



Federal Institute
for Drugs
and Medical Devices

The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V

A Guide for Manufacturers, Service Providers and Users



**>>> WE HAVE
THE ANSWERS.**

Table of Contents

Figure Index	4
Table Index.....	4
Abbreviation Index.....	5
Explanation for the Use of Icons	6
1 Introduction.....	7
1.1 The Fast Track at the BfArM: App on Prescription	7
1.2 The Idea behind the Fast Track.....	9
1.3 The Fast Track-Guide by the BfArM.....	10
1.3.1 Structure of the Guide	11
2 Listing a DiGA in the DiGA directory	12
2.1 What is a DiGA and What Is Not?	12
2.1.1 Combination with Hardware	13
2.1.2 Combination with Services	15
2.1.3 Scope of a DiGA.....	19
2.1.4 DiGA in Prevention.....	21
2.2 The DiGA Directory	23
2.2.1 The Content of the DiGA Directory (Section 20 DiGAV).....	23
2.2.2 Handling of Confidential Information.....	27
2.2.3 The Reading of Data from the Directory by Third Parties	27
2.3 Provisional and Final Listing in the Directory.....	27
2.3.1 Application for Final Listing in the DiGA Directory.....	28
2.3.2 Application for Provisional Listing in the DiGA directory.....	29
2.3.3 Extension of the Trial Phase	32
2.3.4 Technical Details for (Preparing) the Application	32
3 Requirements for a DiGA	35
3.1 Structure of the Checklists Concerning DiGA Requirements	35
3.2 Safety and Suitability for Use.....	36
3.3 Data Protection	37
3.3.1 Permitted Purposes of Data Processing.....	38
3.3.2 Permitted Data Processing according to Section 4 paragraph 2 Clause 1 and 2 DiGAV.....	39
3.3.3 Data Processing Outside of Germany	42
3.4 Information Security	44

3.4.1	Management System for Information Security	45
3.4.2	Security as a Process.....	46
3.4.3	BSI-Grundschutz-Components and Technical Guides	47
3.4.4	Requirements in Case of an Increased Need for Protection	48
3.5	Interoperability	51
3.5.1	Use of Standards and Profiles.....	51
3.5.2	The Cascade of Section 6 DiGAV.....	53
3.5.3	Interoperability Requirements for DiGA.....	55
3.6	Further Quality Requirements.....	64
3.6.1	Robustness	64
3.6.2	Consumer Protection.....	66
3.6.3	Ease of Use	71
3.6.4	Support for Healthcare Providers	72
3.6.5	Quality of Medical Content	73
3.6.6	Patient Safety.....	74
4	Evidence of Positive Healthcare Effect.....	76
4.1	Definition of Positive Care Effects	76
4.1.1	Medical Benefit.....	76
4.1.2	Patient-relevant improvement of structure and processes	77
4.2	Declaration of Positive Care Effects in the Application	80
4.2.1	Specification of the Patient Group.....	80
4.2.2	Specification of the Positive Care Effect.....	81
4.3	General Requirements for Studies to Prove a Positive Care Effect	83
4.3.1	Choice of Methods	84
4.3.2	Realisation in Germany	85
4.3.3	Entry in the Study Registry	85
4.4	Publication of the Complete Study Results	85
4.4.1	International Standards for Study Reports	86
4.5	Application for Provisional Listing.....	86
4.5.1	Justification of the Improvement of Healthcare	86
4.5.2	Evaluation Concept.....	87
4.5.3	Extension of the Trial Phase	87
4.6	Specific Requirements for Study Types and Study Designs	88
4.6.1	Study to Verify Positive Care Effects	89
4.6.2	Studies on Diagnostic Quality	102
5	Course of the Procedure.....	105

5.1	Deadlines for Applicants and the BfArM	105
5.2	Life Cycle of a DiGA in the Directory	107
5.2.1	Obligations of the BfArM after the Listing of a DiGA in the DiGA Directory.....	108
5.2.2	Manufacturer’s Obligations After the Listing of a DiGA in the DiGA Directory .	108
5.2.3	Mandatory Further Development of the DiGA.....	109
5.2.4	De-Listing of a DiGA from the DiGA Directory	110
5.3	Changes to the DiGA.....	110
5.4	Advice by the BfArM.....	112
5.4.1	Consultation before Inclusion in the DiGA Directory	112
5.4.2	Consultation after Inclusion in the DiGA Directory	113
5.4.3	Consulting Fees	113
5.5	Application Fees and Expenses of the BfArM	115
	Glossary	117

Figure Index

Figure 1: Sequence of the Fast Track procedure.....	8
Figure 2: Implementation of the Fast Track procedure.....	10
Figure 3: Application for final listing in the DiGA directory.....	29
Figure 4: Application for provisional listing in the DiGA directory.....	30
Figure 5: Application for an extension of the trial phase.....	32
Figure 6: Requirements and recommendations of the BSI regarding information security.....	44
Figure 7: IOP for DiGA.....	56

Table Index

Table 1: Examples of study design.....	94
Table 2: Chargeable consulting services.....	113
Table 3: Fees for the processing of applications and notifications.....	115

Abbreviation Index

BDSG	Federal Data Protection Act
BfArM	Federal Institute for Drugs and Medical Devices
BMG	Federal Ministry of Health
BSI	Federal Office for Information Security
cl.	Clause
DiGA	Digital Health Application
DiGAV	Digital Health Applications Ordinance
DRKS	German Register of Clinical Studies
DNVF	German Network for Healthcare Research
DMP	Disease Management Program
DVG	Digital Healthcare Act
EBM	German Uniform Assessment Standard
eGK	Health Insurance Card
ePA	Personal Health Record
FDA	Food and Drug Administration
Fig.	Figure
GDPR	General Data Protection Regulation
HSM	Hardware Security Module
ICTRP	International Clinical Trials Registry Platform
ISMS	Information Security Management System
ISO	International Organisation for Standardisation
KBV	Federal Association for Statutory Health Insurance Physicians
MDD	Medical Device Directive
MDR	Medical Device Regulation
MIO	Medical Information Object
mN	Medical Benefit
MPG	Medical Devices Act
pSVV	Patient-relevant Improvement of Structure and Processes
pVE	Positive Healthcare Effect
SDO	Standards Developing Organisation

SGB	(German) Social Code Book
SGB V	(German) Social Code Book V
SHI	Statutory Health Insurance
WHO	World Health Organisation

Explanation for the Use of Icons

You will find graphic elements in the text, so-called icons that mark certain passages. These contain special comments or represent a category of information. The icons enable a structured overview.



Attention: Watch out!



Rule of Thumb



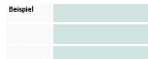
FAQ – Frequently asked questions



Tips



Evidence, forms etc. that must be submitted



Examples from practical experiences

The guideline repeatedly quotes requirements laid down by laws or regulatory texts. These quotes are marked by grey writing:

Definition ISMS [BSI-Standard 200-1]: The ISMS defines the instruments and methods that the management level uses to comprehensibly manage (plan, use, carry out, monitor and improve) the tasks and activities regarding information security.

The abbreviations used in the text are written out when mentioned for the first time. They are also compiled in the abbreviation index at the beginning of the guide.

Disclaimer

This English version of the guide is a service provided by the BfArM, which also includes translations of the German standard texts or references to them.

The corresponding standards in the German version are legally binding; these will also be available in English translation shortly.

1 Introduction

1.1 The Fast Track: App on Prescription

1.2 The Idea behind the Fast Track

1.3 The Guide of the BfArM

The Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG) came into effect on December 19th 2019 introducing the “app on prescription” as part of healthcare provided to patients. This means that around 73 million insured in the statutory health insurance (SHI, German: Gesetzliche Krankenversicherung, GKV) are entitled to healthcare through digital health applications (Digitale Gesundheitsanwendungen, DiGA). These applications can be prescribed by physicians and psychotherapists and are reimbursed by health insurers. Insured persons that can provide their SHI funds a proof of a corresponding indication are also eligible to receive a desired DiGA without a prescription.

Persons insured in the SHI are entitled to healthcare through a digital healthcare application

1.1 The Fast Track at the BfArM: App on Prescription

Prerequisite for the above is that a DiGA must have successfully completed the assessment of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) leading to a listing in a directory of reimbursable digital health applications (DiGA directory, in the following also only called directory).

Assessment procedure at the BfArM

The procedure is designed as a fast-track process: Within a three-month period starting with the filing of the complete application, the BfArM has to assess the DiGA. The essence of this assessment is the examination of the manufacturer’s statements about the product qualities – from data protection to user friendliness - and the examination of the evidence of the positive healthcare effect of the DiGA provided by the manufacturer (*Figure 1* gives an overview of the procedure).

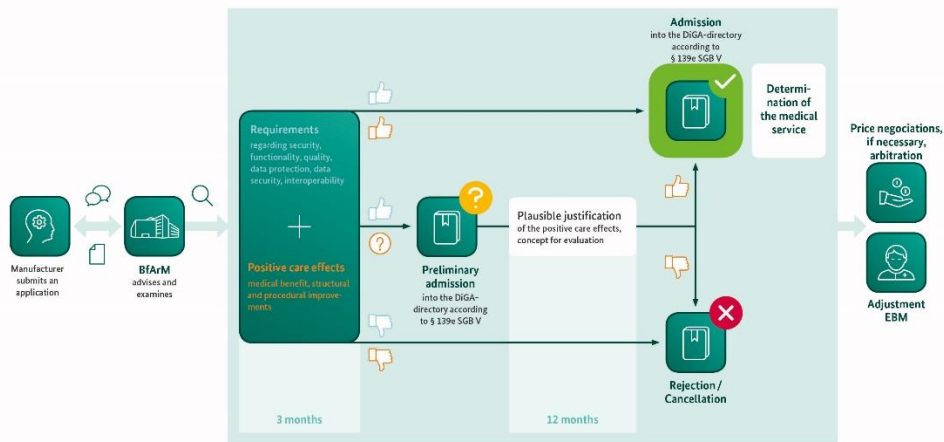


Figure 1: Sequence of the Fast Track procedure.
Source: BfArM.

If the manufacturer cannot provide sufficient evidence for a positive healthcare effect but all other requirements are fulfilled, it will be possible to apply for a provisional listing in the directory. In this case the required comparative study can be conducted within the trial phase of one year, or in exceptions of up to two years. Once the DiGA is listed in the directory, physicians receive an additional reimbursement, in case additional medical services are necessary as part of the treatment.

The Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) has regulated the details of the application procedure, the requirements for the DiGA and the shape of the DiGA directory in the Digital Health Applications Ordinance (Digitale-Gesundheitsanwendungen-Verordnung, DiGAV). The present guide of the BfArM in accordance with Section 139e paragraph 8 clause 1 of Book V of the Social Security Code (German: Sozialgesetzbuch V, SGB V) – regarding the application and notification procedure - interprets the ordinance and supplies details for the practical completion of the procedure at the BfArM.

Application for the final listing and for the admission for a provisional listing for the DiGA directory

1.2 The Idea behind the Fast Track

The newly introduced medical devices will systematically develop the innovative potential of digital applications in German healthcare. A new emphasis is set within the services of the SHI: The Fast Track - and the DiGA implemented through it- focus on the patients' health behaviour, the integration of processes between healthcare providers and patients and leads to reimbursability of these products in the SHI.

Focus on patients' health behaviour and the integration of processes

For the first time, the Fast Track-procedure defines a full set of requirements for DiGA. It is based on the fundamental assumption that digital applications must be safe and easy to use to be successfully established in healthcare. It aims for a successful link between privacy and information security on the one hand and user friendliness and high performance on the other hand.

Definition of a full set of requirements for DiGA

Maximum transparency is a key focus: The path to reimbursability is meant to be predictable for the manufacturers through the formulation of unambiguous requirements and interpretation aids.

Transparency through the DiGA directory

To ensure that insured persons, physicians, psychotherapists and health insurances can make well-informed decisions and develop a confident use, the DiGA directory will provide comprehensive information about the qualities and services of the devices.

DiGA cannot be considered in an isolated way but must be seen as part of digitally enabled healthcare. This becomes clear in the requirements for the devices and it is particularly valid concerning the interoperable, safe and patient-focused interaction with the electronic health insurance card (elektronische Gesundheitskarte, eGK), the electronic personal health record (elektronische Patientenakte, ePA), the digital platforms of the health insurers and telemedicine. The corresponding requirements in the DiGAV must be implemented in parallel to the developing national E-Health infrastructure in Germany by the DiGA manufacturers.

DiGA as a part of digitally enabled healthcare

The schedule for the further realisation of the Fast Track aims at allowing manufacturers to apply for becoming part of the DiGA directory beginning in summer 2020. The directory will become publicly available beginning with the first positive notification and the concurrent listing in the directory.

The illustration below summarises the central milestones for the realisation of the Fast Track and the introduction of DiGA into the standard care of the SHI.

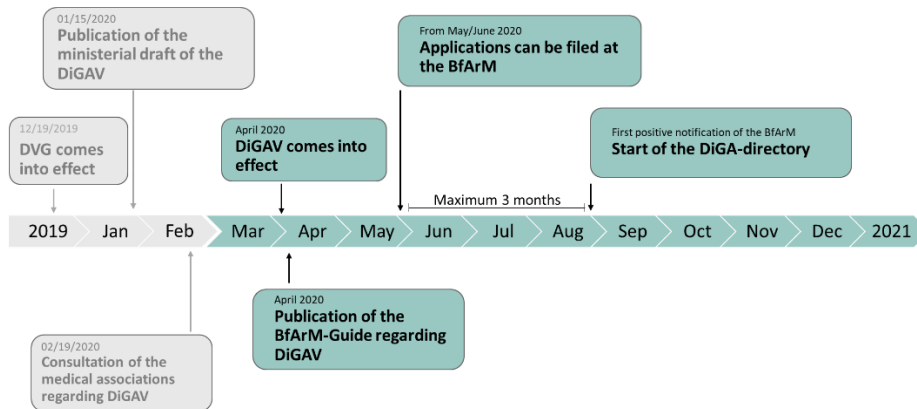


Figure 2: Implementation of the Fast Track procedure.
Source: BfArM.

1.3 The Fast Track-Guide by the BfArM

The guide of the BfArM according to Section 139e paragraph 8 clause 1 SGB V is primarily addressing manufacturers that want to apply for a listing in the DiGA directory. It should:

- present the application procedure in a clearly structured way,
- explain the requirements to be fulfilled by the DiGA and the evidence which must be provided
- present what kind of support options the BfArM offers
- describe the DiGA directory and the contained information on the listed DiGA
- explain the notification procedure in case of significant changes.

The guide serves as a summarising depiction of the ordinance and regulations to be found at various points in the SGB V, the DiGAV and in the attachments to the DiGAV. The BfArM elaborates how it will interpret the normative requirements from the DVG and DiGAV in the guide. It creates transparency about the specific requirements to be fulfilled in the procedure and ensures that all applications are processed and decided according to the same criteria. The guide represents a reliable basis for action for the applicant and the BfArM. It will be adjusted, completed and developed continuously, based on acquired experience.

Summarising depiction of the ordinance and regulations and their interpretation

At the same time, the guide is conceptualised so that all interested parties can acquire a comprehensive understanding of the evaluation criteria and therefore of the characteristics regarding the quality of a DiGA.

1.3.1 Structure of the Guide

For manufacturers, the (provisional) listing of a DiGA in the directory represents the decisive step towards eligibility for reimbursement (standard care) within the SHI. Therefore, the application and the application procedure together with the requirements regarding quality and the evidence for attainable and positive healthcare effect are the subject focus of this guide

- **Chapter 2** gives an overview of the content of the application, the application procedure and the directory for the DiGA. Manufacturers can understand which digital applications fulfill the requirements of an application to be listed in the DiGA directory, what the admission procedure into the directory of a DiGA looks like and which explanations and evidence must be provided with the application.
- The first central part of the application is the confirmation by the manufacturer that the DiGA fulfills the requirements regarding security, suitability for use, data protection, information security and quality that are formulated in Sections 3 to 7 of the DiGAV. The DiGAV contains different checklists regarding the expectations of the BfArM for an adequate implementation of these requirements which are explained in **Chapter 3** of this guide.
- The second central part of the application is the evidence that the DiGA is able to provide positive healthcare effects. **Chapter 4** describes how such positive healthcare effects are defined and how they have to be proven.
- **Chapter 5** contains the operational parts of the application procedure such as deadlines, fees, consultation by the BfArM and obligations of the manufacturer regarding the further development leading to major changes of a directory listed DiGA
- An abbreviation index, a glossary and a list of helpful online sources complete the guide.

References¹

- **Digitale-Versorgung-Gesetz – DVG from the 19th of December 2019**
Available online:
https://www.bgb1.de/xaver/bgb1/start.xav?startbk=Bundesanzeiger_BGB1&start=%2F%2F%2A%5B%40attr_id=%27bgb1119s2562.pdf%27%5D#_bgb1_%2F%2F*%5B%40attr_id%3D%27bgb1119s2562.pdf%27%5D_1585207737499
- **Digitale-Gesundheitsanwendungen-Verordnung – DiGAV**
Available online:
https://www.bgb1.de/xaver/bgb1/start.xav?startbk=Bundesanzeiger_BGB1&jumpTo=bgb1120s0768.pdf

¹ This present English version of the guide is a service provided by the BfArM, which also includes translations of the German standard texts or references to them. The corresponding standards in the German version are legally binding; these will also be available in English translation shortly.

2 Listing a DiGA in the DiGA directory

2.1 What is a DiGA and What is Not?

2.2 The DiGA Directory

2.3 Provisional and Final Listing


The following subchapters illustrate which digital applications can be admitted into the directory and explains and justifies which digital applications cannot be admitted using examples. Furthermore, an overview will be given of the processes and requirements for the provisional and final listing in the directory and of the application procedure.

2.1 What is a DiGA and What Is Not?

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.


DiGA are therefore “digital assistants” in the hands of patients.

 **Must the patient interact actively with the DiGA or can the health data be collected passively and transferred to the physician?**

No, the patient must interact with the application. A DiGA must be used by the patient alone or together with the physician. Applications that only collect and transmit data from other devices such as sensors of smartphones that data are not a DiGA.

 **Will there be changes with the transition from MDD to MDR?**



A DiGA is a medical device of class I or IIa, regardless of the applied regulation of medical devices. If the risk class is upgraded from MDD Class I to MDR Class IIa, it is permissible that the medical device can be a DiGA further on, as long as a valid CE certification is obtained, taking into account the present transitional provisions. The application would not fulfill the basic requirements if an upgrade into risk class IIb or higher becomes necessary and would consequently not be a DiGA according to the DVG.


 **Can a health-app be listed as a DiGA in the DiGA directory that was previously offered in an App-Store with an advertisement-financed business model?**

That is permissible. The BfArM only examines the version or variant of a DiGA for which an application for inclusion in the DiGA directory is made. The BfArM does not register or examine whether there were or are further or parallel versions that follow different business models.

2.1.1 Combination with Hardware

In principle, a DiGA can be a native app as well as a desktop or browser application. A DiGA can also comprise devices, sensors or other hardware in addition to software, such as wearables, as long as the main function is a predominantly digital one, the hardware is necessary to achieve the purpose of the DiGA and the hardware is not a privately financed item of everyday life such as a gym mat or smartphone for implementing the exercises guided by the DiGA. Nevertheless, the DiGA can, for example, obtain data from a smartwatch via a standard interface as long as it has been taken into account and positively assessed in the conformity assessment.


	<p>Example: App as a Desktop / Browser Application</p>
<p>DiGA</p>	<p>Description: A web application supports patients with decreased vision by offering a treatment with digitally supported visual exercises in a virtual vision school.</p> <p>Reasoning: Even browser or desktop applications can be a DiGA if the requirements are met.</p>
	<p>Example: App in Combination with a Chest Band</p>
<p>Not a DiGA</p>	<p>Description: The chest band detects pauses in breathing and the app notifies the user about the number of such pauses during the night.</p> <p>Reasoning: The main function of measuring the breathing pauses is not part of the digital service of the app.</p>
<p>DiGA</p>	<p>Description: The chest band detects the pauses in breathing of patients with sleep apnea and the app notifies the user about the number of such pauses during the night. Furthermore, the app integrates data generated by a smartwatch, which was placed on the market as a medical device and that measures the consecutive heart rate increase. This ensures a much more exact recording and evaluation of the relevant breathing pauses. Further diagnostics can be initiated, if needed.</p> <p>Reasoning: The DiGA has a decisive influence on further diagnostic steps and supports the recognition and monitoring of diseases.</p>

	<p>Example: App with Optional Hardware</p>
<p>Not a DiGA</p>	<p>Description: 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.</p> <p>Reasoning: 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.</p>
<p>DiGA</p>	<p>Description: 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.</p> <p>Reasoning: The DiGA supports the treatment of a (non-severe) illness. The integration of optional hardware does not change this.</p>

2.1.2 Combination with Services

In principal, the DiGA is a digital medical device. Services such as consultation, coaching or services by a private health insurance can be offered by the DiGA or in combination with the use of a DiGA. But these services are not considered when regarding the reimbursability in the SHI. Therefore, the evidence for positive healthcare effect must be made without referring to such additional offers. The manufacturer should clarify in which way such accompanying services might be admissible (in individual cases) in a consultation with the BfArM.

