

- Health data ecosystem
- Electronic Health Record
- DiGA-Fast-Track
- Health AI Regulation
- Digitization Hospitals
- National Healthcare Portal
- Digitization Long Term Care
- Value-Based-Medicine
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
DiGA Fast Track Process

**Application**
for listing in DiGA-registry according to §139e SGB V

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

- positive care effects
  - Patient-related Structural and procedural effects and/or medical benefit

**BfArM**
Consulting (Fees)
Examine & decide (within 3 months)

- ✓
- X
- ?

**Standard Care**

- Listing: DiGA Registry
- Trial period: premilinary listing (12 months)
Further specification of requirements

Proof

of compliances with general requirements

Safety
Functionality
Quality

Privacy
Data-/IT-Security

Proof

of positive care effects – within 12-months trial period where applicable

Structural and procedural effects

and/or

Medical benefit

→ Further specification by DIGAV by BMG and guideline by BfArM
## General requirements

<table>
<thead>
<tr>
<th>Proof of</th>
<th>CE-Marking</th>
<th>Consumer protection</th>
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<tbody>
<tr>
<td></td>
<td>Privacy &amp; Data-Security</td>
<td>Patient safety</td>
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<tr>
<td></td>
<td>Robustness</td>
<td>Interoperability</td>
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<tr>
<td></td>
<td>User friendliness (Patients &amp; Physicians)</td>
<td>Quality of medical content</td>
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</table>
Positive care effects – what’s inside?

**Structural and procedural effects**
- Reduction of therapy related efforts/strains
- Securing standard of care
- Coordination of care
- Access to care
- Health literacy
- Adherence
- Patient safety…

**Medical benefit**
- Morbidity
- Quality of Life
- Mortality
## Positive care effects – specific assessment requirements

<table>
<thead>
<tr>
<th>§ 10 para 1 &amp; 2 DiGAV</th>
<th>§ 10 para 1 &amp; 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Retrospective study</strong></td>
<td>Application of DiGA better than non-application</td>
</tr>
<tr>
<td><strong>(Prospective allowed)</strong></td>
<td>=</td>
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<tr>
<td><strong>Comparative (incl. intraindividual)</strong></td>
<td><strong>Absence of treatment</strong></td>
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<table>
<thead>
<tr>
<th>§ 11 para 1 DiGAV</th>
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<tr>
<td><strong>Prospective study mandatory when lack of significant data or comparability</strong></td>
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<tr>
<th>§ 10 para 3 DiGAV</th>
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<tr>
<td><strong>Quantitative methods</strong></td>
</tr>
<tr>
<td><strong>Methods of clinical sciences or other disciplines</strong></td>
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<tr>
<th>§ 12 DiGAV</th>
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<tr>
<td><strong>Determination of Sensitivity &amp; Specificity</strong></td>
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§ 139e para. 9 SGB V

Further regulation shall be based on principles of evidence based medicine.
Postive care effects – what else to consider?

<table>
<thead>
<tr>
<th>Application for 12 months trial period requires</th>
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<tbody>
<tr>
<td><strong>§ 14 DiGAV</strong></td>
</tr>
<tr>
<td>1. plausible justification of positive care effect (min. systematic review of usage data)</td>
</tr>
<tr>
<td><strong>§ 15 DiGAV</strong></td>
</tr>
<tr>
<td>2. scientific study concept provided by manufacturer-independent institute</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Other aspects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>§ 10 para. 6 DiGAV</strong></td>
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<tr>
<td>Obligation to publish results online and studies in registries (primary or partner registry or data provider of WHO ICTRP)</td>
</tr>
<tr>
<td><strong>§ 10 para. 5 DiGAV</strong></td>
</tr>
<tr>
<td>Studies must be conducted in Germany! Otherwise: Proof of transferability to German healthcare realities!</td>
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</tbody>
</table>
Scientific approaches and data sources

Medical Benefit
- Retrospective comparative studies
- Prospective comparative studies

Structural and Procedural Benefits
- Healthcare research
- Epidemiology
- Social research
- Data Science

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

Trial-Data

12-months trial period where applicable
BfArM Guideline helps (English version available)

- Details requirements
- Software-Hardware-combo
- Further obligations
- Content of registry
- Details DiGA-definition
- Software-Service-combo
- Procedural questions
- Details consulting
Pricing

Intended use (MDR)

Claim

Trial Period

Producer sets price

After Trial Period

Negotiated price

§ 139 para. 4 – Framework agreement Federal associations of GKV and DiGA-producers

Quality of Evidence?

Proven effects?

Prices of self-payers?

Prices within EU?
Detailed DiGA prescription & billing process

1. Paper based DiGA prescription
   (form 16)

2. Upload via insurance app or delivery via mail / service-center or Call at insurance hotline and delivery of prescription if necessary

3. Health insurance
   - Insurance approval: Check insurance validity & entitlement and generate prescription code

4. Providing prescription code
   - Send out reminder, if code is not used in time

5. Download / Start DiGA by patient from the respective app store / platform

6. DiGA manufacturer receives prescription code

7. DiGA manufacturer
   - a) DiGA manufacturer asks server API, if the code is valid. If yes, final activation of the DiGA & reimbursement via web-API (first days of use possible without recipe code)
     - b) Additional metadata may be transmitted if relevant for 'pay for performance' components

8. a) Insurer pays to IK of the DiGA manufacturer, no separate billing process needed
   - b) Web API communicates validity period to ensure consecutive use without delay if prescription is renewed
DiGA – Various healthcare use cases

**Diagnosis-DiGA**
e.g. detection of sleep apnea

**Guidance-DiGA**
e.g. for chronic diseases

**Monitoring-DiGA**
e.g. migraine diary + therapy proposals

**Support-DiGA**
e.g. during cancer therapy

**Rehab-DiGA**
e.g. physiotherapy

**Therapy-DiGA**
e.g. for anti-depression
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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