Digital Health Innovation for the German Healthcare system

DVG Fast Track

16. September 2020 | Starting at 4pm CET

#DiGA
#DiGASummit
September

16.09.2020
International DiGA Summit
Prof. Dr. med. Jörg F. Debatin

Welcome to the International DiGA Summit

#DiGA
#DiGASummit
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

Dr. Philipp Kircher
Privacy, IT-security, MedLaw

Ralf König
Pharmacy

Dr. Henrik Matthies
Managing Director, DiGA

Ecky Oesterhoff
Hospital

Lars Roemheld
AI & Data

Dr. med. Philipp Stachwitz
Outpatient care

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Dr. med. Philipp Stachwitz
Outpatient care
Federal Minister of Health
Jens Spahn
Opening
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.00 pm</td>
<td>Welcome</td>
</tr>
<tr>
<td></td>
<td>Prof. Jörg F. Debatin, Chairman hih</td>
</tr>
<tr>
<td>4.05 pm</td>
<td>Opening</td>
</tr>
<tr>
<td></td>
<td>Jens Spahn, Federal Minister of Health</td>
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<tr>
<td>4.10 pm</td>
<td>The DiGA Fast Track procedure as an important step in the digitization of the healthcare system</td>
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<tr>
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<td>Prof. Karl Broich, President BfArM</td>
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<tr>
<td>4.20 pm</td>
<td>How to 'DiGA'</td>
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<tr>
<td></td>
<td>German healthcare system &amp; DiGA foundations</td>
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<tr>
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</tr>
<tr>
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<td></td>
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<tr>
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<td>Prescription, billing &amp; usage</td>
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<td></td>
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</tr>
<tr>
<td>5.45 pm</td>
<td>Q&amp;A with audience</td>
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<tr>
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<td>live questions via slido</td>
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<tr>
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Livestream: Sep.16. 2020 time zone: CET

Livestream, Sep.16. 2020
https://hih-2025.de/magazin/#DiGASummit #hih2025
President BfArM
Prof. Karl Broich

The DiGA Fast Track procedure as an important step in the digitization of the healthcare system
International DiGA Summit

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7.00 pm  Closing Remarks
Dr. Henrik Matthies, Managing Director (hih)
Today’s content stays public

**video & slides**

- The event will be recorded, available via hih in 2-3 days
- All slides & links will be available via blogpost on hih website soon

➢ If you are registered for this event, we’ll send you video & link to slides via email next week

[www.hih-2025.de](http://www.hih-2025.de)
@hih2025
health innovation hub (hih)
health innovation hub 2025
International DiGA Summit: DiGA Fast Track – challenges and chances

Here you can follow the live broadcast of the International DiGA Summit. Event begins on 16. September at 4pm CET. Take the last minute opportunity and register today! #DiGAsummit #DiGA...

DiGA Summit – Summary, Video, Docs, next steps

This blogpost contains the video of the DiGA Summit, all relevant docs such as the DIGAV & BfArM Leitfaden (manual), the Fast-Track starting date and an outlook to an English speaking DiGA webinar in later May 2020.
Our first **DiGA book** will be out in October 2020, summarizing all DiGA know-how in great detail.

English version coming soon.
Q&A in 2nd half of this event

Post your questions to BMG, BfArM & hih during the event on slido!
Relevance of German health regulations

Germany

Largest integrated healthcare market.

Now with clear access to care for digital applications.

240,000,000,000€
public spending in 2018

73,000,000
people in statutory health insurance (GKV)
(GKV-SV 2017)

DiGA Fast Track

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Dr. Lars Hunze

How to 'DiGA'
German healthcare system & DiGA foundations
How to ‘DiGA‘
Fast Track Application Process
and first experience

Dr. Wolfgang Lauer, Dr. Wiebke Lübker
Dr. Philipp Kircher

How to ‚DiGA‘
DiGA data privacy vs. EU-U.S. Privacy Shield
General Data Protection Regulation (GDPR)

- GDPR harmonizes the level of data protection within the EU / EEA

- **Transfer of personal data to a third country** shall only take place if certain conditions are complied with by the controller and the processor

- Adequacy decision (Art. 45 GDPR)
- Appropriate safeguards (Art. 46 GDPR)
- Binding Corporate Rules (Art. 47 GDPR)
- Derogations for specific situations (Art. 49 GDPR)
Judgment of the ECJ of 16 July 2020 - Case C-311/18 – Schrems II

Background
• In 2015, the ECJ invalidated the "Safe Harbor" agreement on data transfers to the US. (Jdg. of 06.10.2015, Schrems I, C-362/14)
• For the successor agreement "EU-U.S.-Privacy Shield" there was an adequacy decision by the EU Commission of 12.07.2016 in place.
• New referral by the High Court (Ireland) to the ECJ on a complaint by Maximilian Schrems concerning the transfer of personal data to third countries by Facebook Ireland (to the USA).

Essentials of the judgment
• Commission Implementing Decision (EU) 2016/1250 on the adequacy of the protection provided by the EU-U.S. Privacy Shield is invalid.
• Commission Decision 2010/87 on standard contractual clauses for the transfer of personal data to processors established in third countries is valid – but also requires an adequate level of data protection in the third country.
EU adequacy decisions before Schrems II

Adequacy decisions
How the EU determines if a non-EU country has an adequate level of data protection.

The European Commission has so far recognised Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Switzerland, Uruguay and the United States of America (limited to the Privacy Shield framework) as providing adequate protection.