The above is not the case when considering services by SHI-accredited physicians, meaning services that the attending, resident physician (or dentist or psychotherapist) renders in connection to the usage of the DiGA. These services are reimbursed by the SHI within the framework of medical remuneration. Therefore, they can or must be included in the evidence of positive healthcare effect. Maintaining or accompanying services by SHI-accredited physicians can be described by the manufacturer within the application procedure (and can be stated additionally in the form of an EBM-code number, if known; EBM = German Uniform Assessment Standard).

 **Is telemedicine also a DiGA?**

Telemedicinal applications can generally be part of a DiGA, if the central function is mainly based on digital technologies. A purely telemedicinal platform is not permissible. The verification of the admissibility of the (accompanying) telemedicinal applications can be discussed with the BfArM in a consultation in individual cases.

 **Can services by SHI-accredited physicians also be rendered by other healthcare providers such a physiotherapists or occupational therapists?**

No, the invoicing of contract medical services within the scope of the application of the DiGA can only be carried out by registered physicians or psychotherapists.



Example: App in Combination with a Psychotherapeutic Service

Not a DiGA

Description: The app is a digital communication platform to coordinate and carry out video / telephone / chat conversations with a psychotherapist for patients with mental stress situations.


Reasoning: The central function of the app is a pure digitalisation of the communication path and does not contain further therapeutic services and does not meaningfully support these more than, for example, established communication media such as face-to-face conversation, a telephone conversation or a video chat.

DiGA

Description: The app provides a digitally designed healthcare model for patients with mild depressive episodes that gives information about the disease, records and documents moods, registers symptoms, supports the preparation of individual content such as diaries, gives guidance for relaxation or similar exercises and enables contact with a chat bot. If necessary, for example if a severe depressive episode might be coming, the treating physician or psychotherapist is automatically contacted and is prompted to establish contact.

Reasoning: The application has a digitally designed healthcare model that fulfils – as a marketable medical device - all criteria of a DiGA.

Note: The inclusion of services by SHI-accredited physicians needs to be described in the application procedure if required.

	<p>Example: App in Combination with the Services of a Dietician</p>
<p>Not a DiGA</p>	<p>Description: 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.</p> <p>Reasoning: 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.</p>
<p>DiGA</p>	<p>Description: 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.</p> <p>Reasoning: The application has a digitally designed healthcare model that fulfils – as a marketable medical device - all criteria of a DiGA.</p>

2.1.3 Scope of a DiGA


Optional services or functions that the manufacturer offers to the users of the DiGA can be additional functionalities: for example, the linkage with a social network, additional possibilities to connect devices and apps and appointment booking functions or modules belonging to the manufacturer that are certified as an independent medical device.

! The additional function cannot have any influence on the intended medical purpose of the DiGA and cannot endanger or change the positive healthcare effect. It should also be ensured that the additional functions are segregated and do not impact the DiGA in the case of an error.

The additional functions are not examined by the BfArM within the frame of the application procedure and they are not considered regarding the reimbursability by the SHI. Possible, additional costs that may arise are to be paid by the users themselves.

They must also be labelled separately, and the label must make clear that the additional functions are not a part of the tested DiGA.

Additional functions are labelled separately

	<p>Example: App in Variable Function Combinations</p>
<p>Not a DiGA</p>	<p>Description: The app accompanies patients with migraine. The CE-marked medical device contains a symptom-diary, integrates weather data, gives warnings for higher chances of migraine and guides the patient to adopt preventive behaviour and small acute treatments. The manufacturer excludes the guiding elements for the application to the DiGA, as he fears to complicate the evidence of the positive healthcare effect.</p> <p>Reasoning: The digital main function of the app must be consistent with the intended use of the medical device with CE-mark. Functions that are part of the fulfilment of the intended medical purpose must account for the functional scope of the DiGA. A tailored part of the medical device cannot be marketed as an independent product and is therefore not considered as a DiGA.</p>

DiGA

Description: The app accompanies patients with migraine. The CE-marked medical device contains a symptom-diary, integrates weather data, gives warnings for higher chances of migraine and guides the patient to adopt preventive behaviour and small acute treatments. Additionally, the manufacturer offers the fee-based linkage to social networks where the user can interact with other affected persons. The fee-based additional function is labelled as “not an aspect of the assessed DiGA according to Sec. 33a SGB V”.

Reasoning: The application has a digitally designed healthcare model that fulfils – as a marketable medical device - all criteria of a DiGA and labels non-assessed functions.



Example: App in Variable Function Combinations

Partially DiGA

Description: An app consists of two different modules that have been legally marketed as separate medical devices. Module 1 contains a digital healthcare model for the treatment of high blood pressure. Patients can document their blood pressure levels, get readings, are informed about the symptoms of hypertension and secondary diseases and are guided in lifestyle changes. Module 2 is an evaluation program for physicians which takes the levels of the patient into consideration and makes active suggestions to the physician to regulate the medication.

Reasoning: The first module is a classical DiGA. Because module 1 was marketed as an individual medical device it can be a DiGA in its own accord. The safety and suitability for module 1 are certified independently from module 2 and can be legally marketed separately. Module 2 is not a DiGA: It primarily addresses physicians and supports therapeutic recommendations.

DiGA

Description: An app consists of several different modules that are marketed as a medical device. Module 1 comprises a digital healthcare model for the treatment of depression. Patients can document their mood levels, receive evaluations, are informed about the symptoms of depression and guided toward mindfulness. Module 2 is for the treating psychiatrist or psychotherapist. The module informs the medical healthcare provider about a trend of worsening of the condition of the patient. The treating psychiatrist or psychotherapist can summon the patient on shorter notice.

Reasoning: The placing on the market of the entire app consisting of module 1 and 2 as a DiGA is admissible. The necessary services of the healthcare provider must be identified when filing the application. Removing module 2 is not permissible if it is due to manufacturer's doubts regarding the inclusion of a healthcare provider in the DiGA because it might lead to potential hurdles for a prescription. The medical device is only CE-certified as safe and suitable as a whole and must be marketed that way.


2.1.4 DiGA in Prevention

Primary prevention is directed at the general population and serves to impede the development of diseases. It is relevant when citizens are not (yet) sick. The promotion of a healthy lifestyle (nutrition, exercise etc.) in so-called prevention courses is an example for a measure taken as a part of primary prevention.

Digital applications serving primary prevention cannot be included in the directory. DiGA serve to support the "recognition, monitoring, treatment or alleviation of diseases" or the "recognition, treatment, alleviation or compensation of injuries or disabilities". The legal definition of DiGA does not contain the aspect of avoiding or preventing a disease.

Digital applications serving primary prevention are not DiGA

DiGA that contribute to prevent the worsening of a disease (secondary prevention) or a secondary disease or complication (tertiary prevention) are contained within the term "treatment". Prerequisites are that there is a risk factor in the sense of a disease and that this risk factor can be coded as a diagnosis.

	<p>App in Combination with a Scale</p>
<p>Not a DiGA</p>	<p>Description: The scale measures the weight of the patient and estimates the body fat percentage. The app documents and visualises the data.</p> <p>Reasoning: The main function of determining the weight or the body fat percentage is not part of the app. The app is not a medical device if it purely shows the data.</p>
<p>Not a DiGA</p>	<p>Description: The scale measures the weight of the patient and estimates the body fat percentage. The app documents and visualises the data. Additionally, the control and monitoring of the weight is part of a more complex accompanying program with i.e. additional information about nutrition and fitness or training plans for endurance sports and similar offers for healthy people.</p> <p>Reasoning: The app is directed at healthy people and falls into the realm of primary prevention. Therefore, the app does not serve the “recognition, monitoring, treatment or alleviation of diseases” and cannot be assigned to a therapeutic indication. Moreover, the app might not be a medical device without a medical intended use.</p>
<p>DiGA</p>	<p>Description: The scale measures the weight of the patient and estimates the body fat percentage. The app documents and visualises the data. Additionally, the control and monitoring of the weight is part of a more complex accompanying program with i.e. additional information about nutrition and fitness or training plans for endurance sports and similar offers for people with high blood pressure.</p> <p>Reasoning: The app is aimed at patients with high blood pressure and serves the treatment of a disease. It can also be ascribed to secondary-prevention-measures due to consecutive cardiovascular disease.</p>

2.2 The DiGA Directory

DiGA, which have successfully passed the test procedures of the BfArM, are listed in the DiGA directory. The most important goal of the DiGA directory is to enable and strengthen a trusting use of DiGA in healthcare by patients and healthcare providers. Moreover, many of the entries are aimed at enhancing the integration of DiGA in the structures and procedures of healthcare on an organisational, technical and practical level.

The BfArM will link to the directory on its website with the activation for the public at the latest.

2.2.1 The Content of the DiGA Directory (Section 20 DiGAV)

The directory offers comprehensive information about the characteristics and performance of the listed DiGA and thereby creates a high degree of transparency.

The directory is meant to be designed as a web portal which is structured in a user-friendly and target-audience specific way. For example, it offers different views for physicians and for patients which present the information relevant for those groups clearly. User-friendly search and filter functions ensure a comprehensive retrievability of information and support the comparison and selection of DiGA. Compulsory specifications that underlie a certain dynamic – i.e. confirmation of compatibility regarding browser-versions or the information about the interoperable export-interfaces – are maintained by the manufacturer on the application-website and are linked to in the DiGA directory.

The directory is designed in a user-friendly and target-audience specific way

The information in the directory is intended to show comprehensively which requirements the DiGA must fulfil not only regarding the positive healthcare effect and the financing by the SHI, but also regarding regulation of data protection and medical device law. In the following passages an overview is given of the content of the DiGA directory. The references at the margin offer pointers to the chapters which deal in more detail with individual manufacturer's entries which are published in the DiGA directory.

2.2.1.1 Basic Data and Information About Medical Devices

The basic data identifies the DiGA and its manufacturer both for the BfArM and for the future user. They allow for an explicit referencing of the DiGA. The directory also supplies central information about the DiGA as a medical device. This information can be relevant for both: the insured and the prescribing person.

