How to „DiGA“ – Fast Track application process & first „lessons learnt“

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How to „DiGA“ – Fast Track application process & first „lessons learnt“

The „road“ to the DiGA Fast Track at the BfArM

The Guidance Document on the Fast Track Procedure: What is a DiGA? What are the requirements?...

First lessons learnt: Sharing experiences

Next steps

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The „road“ to the DiGA Fast-Track at the BfArM
Digital Medical Devices - familiar terrain: Initiatives of the BfArM

- **BfArM- Guidance „Medical Apps“**
  - 2014

- **Innovation Office Support & Advice – „Project Guidance“**
  - 2015 | 2016

- **Public Health Journal „E-Health and Medical Devices“**
  - 2018

- **BfArM im Dialog „Medical Apps“**
  - Apps as Medical Devices;
  - Clinical trials,
  - data safety,
  - reimbursement

- **BfArM im Dialog „Cyber Security“**
  - Perspectives:
  - Hacker,
  - Manufacturers;
  - Sensitization
  - Support
The central milestones for the realisation of the DiGA Fast Track

- 02/19/2020: Consultation of the medical associations regarding DiGAV
- 12/19/2019: DVG comes into effect
- 01/15/2020: Publication of the ministerial draft of the DiGAV

- April 2020: Publication of the BfArM-Guide regarding DiGAV
- From May/June 2020: Applications can be filed at the BfArM
- First positive notification of the BfArM: Start of the DiGA-directory
The DiGA Fast Track Procedure

The procedure involves the following steps:

1. **Manufacturer submits an application**
2. **BfArM advises and examines**
3. **Requirements regarding security, functionality, quality, data protection, data security, interoperability**
4. **Positive care effects**
   - Medical benefit, structural and procedural improvements
5. **Requirements are reviewed**
6. **Preliminary admission into the DiGA-directory according to § 139e SGB V**
7. **Plausible justification of the positive care effects, concept for evaluation**
8. **Admission into the DiGA-directory according to § 139e SGB V**
9. **Determination of the medical service**
10. **Price negotiations, if necessary, arbitration**
11. **Adjustment EBM**

The process can take up to 3 months for the initial review and 12 months for the final determination.

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The Fast Track-Guide by the BfArM

Note:
The English version of the guide is a service provided by the BfArM, which also includes translations of the German legal texts or references to them. The corresponding standards in the German version are legally binding; these will also be available in English translation shortly.
Guide for Manufacturers, Service Providers and Users

DiGA-Guide

Information for the manufacturer on the application procedure, the requirements and the possibilities of support by the BfArM.

www.bfarm.de/diga_en

https://www.bfarm.de/diga_en
The DiGA Guide in more detail

„Interpretation- and Reading aid“:
- icons that mark certain passages/Contain special comments

Attention: Watch out!

Rule of Thumb

FAQ – Frequently asked questions

Tips

✓ Evidence, forms etc. that must be submitted

Examples from practical experiences

- Links to relevant references:

References
- BSI Standard 200-1. Available online:
- 2001_en_pdf.pdf?__blob=publicationFile&v=3
### Many practical examples

<table>
<thead>
<tr>
<th>DiGA</th>
<th>Example: App as a Desktop / Browser Application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description:</strong></td>
<td>A web application supports patients with decreased vision by offering a treatment with digitally supported visual exercises in a virtual vision school.</td>
</tr>
<tr>
<td><strong>Reasoning:</strong></td>
<td>Even browser or desktop applications can be a DiGA if the requirements are met.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not a DiGA</th>
<th>Example: App with Optional Hardware</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description:</strong></td>
<td>A platform application enables the use of several legally marketed DiGA also on a smartwatch. Data can be entered, results can be registered, and notifications can be received.</td>
</tr>
<tr>
<td><strong>Reasoning:</strong></td>
<td>The digital services are primarily provided by other legally marketed DiGA. The app is not a medical device since it provides a pure platform function.</td>
</tr>
</tbody>
</table>

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<tr>
<td><strong>Description:</strong></td>
<td>The app reminds patients to take pain medication and provides a dosage recommendation according to the current condition. It enables patients to receive a reminder for the required medication intake via a smartwatch as optional hardware and allows to confirm this directly.</td>
</tr>
<tr>
<td><strong>Reasoning:</strong></td>
<td>The DiGA supports the treatment of a (non-severe) illness. The integration of optional hardware does not change this.</td>
</tr>
</tbody>
</table>
What makes this Guide special?