• Adequacy decision of the EU Commission regarding the USA was limited to the EU-U.S.-Privacy Shield!
Digital Health Applications Ordinance (DiGAV)

Strict data protection requirements in Section 4 DiGAV – **additional to GDPR!**

- Consent is limited to the purposes listed in Section 4 (2) DiGAV
- **Transfers to third countries are restricted according to Section 4 (3) DiGAV**
Restricted transfers to third countries acc. to Section 4 (3) DiGAV

Section 4 (3) DiGAV (translated)

(3) In the context of a digital health application, the processing of personal data by the digital health application itself as well as in the case of processing of personal data by a data processor on behalf of the data controller may only be done in Germany, in a member state of the European Union or in one of the countries in accordance with Section 35 (7) of the First Book of the Social Code, or if there is an adequacy decision in accordance with Article 45 of Regulation (EU) 2016/679, in a third country.

- DiGAV always requires an adequacy decision!
- Further instruments under Art. 46, 47 GDPR are excluded!

Reasoning to Section 4 (3) DiGAV (translated)

The regulation extends the social data protection restrictions on order data processing using foreign service providers in accordance with Section 80 (2) of Book 10 of the Social Code to the data processing of digital health applications as well as processing of data on behalf of the use of the digital health application. This ensures that the data sovereignty of the insured is maintained even when the manufacturer uses cloud services, for example. The far-reaching exceptions according to Articles 46 and 47 of Regulation (EU) 2016/679 are not applicable to digital health applications due to the special need for protection of the processed data. As part of the risk analysis of the protection requirement determination, the geographical location of the server locations to be specified according to § 2 must also be taken into account.
Impact on DiGA manufacturers - summary

- There is no valid adequacy decision concerning the USA in force.
- The possibility of using other instruments of the GDPR (e.g. standard contractual clauses) is already excluded by DiGAV.
- A new EU decision on the adequacy of the level of data protection in the USA would therefore be needed.
- The transfer of personal data to the USA by a DiGA manufacturer (data controller) or a data processor is no longer permitted.

btw: BfArM has already updated the DiGA Guide with respect to the ECJ’s decision!
Jan B. Broenneke

How to 'DiGA'
Generating scientific evidence for DiGA
Scientific Evidence for DiGA – basics

Proof of general requirements
- Safety
- Functionality
- Quality
- Data Protection
- Information Security

Proof of positive care effects
- Structural and procedural effects
- and/or
- Medical benefit

→ Further specification by DiGAV by BMG and guide by BfArM

12-months trial period where applicable
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
# Regulatory requirements for study design – SGB V & DiGAV

### § 139e para. 9 SGB V
Further regulation shall be based on principles of evidence based medicine

| § 10 para 1 & 2 DiGAV | • Retrospective study  
• (Prospective allowed)  
• Comparative (incl. intraindividual) |
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<tr>
<td>§ 11 para 1 DiGAV</td>
<td>• Prospective study mandatory when lack of significant data or comparability</td>
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</tbody>
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| § 10 para 3 DiGAV | • Quantitative methods  
• Methods of clinical sciences or other disciplines |
| § 12 DiGAV | + Determination of Sensitivity & Specificity |

### § 10 para 1 & 5
Application of DiGA better than non-application

=  
• Absence of treatment  
• Treatment without DiGA  
• Treatment with other DiGA +  
Comparer = realities of care
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

New approaches needed

That's new!
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! |
Julia Hagen, Dr. Henrik Matthies

How to 'DiGA‘
Prescription, billing & usage
Prerequisites for the prescription process

- Solution needs to fit to all >100 Statutory Health Insurances
- Operational when first DiGA is available
- Compliant with the requirements of the Social Code, incl. requirements for „Sozialdaten“ - specific German category for data in the hands of the health insurance funds
- Little to no friction in providing access to DiGA
- Handling of data for billing

- As easy and digital as possible
- Principle of benefit-in-kind
- Accessibility to all users (catering to different needs)
- No additional costs
- No additional administrative burden
- Existing processes

Interim solution until availability of ePrescription Service
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. **Detailed DiGA prescription & billing process**
   - **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**
Checklist for native App-DiGA developers

Before submitting your App-/Play Store application, check:

- **App Description**
  - mention that you are a listed DiGA, approved by BfArM, incl. link to BfArMs central DiGA-registry
  - if not necessary, do not mention Covid-19

- **App Review Information**
  - add >3 test accounts and test prescription codes for the store review team

- **inApp Purchase**
  - enable inApp purchase parallel to prescription code access
Without buy-in from physicians/therapists, no DiGA will be prescribed

**Medical product**

… class I - IIa (MDR)

→ Any risk for the prescribing physician?

**Intended use**

… supports the patient

→ Is the DiGA easing handling/treatment of the patient for the physician?

**Main function**

… relies on digital technology

→ Does the physician understands the application?

**Functionality**

→ How is the mechanism of action?

→ What does the physician need to know / explain to the patient?
Be part of the discussion!
DiGA-Manufacturers’ Organisations in Germany

Joint development of **prescribing solution** with the National Association of Statutory Health Insurance Funds and individual Health Insurance Funds

Negotiation of the **framework agreement** on pricing with National Association of Statutory Health Insurance Funds

DiGA-Manufacturers’ Organisations:
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Vote for your favorite question to BMG, BfArM & hih now on slido!
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Closing
Dankeschön.