The information provided about the basic data and medical devices comprise the following:

- Manufacturer

- Product name
- Unambiguous DiGA directory number
- The Notified Body taking part in the certification as a medical device (if that is the case)
- Intended medical purpose according to medical device law
- Instruction manual according to medical device law
- Manufacturer's liability insurance according to medical device law and the amount of the sum insured if a personal injury occurs.



Who defines the unambiguous DiGA directory number for my DiGA?

The number is automatically generated in the application procedure and supplied by the BfArM.

2.2.1.2 Information for Insured Persons and Patients

Insured persons can get approval for a listed DiGA without a medical prescription. The information presented in the directory is meant to support insured persons in the search for a suitable DiGA or the comparison of similar DiGA:

- Goal, operating principle, content and usage of the DiGA in a generally comprehensible description
- Functions of the DiGA
- Confirmed checklist regarding data protection and information security (Annex 1 DiGAV)
- Confirmed checklist regarding the quality requirements (attachment 2 DiGAV) including the reasoning handed in by the manufacturer in case there are deviations from the regulatory guides in individual cases
- Additional costs, i.e. for accessories or functions that can be optionally booked by the users of a DiGA and are paid for by the user (In-App purchases)
- Locations where the data is processed



Can the manufacturer refresh the product description submitted during the application if there is an update of my product?

In general, yes. For the prerequisites and the process see [Chapter 5.2 Life Cycle of a DiGA in the directory](#).



Will the DiGA directory contain contact information and / or support-addresses for technical and privacy questions?

No, these obligations to provide information are regulated in other laws and regulations which are applicable (i.e. article 13 GDPR). These laws and regulations regulate when, where and how contact information must be made available.

2.2.1.3 Information for Healthcare Providers

The information contained in the directory should enable healthcare providers to prescribe the most appropriate DiGA for that particular healthcare situation. Physicians should be able to recognise whether the prescription of a DiGA is connected to other services, regardless whether these are provided by the prescribing physician him- or herself or by other physicians.

The following information which is relevant for the decision whether to prescribe a DiGA is contained in the directory:

Relevant information for the prescription

- Is the DiGA finally listed in the directory or provisionally?
- Duration of the trial phase in case of a provisional listing
- Patient group / indication for the positive healthcare effect (see [Chapter 4.2.2 Specification of the positive healthcare effect](#)) that has been proven or need to be proven
- Proven or yet to be proven positive healthcare effect
- Sensitivity and specificity of the diagnostic instrument if one is contained within the DiGA
- Recommended minimum and possible maximum period of usage
- Necessary services by SHI-accredited physicians that arise in connection to the use of the DiGA (if applicable)
- Information about the applications quality control
- Explanations about the intended user roles for patients, relatives, physicians and other healthcare providers
- Suggestion for patient information about the use of the DiGA within a treatment which can be used by healthcare providers
- Currently valid price: manufacturer's price ("actual price", valid in the first year after listing in the DiGA directory) or the negotiated price ("remuneration sum", valid after the 13th month of the listing in the directory)

**Does the physician have to take the price into consideration in his or her decision to prescribe?**

Physicians underlie the efficiency rule according to Section 12 SGB V. It can be mandated for the prescribing physician in individual cases that the more cost-efficient DiGA is prescribed if no difference can be discerned between two or more DiGA regarding the therapeutic support in specific treatment cases.

2.2.1.4 Specialised Medical Information

Medical professional societies, medical associations and other institutions, which fall under the term “professional public” are not only important multipliers for good DiGA. They can also evaluate and recommend DiGA due to their expertise and experience and support physicians, insured persons and other target audiences in their choice of a suitable DiGA. For this, it is essential that the information regarding the medical and professional categorisation and evaluation of a DiGA is available to such a professional public:

Information regarding the medical and professional categorisation

- Study that was submitted for the evidence of positive healthcare effect (complete publication latest twelve months after completion of the study, link available at the place of publication)
- Study report for the study that was presented to prove the positive healthcare effect
- Scientific institute that compiled the evaluation concept for the trial of the DiGA (if applicable)
- Further studies that were carried out with the DiGA
- Sources for the medical information provided in the DiGA (link to the application-website where an overview of relevant references is maintained)
- Medical establishments or organisations which are involved in the development of the DiGA, if applicable

**Does the entire Clinical Study Report (CSR) have to be published?**

The entire Clinical Study Report must be published except for personalised data and / or trade and business secrets.

2.2.1.5 Technical Information

The technical information given in the directory ensures that insured persons can use the DiGA with the devices that they have at hand and that they can export the data from the DiGA in a format which allows a specific form of individual further use of the data.

Information about the usability with individually-owned devices and about data export

- Confirmation of compatibility by the manufacturer regarding supported platforms, devices and potential additional products

- Interoperable standards and profiles used for data

2.2.2 Handling of Confidential Information

The application form makes it clear to manufacturers which information will be made public in case the DiGA is listed in the directory. The BfArM will not change the description and information that manufacturers made in the application form when listing the DiGA.

! The manufacturer can mark the information in the application procedure which may not be made public due to legal requirements. Examples are the protection of trade and business secrets, protection of personalised third-party data or the protection of intellectual property.



The application form must be completed in full. If a manufacturer claims interests or requirements that conflict with publication, the relevant information must nevertheless be entered in the application form, as all application content must be stated and are subject to the application review by the BfArM.

BfArM staff will under no circumstances pass on information that they receive in the course of an application procedure to third parties. The information is subject to the duty of confidentiality regarding official matters, i.e. a separate declaration of confidentiality on the part of the BfArM is not required and will not be issued.

2.2.3 The Reading of Data from the Directory by Third Parties

The data in the directory will be made available to other interested public and non-profit institutions via an Application Programming Interface from 2021. Specialist societies, health insurance funds, physicians' associations, research institutions, foundations, local authorities, patient associations and other players will thus have the opportunity to query information electronically from the DiGA directory in order to disseminate it further, make further comparisons and assessments, make recommendations for their respective target groups and thus provide broad support for informed usage decisions.

Details on the Application Programming Interface and its use (registration, test access etc.) will be published by the BfArM on its website within 2020.


2.3 Provisional and Final Listing in the Directory

Before an application is made, the manufacturer of the DiGA has first to decide whether to apply provisionally or directly for final listing in the directory. This decision essentially depends on whether the manufacturer of the DiGA can


already present a comparative study to prove a positive healthcare effect that meets the requirements of Sections 10 to 12 DiGAV (see also [Chapter 4 Evidence of Positive Healthcare Effect](#) of this guide).

 **Can I make individual agreements with the BfArM before the application?**

The BfArM is bound by the normative requirements of the SGB V and the DiGAV. Agreements can only be made within this framework and then, for example, concern the selection of the study design or the specific implementation of the quality requirements. The BfArM's advisory services can be used for this purpose.

 **Can a DiGA manufacturer include one and the same product in the Fast Track procedure for one indication, if evidence is already available, and in application to provisional listing for another indication?**

Yes, this is possible. These are two different DiGA, which are listed and possibly reimbursed separately and for which separate applications for inclusion in the DiGA directory must be submitted.

 **Can I apply for final listing even if my study is not yet fully completed?**

No, the results of a completed study must be submitted. However, within the framework of a provisional listing, a study that has already been started can be completed if it can be plausibly demonstrated that this will result in evidence of a positive healthcare effect. In such a case, the BfArM may decide on a shorter trial phase than twelve months.

A DiGA has full nationwide reimbursability in the SHI system from the day of inclusion into the directory, irrespective of whether it is provisionally listed in the directory or has already been admitted definitively. This means that more than 170,000 physicians, dentists and psychotherapists in Germany can prescribe DiGA for around 73 million insured persons and that DiGA can be approved by all SHI- funds even without a prescription - e.g. if the indication is proven.

2.3.1 Application for Final Listing in the DiGA Directory

Manufacturers who have already conducted a comparative study with their DiGA that is suitable for demonstrating a positive healthcare effect can apply for final listing and, if the notification is positive, be included in the DiGA directory no later than three months after the complete application has been submitted and the BfArM has issued a positive decision (see Figure 3). Anyone who is unsure whether a study is suitable for proving positive healthcare effect can seek advice from the BfArM in advance (see [Chapter 5.4 Advice by the BfArM](#)).

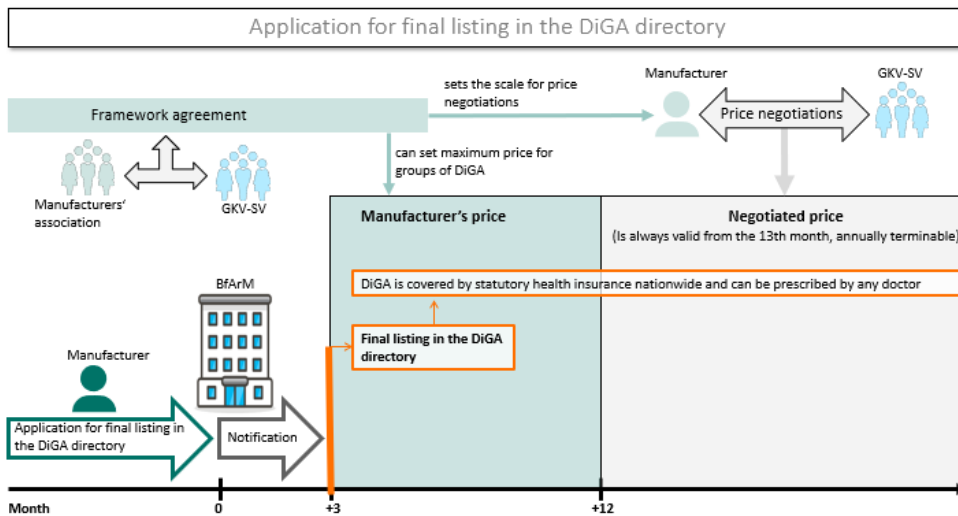


Figure 3: Application for final listing in the DiGA directory.
Source: BfArM.

I applied for final listing, but my submitted study was refused because the evidence for the positive healthcare effect was insufficient. Can I then switch to an application for provisional listing and subsequently submit a study design for testing? Or do I have to submit a completely new application?

If an application for inclusion in the directory has been refused, a new application can only be submitted after one year has elapsed, which must also include new evidence of positive healthcare effect. This does not apply, however, if the manufacturer has withdrawn the application on his own initiative before the BfArM has issued its decision. It is not possible to apply for preliminary listing and for final listing in the directory for one DiGA at the same time.