• Interpreting the ordinance, supplying details for the practical completion of the procedure
• User / Reader friendliness, readability and comprehensibility with regard to the legal requirements
• High level of transparency for all stakeholders regarding assessment (criteria)
• Supplying details for the practical completion of the procedure
• Feedback which has been incorporated into updates
• Living document - regular updates, additions FAQ and (non-exhaustive) examples from practical experiences
Structure & contents of the Guide

• **Focus on:**
  ✓ Application requirements/process
  ✓ Requirements for Quality and Evidence of the positive healthcare effects that need be achieved

• **Not on:**
  – Negotiations/Pricing
  – Reimbursement
  – Prescription

1: Overview and introduction
2: Listing in the DiGA directory: Application requirements, contents of the application, application procedure and DiGA directory
3: Proof of the requirements for Safety, functionality, data protection, information security and quality
4: Evidence of positive healthcare effects
5: Operational/technical part of the application procedure, deadlines, obligations; consultations, fees

Abbreviations, glossary, version tracking
2 Listing a DiGA in the DiGA Directory
What is a DiGA – and what is not?

Definition:

A DiGA is a **medical device** that has the following properties:

- Medical device of the risk class I or IIa (according to MDR or MDD as part of the transition regulations until the beginning of the validity of the MDR on May 26th 2021) (see also Chapter 3.2 Safety and Suitability for Use)
- The main function of the DiGA is based on digital technologies.
- The DiGA is not a digital application that serves only for the collection of data from a device or for controlling a device. The medical purpose must be achieved through the main digital functions.
- The DiGA supports the recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment or alleviation or compensation of injuries or disabilities.
- The DiGA does not serve primary prevention (see also Chapter 2.1.4 DiGA in Prevention).
- The DiGA is used only by the patient or by the patient and the healthcare provider. This means that apps that are only used by the physician to treat patients (practice equipment) are not a DiGA.

Guide: Explanation based on examples:

<table>
<thead>
<tr>
<th>Example: App in Combination with the Services of a Dietician</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description:</strong> The app accompanies patients with chronic inflammatory bowel syndrome by bringing them in contact with non-medical healthcare providers such as dieticians for a consultation through a chat function or telephone calls.</td>
</tr>
<tr>
<td><strong>Reasoning:</strong> The main function of the app is provided by an “analogous” healthcare provider. If the dietician’s service is “removed”, a mainly digital central function is not given any longer.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not a DiGA</th>
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<tr>
<td><strong>Description:</strong> The app offers patients with chronic inflammatory bowel syndrome a digitally designed healthcare model that provides information about the disease and nutrition, documents symptoms (i.e. in a diary), gives instructions how to design a nutrition plan and supports their creation through algorithms, offers a digital shopping guide with scan function for foodstuffs and evaluates these individually and makes the contact with a chat bot for consultation possible if necessary.</td>
</tr>
<tr>
<td><strong>Reasoning:</strong> The application has a digitally designed healthcare model that fulfills – as a marketable medical device - all criteria of a DiGA.</td>
</tr>
</tbody>
</table>

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2 Application procedure for...

provisional...

Application for final listing in the DiGA directory

- Manufacturer
- Manufacturer's association
- RKV-SV
- Framework agreement
- Manufacturer's price
- Negotiated price
  (is always valid from the 12th month, annually terminable)
- BAfArM
- Final listing in the DiGA directory

....or final listing in the DiGA directory

Application for provisional listing in the DiGA directory (Trial)

- Manufacturer
- Manufacturer's association
- RKV-SV
- Framework agreement
- Manufacturer's price
- Negotiated price
  (is always valid from the 12th month, annually terminable)
- BAfArM
- Provisional listing in the DiGA directory
- Final listing in the DiGA directory

2 The DiGA Directory according to § 139e SGB V - What kind of information will be shown?

- Listing of the DiGA who have successfully passed the Fast Track at the BfArM after application
- Goal: Enable trustworthy use of DiGA
- DiGA directory contains basic data and specific information for
  - Users/Patients
  - Service providers (medical doctors and psychotherapists)
  - Specialist medical information (e.g. for medical societies, etc.)
  - Technical information

- Guide explains
  - what information this is in concrete terms (§ 20 DiGAV)
  - how confidential information is handled: what information is included in the register and how/to what extent labelling by applicants is possible (the case of personal data/company and business confidentiality)
3 Requirements for a DiGA

...according to SGB V and DiGAV:

In order to be listed in the directory according to Section 139e SGB V, a DiGA must meet the requirements defined in Sections 3 to 6 of the DiGAV concerning

- Safety and suitability for use
- Data protection and information security
- Quality, especially interoperability.

Manufacturers have to demonstrate this to the BfArM with emphasis on the completed checklists of the appendices 1 and 2 of the DiGAV as well as the evidence of compliance with regulatory requirements for medical devices.

The BfArM can request further evidence on individual quality features during the application assessment and check the accuracy of the information. In any case, free access (login data) to the DiGA must be provided to the BfArM (Section 2 paragraph 4 DiGAV) by the manufacturer.