2.3.2 Application for Provisional Listing in the DiGA directory

Manufacturers who have not yet conducted a suitable study with their DiGA to prove positive healthcare effect apply for provisional listing in the directory. In this case, the DiGA must already meet all requirements in accordance with Sections 3 to 6 DiGAV (security, functional capability, quality, data protection and information security) at the time of application. Only the study to prove the positive healthcare effect can be conducted retrospectively within the framework of a trial phase lasting up to twelve months.

In order to plausibly substantiate that DiGA contributes to the improvement of healthcare and that evidence of this can be successfully provided in the trial phase, the manufacturer shall enclose with the application the results of systematic data analyses on the use of the DiGA (see [Chapter 4.5 Application for](#)

Admission to the Trial Phase). How the evidence is to be provided in specific terms is to be set out in an evaluation concept, also to be submitted to the BfArM, which has been prepared by a manufacturer-independent scientific institution (see [Chapter 4.5.2 Evaluation Concept](#)). The evaluation concept must consider the results of the data analyses submitted.

Is it possible, in consultation with the BfArM, to set a later start date for the trial phase than the accepted application (e.g. due to a delay in the start of studies)?

No, the trial phase begins with the positive notification of BfArM. It may be advisable to submit the application at a later date, as there is the possibility of refusal if it is foreseeable from the outset that evidence of the positive healthcare effect cannot be provided within the maximum duration of the trial phase.

From provisional to final listing

After provisional listing in the directory, the study to prove positive healthcare effect is carried out or a study already in progress at the time of provisional listing is terminated and the results of the study are submitted no later than at the end of the trial phase defined by the BfArM. The BfArM will then decide within three months by means of an official notification (see Figure 4). If no study results are submitted or if the application is refused, the DiGA is de-listed from the directory by the BfArM. In this case, the manufacturer can submit a new application at the earliest twelve months after the refusal of the BfArM. This is only possible if new evidence of positive healthcare effect is submitted. Repeated provisional listing in the directory for trial purposes is not permitted.

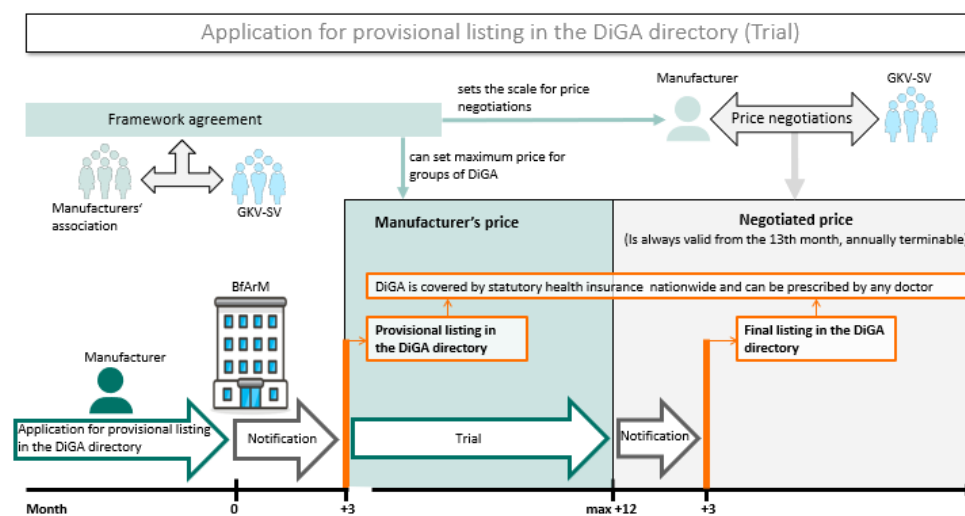


Figure 4: Application for provisional listing in the DiGA directory. Source: BfArM.



Must all patients and physicians who prescribe or use a DiGA in the trial phase participate in the study to prove positive healthcare effect?

No. The DiGA can be prescribed and used completely independently of participation in a study. It remains the responsibility of the manufacturer to recruit the test persons who may be required to conduct the study.



What happens in the period between the end of the trial phase and the decision on the final listing? Will the DiGA be deleted from the directory in the meantime?

No, the DiGA remains listed and can still be prescribed and reimbursed. The BfArM can only carry out a deletion once it has lifted the notification on the original listing.

Manufacturers applying for a trial must consider that during the trial phase they will be reimbursed for the costs of the product by way of regulations and authorizations, but that they will bear the costs of the study themselves.

In addition, the cost for DiGA provisionally listed may be lower than in the case of a final listing in the directory. This results from the provisions of the framework agreement concluded between the manufacturers' associations and the National Association of Statutory Health Insurance Funds (German: GKV-Spitzenverband) on pricing: This may provide for group-related maximum prices for the first year, and if this is the case, a lower maximum price must then be provided for the provisionally listed DiGA than for the finally listed DiGA.

Framework agreement may lead to group-related maximum prices in the first year

2.3.3 Extension of the Trial Phase

In individual cases, the trial phase may be extended once for up to twelve months. This is subject to the condition that the test results submitted make it likely that evidence will be provided later. In order to obtain an extension of the trial phase, the manufacturer has to apply for the extension of the trial phase to the BfArM at least three months before the end of the trial phase. This application must explain, why an extension is necessary and why it is probable that significant data will be available by the end of the extended trial phase (see figure 5).

Trial phase may be extended once for up to twelve months

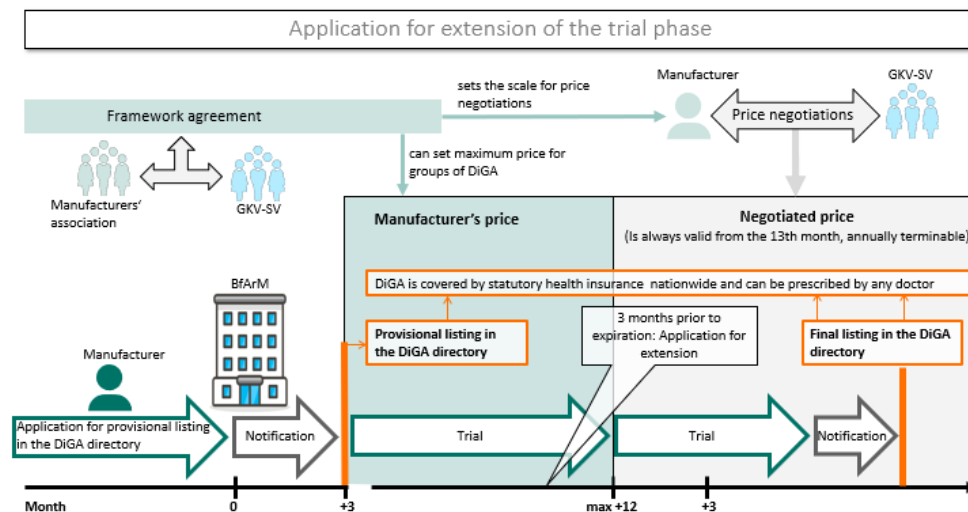


Figure 5: Application for an extension of the trial phase. Source: BfArM.

2.3.4 Technical Details for (Preparing) the Application

Before the application procedure begins, the BfArM provides information on all questions of content and form within the scope of its advisory services (see Chapter 5.4 Advice by the BfArM). The application procedure begins with the submission of the application.

A DiGA can only be included in the DiGA directory at the request of the manufacturer. Instead of the manufacturer, an authorised representative according to the Medical Devices Act, authorized by the manufacturer in accordance with article 2 number 32 MDR or Section 3 paragraph 16 MPG or a third party authorised by the manufacturer to submit the application may also submit the application. In this case the applicant proves his authorisation to the BfArM by a corresponding power of attorney of the manufacturer.

Application by the manufacturer or a person authorised by the manufacturer

! All information about the application forms and the use of the application portal can be found on the BfArM website. Applications can only be submitted digitally, no paper forms are provided, and in general no documents and

information submitted to BfArM by means other than via the application portal can be considered. An application submitted elsewhere must be refused only for formal reasons without further examination of the content.

In addition to the information provided in the application forms, the BfArM offers advice in advance as well as an application guide. Supporting documents such as the power of attorney for the eligibility to apply, the manufacturer's declaration of conformity, the Notified Body's declaration of conformity or other documents are uploaded as scans; original signatures are also not required. The application can be processed over a longer period and intermediate results can be saved before it is submitted by the applicant.

The following online forms for applications and notifications are available:

- Application for final listing of a DiGA in the DiGA directory
- Application for admission for trial phase of a DiGA into the DiGA directory
- Application for extension of the trial phase
- Application for de-listing a DiGA from the DiGA directory
- Notification of a significant change (see [Chapter 5.3 Changes to the DiGA](#))

The application must include evidence of the safety and functional capability of the DiGA. This is proven by successfully completing the conformity assessment according to MDR or MDD (valid until 25.05.2021). The certificates (or corresponding confirmation by the Notified Body that the products covered by the application fall within the scope of the certificates, if they do not exclusively relate directly to individual products, in this case the relevant DiGA) shall be attached to the application. For medical devices of class I the declaration of conformity according to MDR or MDD (valid until 25.05.2021) must be submitted. Further details are described in [Chapter 3.2 Safety and Suitability for Use](#) of this guide.

The application also includes the checklists on data protection, information security and quality, which are contained in the DiGAV as Annexes 1 and 2. The checklists contain statements on the characteristics of the DiGA or on the presupposed processes and structures, which the manufacturer must confirm to be correct. It applies for both checklists that basically all statements must be confirmed, deviations can only be one of the reasons given within the checklist.

[Checklists](#)

In the annexes, "no"-answers with an individual justification by the manufacturer are only possible in exceptional cases. Such a justification must either show that the requirement is either not reasonably practicable in the required form due to specific characteristics of the DiGA or that the objective of the requirement has been achieved by other equally or better suited means. Further details are described in [Chapters 3.3 to 3.6](#) of this guide.



We offer a digital health application as white label with our requirements. Who makes the application? We or the third party?

The application for the listing of a DiGA in the DiGA directory is always submitted by the defined manufacturer of the medical device. The manufacturer can authorise a third person to submit the application.



Are the application forms also available in English?

Yes, all application and notification forms are also available in English. Information that is transferred to the DiGA directory **must be provided in German**. All other information and possible further supporting documents that are only relevant for the examination by the BfArM can be submitted in English.

3 Requirements for a DiGA

- 3.1 Structure of the Checklists Concerning DiGA Requirements
- 3.2 Safety and Suitability for Use
- 3.3 Data protection
- 3.4 Information security
- 3.5 Interoperability
- 3.6 Further Quality Requirements

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.

3.1 Structure of the Checklists Concerning DiGA Requirements

The checklists of the appendices 1 and 2 of the DiGAV are structured by subjects:

- Annex 1: Requirements for data protection and information security
- Annex 2: Requirements for interoperability, robustness, consumer protection, ease of use, support of healthcare providers, quality of medical service and patient safety.

The compliance with every criterion is queried with one or more yes-no-statements.

All statements are formulated in a way that the compliance with the required criteria is given when all associated statements have been ticked as ‚applicable‘. Individual statements refer to certain product features of DiGA, which are not

necessarily required for all DiGA. In these cases, the checklists provide prespecified “not applicable” answers that have no negative impact on the compliance of the overall criteria.

The requirements in Annex 1 aim at a state-of-the-art implementation of data protection and information security, in which the manufacturer must consider in particular the risks specific to the DiGA and its context of use when selecting suitable measures. In individual cases, it may happen that a statement in this Annex applies in principle to a DiGA, but the manufacturer must nevertheless answer this statement with “not applicable”. For example, if assumptions are made about the state-of-the-art which do not apply in the context of the specific DiGA or at least are not without alternatives. These individual cases must be sufficiently justified in writing as part of the application in addition to the completed Annex 1.

Since the requirements in Annex 2 to the DiGAV touch on aspects which reflect the innovation potential of the DiGA and are therefore subject to a high degree of dynamism, the manufacturer of a DiGA can also justify in individual cases why a criterion applies to his DiGA while he must nevertheless answer a particular statement with “not applicable”. The justification must show that the means chosen by the manufacturer in the DiGA are at least equivalent to the implementation implied in the statement with regard to the fulfilment of the overall criteria.

If the manufacturer can foresee that he will have to mark several statements in Annexes 1 and 2 with “not applicable”, it is urgently recommended to seek consultation from the BfArM before submitting the application.



A “not applicable” answer not specified for selection in Annex 1 or 2 requires a written justification why the overall criteria of the statement are nevertheless fulfilled. The application is considered incomplete if such a justification is missing, and a request to submit the justification will follow after the initial formal check by the BfArM. If the manufacturer does not provide a plausible justification within the set time limit, the application must be refused by the BfArM without further examination.

3.2 Safety and Suitability for Use

The SGB V requires manufacturers of a DiGA to prove the safety of the device and its suitability for use as part of the application procedure.

Compliance with the requirements concerning the safety of the device and suitability for use is regarded as proven with a valid certificate of conformity / EG Certificate respectively the declaration of conformity of the manufacturer.

As a rule, the BfArM only carries out checks on the formal legality of the CE marking for this requirement.



I cannot get a timely appointment for certification with a Notified Body because everything is fully booked. Are there any exceptions to be made so that, in the absence of capacity, the company can be included, at least provisionally, even without certification as a medical device?

No, exceptions are possible. Prerequisite for inclusion in the DiGA directory is the completed conformity assessment procedure and the marketability of the DiGA as proven by the CE marking.

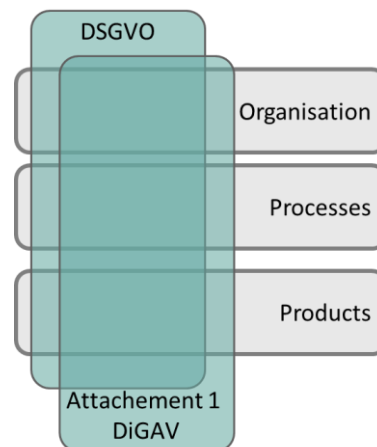
3.3 Data Protection

Insured persons as users of a DiGA must be able to rely on the fact that the manufacturer complies with legal requirements for data protection, handles their data carefully and implements measures to protect confidentiality, availability and integrity. Therefore, the DiGAV specifies and supplements the requirements of the General Data Protection Regulation (GDPR) and other data protection regulations for the manufacturer, for the DiGA itself and for all systems in connection with the DiGA (including processors such as cloud providers).

Manufacturers of DiGA will generally be private sector companies. In addition to the GDPR, the Federal Data Protection Act (BDSG) applies to these companies. In the BDSG, the regulations for non-public bodies then apply. If a manufacturer is a public body of a federal state or the federal government, the BDSG would also apply, as these bodies are public-law companies in competition with non-public bodies and these bodies are therefore also treated as non-public bodies (cf. Section 2 paragraph 5 BDSG)

The main regulation for the processing of health data is Section 22 BDSG (in conjunction with Article 9 GDPR, if applicable). For special areas, further data protection regulations from other laws may be relevant, which may result from regulations concerning medical devices or SGB V. For example, it must be paid attention to Section 302 SGB V regarding billing issues.

The DiGAV also contains very specific requirements in form of Annex 1, which are essential for a listing in the DiGA directory. The checklist to be completed by the manufacturer of the DiGA for the application contains 40 statements which take into account both the technical implementation of the DiGA (e.g. technical and organisational measures in accordance with Article 32 GDPR) and the organisation of the manufacturer and its processes (e.g. ensuring cooperation with external healthcare providers are in accordance with data protection regulations by contracts for processing on behalf of a data processing agreement).



Not all aspects of the GDPR are explicitly queried here, but individual requirements of the GDPR for the use of digital devices in the healthcare sector are further specified (see adjacent chart). This in particular applies to:

- permitted purposes of data processing
- the non-reliability of data processing abroad on the basis of Article 46 GDPR,


which will be specified in the following chapters.

3.3.1 Permitted Purposes of Data Processing


Section 4 paragraph 2 DiGAV restricts the possibility otherwise available under the GDPR of obtaining consent for the processing of personal data - and here in particular health data - by the manufacturer of a DiGA to certain purposes. However, if processing is permitted under other laws or regulations, the DiGAV does not prohibit such processing.

For the manufacturer of a DiGA this means:

- The processing of personal data for the purposes listed in Section 4 paragraph 2 DiGAV requires the express consent of the person concerned.
- Data may also be processed without consent if other legislation permits or orders it. This concerns in particular:
 - o The billing of the DiGA manufacturer to the statutory health insurance funds according to Section 302 SGB V
 - o Compliance with requirements of medical device regulations (e.g. according to MDR (MDD / Medical Devices Act until 25.05.2021, respectively).
- It is not permitted to obtain consent of the person concerned to legitimise the processing of health data for purposes other than those specified in Section 4 paragraph 2 clause 1 DiGAV

 **In the DiGAV there is no explanation of which data I can process for billing with health insurance companies. Section 4 paragraph 2 clause 1 DiGAV does not even list such a billing as a permissible purpose of data processing. Does this mean that I may only use the data collected for the purposes of Section 4 paragraph 2 clause 1 DiGAV for billing purposes and may not collect any further data for this purpose?**

No. The billing of digital health applications to the health insurance funds falls under Section 4 paragraph 2 clause 3 DiGAV (data processing authority according to other regulations remain unaffected), as the billing is regulated in Section 302 SGB V. This means that regarding the permissible purposes and legitimately processed data for billing, the DiGAV specifications are not to be considered, but the specifications from Section 302 SGB V.

 **As a DiGA manufacturer, I do not want handle billing for the DiGA usage with all statutory health insurance funds individually and would like to use billing office instead (analogous to what pharmacies do). Can I do that? Do I need to obtain the consent of the insured person?**

Section 302 paragraph 2 SGB V explicitly permits the use of data centers by healthcare providers for billing purposes. The billing being handled by a healthcare provider, who is involved via a data processing agreement is thus permissible and does not require additional consent. However, the manufacturer must at least inform the users in the privacy notice for the DiGA which data are processed by which processor for which purpose in accordance with Article 13 GDPR.

3.3.2 Permitted Data Processing according to Section 4 paragraph 2 Clause 1 and 2 DiGAV

At the beginning of the use of DiGA and prior to the collection and further processing of personal data by the DiGA, a voluntary and informed, explicit consent of the person concerned must be obtained. The consent does not have to be in writing but can be given electronically. Numbers 1 to 3 of Section 4 paragraph 2 clause 1 DiGAV focus on data processing that results directly from the Fast Track procedure and the use of DiGA in the SHI:

1. **Intended use of the DiGA by the users:** This includes all data collection and processing, which is necessary to use the DiGA in accordance with its intended use in the context of medical treatment. Which data are necessary for this, depends to a large extent on the respective DiGA. The standards of the GDPR, in particular data minimisation and data protection-friendly technology design through *Privacy by Design* and *Privacy by Default*, continue to apply without restriction.
2. **Evidence of positive healthcare effects in the context of a trial according to Section 139e paragraph 4 SGB V:** In case of a preliminary

listing in the DiGA directory a comparative study must be carried out in order to prove the proclaimed positive healthcare effects. Personal data, including health data, may be collected and processed for this purpose with the consent of the users participating in the study. In particular, the requirements of the GDPR with regard to adequacy and the respective purpose must already be considered in the study design. An approach following the principle “we record everything we can get and then we see what we really need” is not according to the guidelines.

3. **Verification in the case of agreements according to Section 134 paragraph 1 clause 3 SGB V:** The mentioned regulation requires performance-related price components for price agreements between SHI funds and DiGA manufacturers. For example, performance indicators of the DiGA, such as a low dropout rate, can be defined here and included in the reimbursement. The collection and / or processing of data required for this purpose are permitted with the consent of the persons concerned. Again, the requirements of the GDPR regarding adequacy and the respective purpose must be considered when creating the concept for measuring the agreed performance indicators.

! The processing of data for these purposes is not permitted by default. The consent of the insured person must be obtained.

The listed processing purposes according to Section 4 paragraph 2 clause 1 number 1 to 3 DiGAV can be combined in one consent. This applies in particular if data is required for the purposes of numbers 2 and 3 (cumulatively), in addition to data for the purpose of using the app (number 1), in order to carry out a trial or to be able to determine performance-related price components. In this case, a separation of consents would not be possible because the DiGA would then not be offered. This can be done by means of a declaration of informed consent provided unilaterally by the DiGA manufacturer. However, requirements of the GDPR with regard to being informed, voluntariness, explicitness and the right to withdraw must be considered. Here, statements 2 to 10 in Annex 1 of the DiGAV offer a good initial orientation.