Guide explains:

- ... what to consider when completing the checklists
- Provides hints on....
  ✓ Permitted purposes of data processing / data export
  ✓ specifications / recommendations, e.g. on information security, management systems
  ✓ technical guidelines
  ✓ using standards
4 Evidence of Positive Healthcare Effect

Requirements & definition according to SGB V & DiGAV:
“As already laid out in the definition of DiGA according to Section 33a SGB V, the focus of the effects to be demonstrated should be patient-centered. Both medical benefits as well as patient-relevant improvements of structure and processes refer directly to the patient and shall be demonstrated by appropriate endpoints. The workload of medical staff or economic indicators of healthcare are not patient-relevant endpoints that can be used to prove medical benefit or patient-relevant improvement of structure and processes.”

Guide provides information on:

- specification of positive healthcare effects in the application:
  - Information on patient group / indication (ICD-10)
  - Evidence of positive effects of care: medical benefits or structural/procedural improvements
  - Based on examples: Requirements for comparative studies for evidence generation (not conclusive)
  - Advice on method selection
  - Advice on carrying out the verification (e.g. supply context)
  - Notes on the comparator
  - Evaluation concept
### 4 Evidence of Positive Healthcare Effect – Specific requirements for studies

**Guide explains:**

Based on examples -

What is acceptable and what is not - and why?

<table>
<thead>
<tr>
<th>possible</th>
<th>Permissible Studies for the Evidence of Positive Care Effects</th>
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<tbody>
<tr>
<td>-</td>
<td>Structured recording of mortality through statistical analysis of data from patients with status after melanoma</td>
</tr>
<tr>
<td>permissible</td>
<td>- Structured recording of the health-related quality of life through a quantitatively evaluable questionnaire such as the Short Form (SF-36) Health Survey (SF-36) for rehabilitation patients after a stroke</td>
</tr>
<tr>
<td>permissible</td>
<td>- Structured recording of adherence using a quantitatively evaluable questionnaire such as the Medication Adherence Questionnaire (MAQ) in patients with drug-treated rheumatic diseases</td>
</tr>
<tr>
<td>not permissible</td>
<td>- Structured interview with interpretative evaluation to record the patient autonomy of patients with beginning dementia syndrome</td>
</tr>
</tbody>
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- **Possible Retrospective Study for the Evidence of Positive Care Effects**

<table>
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<td>-</td>
<td>Compare data from a DiGA to support breast cancer patients against complete and high-quality historical data from a breast cancer registry</td>
</tr>
<tr>
<td>permissible</td>
<td>Compare data from a DiGA in support of stroke patients against historical data collected at a time when treatment guidelines differ significantly from today's treatment reality (e.g. no systemic intravenous lysis therapy)</td>
</tr>
<tr>
<td>permissible</td>
<td>Compare data of a DiGA for treatment / support of patients with pollen allergy, e.g. collected in the allergy peak season, with historical data collected in winter, at low pollen load</td>
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5 Course of the Application Procedure

- Guide: Information on the procedure

  ✓ Application procedure (provisional and final) and notifications of amendment exclusively electronically via the application portal;

  further information on the portal:

  www.bfarm.de/diga // https://diga.bfarm.de/antrag/de

  Guidance Document for filling out the application on the portal

  ✓ Deadlines for Applicants and the BfArM

  ✓ Completeness checks
5 Advice by the BfArM

- Guide informs about:
  ✓ Extensive consulting services offered by BfArM: before and after listing in the directory
  ✓ Application forms, further information, contacts, consulting fees

- Eligibility to apply
- Methodological requirements,...
- Assessment of significant changes; details on study designs, etc.
- General questions on formal requirements of the application procedure
First lessons learnt: Sharing experiences
First lessons learnt – sharing experiences

Digital function ↔ human influence

Evaluation concept (application for provisional listing):
First Data required, gained with the DiGA

Privacy Shield – consequences of cancellation by the Court of the Justice of the EU

Provisional ↔ final listing:
Data sufficient for final listing?

Information for the DiGA Directory

DiGA-ID (“PZN”)

Study reports / study protocols:
lack of information
Next steps

... & where to find relevant updates & information
The next steps

- Publication DiGAV / §§ 33a, 134, 139e SGB V translation (english; service provided, german version binding)
- Publication of the DiGA Directory (www.bfarm.de/diga)
- More detailed information on the evaluation concept
- Update of the DiGA Guide

Publication DiGAV:
- §§ 33a, 134, 139e SGB V
- Translation (english; service provided, german version binding)

Publication of the DiGA Directory:
- www.bfarm.de/diga

Detailed information on the evaluation concept:
- More information available at www.bfarm.de/diga

Update of the DiGA Guide:
- Latest updates and revisions to the DiGA Guide are available at www.bfarm.de/diga
Any further questions on the DiGA Fast Track....?

You want to know more about requirements, deadlines, fees...?
Where can I find relevant information on the DiGA Fast Track, Consultation by BfArM, Application...?

Guide: Portal for application:
https://www.bfarm.de/diga_en

Consulation:
www.bfarm.de/innovation
Thank you very much for your attention!

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