The collection of consent components according to numbers 1 to 3 must be adapted to the circumstances of use, i.e. consent to data processing within the framework of a study to prove positive healthcare effects can only be obtained from users who also participate in this study - possibly only as a comparison group. This is a consequence of the coupling prohibition according to Article 7 paragraph 4 GDPR in which the fulfilment of a contract - here the DiGA user-relationship with insured persons may not be made dependent on consent to the processing of personal data which is not necessary for the fulfilment of the contract. This requirement only applies if performance-related price components have already been agreed with the Electronic Identities and Trust Services in E-Government or if data collection is necessary in the course of the trial phase. Provided a respective adjustment is made, the insured person cannot exclude some of the data processing operations referred to in numbers

1 to 3 which means: If the manufacturer has agreed performance-related price components with the health insurance funds and if certain data must be processed to measure them, the insured person can only object to this by objecting to the consent as a whole and thus to the use of the DiGA. Irrespective of this, the user must be able to recognise optional consents as such and individually refuse or revoke them. If performance-related price components or the inclusion of data in the trial phase is therefore not mandatory, further differentiation could (and should) be made.

Beyond the three above-mentioned purposes, the manufacturer of the DiGA may obtain additional consent for the fourth data processing purpose mentioned in Section 4 paragraph 2:

- 4. Permanent guarantee of the technical functionality, ease of use and further development of the DiGA:** The stated data processing objectives do not relate to system logs and operational metric necessary for the regular maintenance of secure operations. These should either not be processed on a person-related basis or, unless technically feasible, be considered as part of numbers 1 to 3.

The data processing referred to in number 4 is primarily in the interest of the manufacturer in order to optimise feedback, sustainability and further development. It only indirectly affects the current operation and use. The display of user questionnaires via the DiGA for the collection and subsequent processing of feedback on user experience or on possible technical problems is therefore permitted – provides that consent has been obtained beforehand data processing for further development of the DiGA is also permitted by means of consent in accordance with number 4. However, comprehensive tracking of user activities is not permitted.



If the insured person refuses or revokes the consent under number 4, the consent under numbers 1 to 3 is not be affected by this. The insured person must be able to continue using the DiGA without restrictions.

This requirement suggests the fact that the processing purpose according to number 4 is not decisive for the functionality of the DiGA and that the corresponding consent is optional. As it is clearly stated in number 4 that it is only due to internal purposes and processing by the DiGA manufacturer, a refusal to give this consent cannot have any influence on the functionality visible to the user.

Example

A DiGA reads out data from heart rate monitors. In accordance with Section 6 DiGAV, a standardised interface is used for this purpose, so that insured persons can use the DiGA with any medical device that supports this interface. By way of consent in accordance with Section 4 paragraph 2 clause 1 number 4 DiGAV (see above), the manufacturer asks the user if the DiGA may also collect product data and other operating data on the heart rate monitor used and pass it on to the manufacturer.

Good practice: permitted target of the manufacturer

This enables the manufacturer to identify which devices are particularly popular (e.g. in order to support them even more specifically) and, if necessary, which types of errors occur frequently in which device configurations (e.g. in order to make direct contact with the manufacturers of these heart rate monitors).



Do restrictions and requirements of the DiGAV that go beyond the GDPR have to be implemented before the application is submitted or is compliance with the GDPR sufficient until then?

Upon application, the requirements of the DiGAV regarding privacy and data protection must be fully implemented and proven. Any applicable law relevant to health applications, such as the GDPR, remains unaffected and applies even before the application is submitted (and of course afterwards).



Does a general coupling prohibition apply to the DiGA or would it be permissible to release certain additional functions for users only in exchange for data?

A general coupling prohibition applies to the DiGA, i.e. a “payment” with data for features within a DiGA is not permitted. This would require consent, which, however, would not be justified by any of the permissible purposes from Section 4 paragraph 2 and could also not be justified by data processing requirements from other regulations.

3.3.3 Data Processing Outside of Germany

The GDPR allows data processing within the EU. Data processing outside the EU in a so-called third country is permissible when a comparable level of data protection exists in the third country (adequacy decision according to Article 45 GDPR). The extensive exceptions according to Articles 46 and 47 GDPR are not applicable to DiGA due to the special need for protection of the processed data, which can be assumed as a rule.

Just like the rules applicable to health insurance funds (Section 80 of the SGB X), the DiGAV restricts the place of data processing to the Federal Republic of Germany, the member states of the EU, the contracting states of the Agreement on the European Economic Area and Switzerland and states for which an

adequacy decision has been made in accordance with Article 45 GDPR. Processing of personal data outside the EU on the basis of Article 46 GDPR (standard contractual clauses) or Article 47 (Corporate Binding Rules) is not permitted for DiGA.

An up-to-date list of states, for which an adequacy decision according to Article 45 GDPR has been made, included the USA. This adequacy decision applied for companies was covered by the EU-US Privacy Shield. However, the Court of Justice of the European Union invalidated Decision 2016/1250 of the European Commission from July 12th 2016 on July 16th 2020 with their judgement in case C-311/18. The Court of Justice decided that Decision 2016/1250 is irreconcilable with Article 45 of the GDPR because Article 1 of it is incompatible with the rights resulting from article 7 and 8 of the Charter of Fundamental Rights of the European Union and does not provide sufficient legal protection with regard to article 47 of the Charta. Decision 2016/1250 is therefore invalid in its entirety.

Processing of health data in the USA is therefore not permissible for a DiGA.

References:

- **List of states subject to an adequacy decision):** Available online: https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en

3.4 Information Security

The requirements concerning data protection refer to the protection of confidentiality, integrity and availability of all data processed via a DiGA.

Criteria for information security are summarised under two sections “Basic Requirements that Apply to All Digital Health Applications” and “Additional Requirements for Digital Health Applications with a Very High Need for Protection” in Annex 1 to a DiGA. All requirements for information security listed under the heading “Basic Requirements” must be fulfilled without exception or must not be applicable to certain types of a DiGA due to their non-applicability. The requirements under the heading “Additional Requirements with Very High Need for Protection” need only be considered if a very high protection need has been identified for the DiGA due to the type of data processed, the addressed care scenarios and / or the context of use.

The specifications in the DiGAV for information security are based on the relevant publications and recommendations of the Federal Office for Information Security (BSI) starting from the processes of a management system for information security described in the BSI standards 200-1, 200-2 and 200-3. These are supplemented by components of the IT-Grundschutz catalogues (IT-basic data protection), which focus on the subject area of a DiGA (use of digital applications in healthcare).

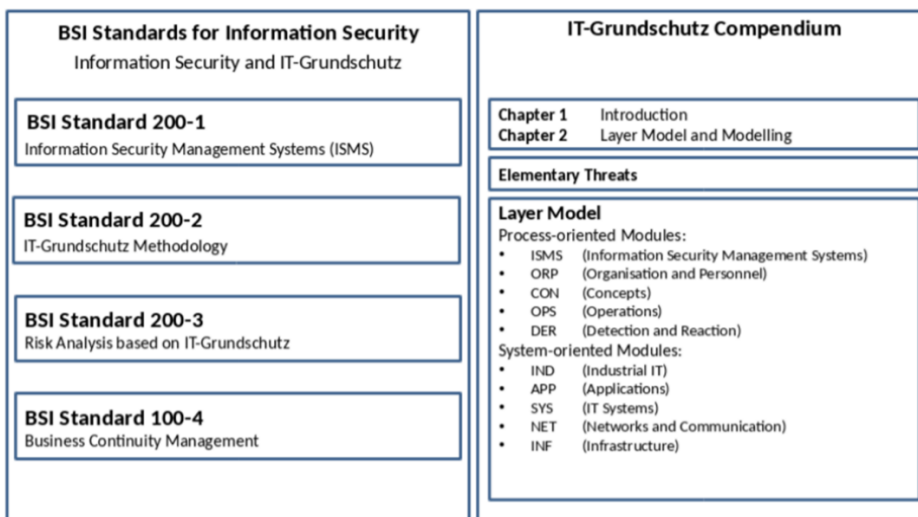




Figure 6: Requirements and recommendations of the BSI regarding information security.
Source: BSI-Standard.

 **In a DiGA, can the mechanisms offered by iOS or Android for sharing data such as AirDrop, email or WhatsApp be used to send health data to physicians or relatives?**

The DiGAV does not contain any separate ordinance in this regard; general data protection law applies. This means that such possibilities are not basically excluded for a DiGA. However, for the specific DiGA and its typical user group,

risks to data protection and information security must be analysed and evaluated and, if necessary, appropriate measures must be taken to protect them. Informed consent and transport layer security will probably be unavoidable here. In the case of a very high protection requirement, measures of end-to-end encryption will certainly also have to be provided.

 **In principle, a DiGA can transfer data to other DiGA, to platform services such as Apple Health or to third-party software. Does number 39 of the checklist, which makes consent for data transfers mandatory, always apply?**


If data are transferred to another DiGA, this falls under number 39 of the checklist, i.e. consent is required in any case. If data is transferred to Apple Health, the GDPR applies. This means that consent is required, as is already the case with Apple Health. If data is transferred to other software, the GDPR also applies, but then the need for consent depends primarily on whether third parties should or can access the data.

3.4.1 Management System for Information Security

A challenge in ensuring information security is the aspect that a “secure DiGA” is always only a snapshot: The DiGA evolves in short release cycles, and new threats and risks affect it from outside. Security measures that are state-of-the-art today can therefore be ineffective in just a few months.

In order to meet the high market dynamics and the fast release cycles of DiGA, the DiGAV takes the approach of regarding information security less as a conglomerate of technical measures, but rather as a process to be anchored in the company. Such a process manifests itself in a management system for information security (ISMS), as it is described, for example, in ISO standard 27001 and the BSI standard 200-1, which is based on the ISO standard 27001:

Definition ISMS [BSI-Standard 200-1]: The ISMS defines the instruments and methods that the management level uses to comprehensibly manage (plan, use, carry out, monitor and improve) the tasks and activities regarding information security.

 **ATTENTION:** The implementation of a complete ISMS in accordance with requirement 1 on information security in Annex 1 to the DiGAV is only required for DiGA that file an application for inclusion in the DiGA directory after 1.1.2022. In further updates of this guide the BfArM will announce which structures and processes are to be set up, so that an ISMS is regarded as comparable to the ISO 27000 series or BSI standard 200-2. The exact requirements for Evidence to be presented that is comparable to a certification will also be specified in this context.

3.4.2 Security as a Process

Even though DiGA manufacturers are not yet required to implement an ISMS according to the ISO 27000 series or BSI Standard 200-2 by 2022, the Annex 1 to the DiGAV requires the establishment of a series of processes for all DiGA in order to anchor the basic idea outlined above of security as a process at the manufacturer and to ensure the continuation of a security level once achieved:

- **Protection requirement analysis:** The manufacturer must carry out a structural analysis of the DiGA and its life cycle (including operation and billing), on the basis of which the protection requirements of data, applications, systems etc. are determined. If a very high need for protection is determined here, the checklist of additional requirements for digital health applications with a very high need for protection (also part of Annex 1 to the DiGAV) must be completed in addition to the checklist of basic requirements. Substantial changes to the DiGA require a re-evaluation of the need for protection in any case.
- **Release-, Change- und Configuration-Management:** DiGA are characterised by quickly adapting to new customer and market requirements, which is expressed among other things in short update and release cycles. On the other hand, there are the formalised processes of the MDR (or the MDD / MPG) and the DVG for dealing with changes to a DiGA. The release, change and configuration management processes to be set up by the manufacturer of a DiGA are intended to build a bridge, here, by structuring the evaluation of updates and releases in relation to the regulatory framework of MDR (or MDD / MPG) and DVG as well as to the necessary re-evaluation of protective measures, risks and other measures. This prevents, for example, the possibility that a significant change to the DiGA according to Section 18 DiGAV, which would require notification according to Section 139e paragraph 6 SGB V, is only recognised as such after development has been undertaken
- **Directory of libraries in use and market monitoring:** Third-party software such as libraries and frameworks developed by third parties are not only subject to their own update and release cycles, but also potentially to risks and threats resulting from the technical implementation appearing as a black box to the DiGA manufacturer. The promises regarding information security which the DiGA manufacturer makes to the BfArM and not least to its customers extend beyond its own code and operation to this third-party software. In order to fulfil the information security requirements of a DiGA, the manufacturer must keep a list of the third-party products (including open source) used in the DiGA and have set up processes which are suitable for the purpose of market surveillance in order to obtain and evaluate security-relevant, device-related information as quickly as possible. Examples are:
 - Security critical updates are available.

- New attacks have become known.
- There are new best practice recommendations for configuration and / or operation.
- Support expires or the community of an open source component no longer ensures further development to the required extent.



My company has an ISMS certified according to ISO 27000 series or BSI Standard 200-2, which covers the entire life cycle of my DiGA, including operations. Is this sufficient as evidence of implementation of the information security requirements or do I still have to fill out the information security checklist in Annex 1 of the DiGAV?

In this case, adequate solutions for implementing most of the requirements in the information security checklist in Annex 1 of the DiGAV for DiGA and its operations should already be implemented from the processes controlled via the ISMS. This must nevertheless be verified by the manufacturer and documented in a binding manner by completing the checklist accordingly.

3.4.3 BSI-Grundschutz-Components and Technical Guides

The majority of requirements named in the checklists for information security is derived directly from the requirement catalogues of the BSI-IT-basic data protection, whereby its specifications were limited or adapted as far as possible to the specifics and the application context of DiGA.

The BSI formulates possible threats to IT security and requirements for measures against these threats in the IT-basic protection compendium. Additional specifications and recommendations for such measures are given via the individual components of basic IT protection. For the understanding and implementation of the requirements of the checklists for information security in Annex 1 of the DiGAV, depending on the technical implementation of the DiGA, the explanations of the BSI IT basic protection compendium on the following modules are particularly helpful- but not finalized:

- APP.1.4: Mobile Applications (Apps)
- APP.3.1: Web applications
- SYS.4.4: General IoT Device

The exact procedure for taking appropriate measures on the basis of a protection requirements determination is described in the BSI standards 200-2 and 200-3.



Which technical guidelines of the BSI do I need to know in order to implement the requirements formulated in the checklist for information security in Annex 1 with state-of-the-art technology?

In particular - but not conclusively! - the following guidelines should be mentioned:

- BSI TR-02102-1 Cryptographic Mechanisms: Recommendations and Key Lengths
- BSI TR-02102-2 Cryptographic Mechanisms: Use of Transport Layer Security (TLS)
- TR-03107-1 Electronic Identities and Trust Services in E-Government



Many existing medical devices and wearables do not allow to intervene from a DiGA into the device configuration or to delete data in the device (and / or the manufacturer forbids this via general terms and conditions). For such devices, a DiGA cannot fulfil the requirements 33 and 34 from the data protection checklist.

The requirements for controlling external medical devices and wearables always refer to what is technically feasible. If individual sub-items in the criteria 33 and 34 of the data protection checklist cannot be implemented for the devices used by the DiGA due to missing interfaces or legal restrictions (e.g. also liability risks), this must be justified accordingly in the application. See also [Chapter 3.1 Structure of the Checklists Concerning DiGA Requirements](#).

3.4.4 Requirements in Case of an Increased Need for Protection

If the protection requirements determination (requirement 2 in the information security checklist in Annex 1 of the DiGAV) has identified very high need for protection of the DiGA, the manufacturer must also complete the checklist of additional requirements for DiGA with very high needs for protection (also part of Annex 1 of the DiGAV). The additional requirements identified in this case concern the following issues:

- For the device version (major release) for which listing in the DiGA directory is requested, a penetration test must have been performed for all system components connected to the internet. These tests must be repeated as required, e.g. when new interfaces are added to the internet (see question below)
- Data stored on servers (e.g. in a cloud) must be encrypted. Whether hard disk encryption, database encryption, encryption of containers or other technical procedures are sufficient, whether a hardware security module (HSM) is required and how the keys are to be managed must be determined and justified on the basis of the definition of protective needs and risk analysis.
- Access to health data is only permitted as a result of a 2-factor authentication of the person accessing the data. A list and evaluation of various technical implementations can be found in the BSI publication "Evaluation of Authentication Solutions According to TR-03107". [https://www.bsi.bund.de/SharedDocs/Downloads/DE/BSI/Publikationen/TechnischeRichtlinien/TR03107/TR-03107-1_Anforderungen.pdf?__blob=publicationFile&v=4].

From 2021, a 2-factor authentication of insured persons must also be supported via the NFC interface of the current generation of the health insurance card (eGK). The BMG has already carried out a project for a technical evidence of concept for this matter in 2017. The documentation for this, including notes on possible technical implementation (including source code as open source), can be found at <http://ask.fokus.fraunhofer.de/ergebnisse>.

When does a DiGA have a very high need for protection?

For the classification of the protection requirements, the specifications of the BSI standard 200-2 apply, and Chapter 8.2 of this standard describes the procedure for determining the protection requirements of a DiGA. Table 4 on page 107 lists criteria for a very high need for protection requirement. When examining the checklist for data protection in Annex 2 of the DiGAV, the BfArM will use this table as a guide and, if necessary, request an explanation from the manufacturer why the DiGA does not have the properties listed in Table 4 of the BSI Standard 200-2.

We develop agile and plan to distribute an update of a DiGA every four weeks via the App-Stores. Do I have to do pen tests for each update?

Security as a process: For each change to the DiGA and / or the framework conditions, it must be examined how this changes the risks and threats analysed and whether the protective measures are still enough. This must be done continuously even without updates, e.g. if a security vulnerability is detected in a library in use. If the DiGA security risk assessment concludes that there are new threats that can be better analysed / detected by a pen test, then such a test must be repeated. If not, no new pen test must be performed. In general, however, it should be considered: At a certain point in time, the point at which a new penetration test is needed will be typically reached, since significant changes have occurred since the last penetration test. The execution of a penetration test does not have to be reported to the BfArM again.

References²

- **BSI Standard 200-1.** Available online:
https://www.bsi.bund.de/SharedDocs/Downloads/DE/BSI/Grundschatz/Kompendium/standard_200_1.pdf?__blob=publicationFile&v=8
- [2001_en_pdf.pdf?__blob=publicationFile&v=3](https://www.bsi.bund.de/SharedDocs/Downloads/DE/BSI/Grundschatz/Kompendium/standard_200_1.pdf?__blob=publicationFile&v=3)
- **BSI Standard 200-2.** Available online:
https://www.bsi.bund.de/SharedDocs/Downloads/DE/BSI/Grundschatz/Kompendium/standard_200_2.html;jsessionid=0AFFF7A85700D6647133F711AD3F0152.1_cid341

² Some of the BSI Standards are also available in English language. However, the English version is not matching exactly with the German version. Therefore, this guide is referencing the German version.

- **BSI Standard 200-3.** Available online:
https://www.bsi.bund.de/SharedDocs/Downloads/DE/BSI/Grundschutz/Kompendium/standard_200_3.html
- **BSI IT-Grundschutz-Kompendium – Werkzeug für Informationssicherheit.** Available online:
https://www.bsi.bund.de/DE/Themen/ITGrundschutz/ITGrundschutzKompendium/itgrundschutzKompendium_node.html
- **BSI TR-03161 Safety requirements for digital health applications**
Available online:
https://www.bsi.bund.de/SharedDocs/Downloads/DE/BSI/Publikationen/TechnischeRichtlinien/TR03161/BSI-TR-03161.pdf?__blob=publicationFile&v=2

3.5 Interoperability

Interoperability refers to the ability of technical systems to cooperate on a technical-syntactical, semantic and organisational level.

Technical and syntactical interoperability aims at the exchangeability of data over networks in a specific data format, so that sender and receiver can identify the same information units. **Semantic** interoperability is intended to ensure that sender and receiver have a uniform and identical understanding of the meaning of the exchanged information and its context. **Organisational** interoperability defines the social and legal framework in which, for example, the roles of the actors and their access and interaction authorisations are recorded.

Definitions: technical-syntactical, semantic and organisational interoperability

Interoperability is becoming increasingly important for healthcare by the SHI. It is the only way DiGA and other digital applications can be used sensibly and efficiently with network effects being achieved. DiGA should prospectively communicate with each other and interact with other services and applications on the national e-health infrastructure, so that real added value for healthcare can be achieved. Examples are automated testing for drug interactions in a physician's system or the visualisation and explanation of laboratory data in a patient app in the personal health record (ePA).

Therefore, interoperability is an essential quality feature of DiGA and thus falls under the requirement in Section 139e paragraph 2 SGB V. This is further specified in Sections 5 and 6 DiGAV and in Annex 2 of the DiGAV ("Interoperability"). These specify which interfaces of a DiGA are to be designed as interoperable and how interoperability must be achieved by using standards.

3.5.1 Use of Standards and Profiles

In order to achieve interoperability, specifications are made on the format, content and meaning of data exchanged between technical systems, which are to apply within a specific context of the interaction of these systems. Such specifications can be standards, profiles or guides.

- **Standards** are definitions of the format and semantics standard of data streams that have been agreed by a standardisation organisation in a participatory process that follows clear rules (consensus standard).

Definition: standards

International standards are often rather general, as they are intended to address a variety of application scenarios in as many national checklist systems as possible. For example, a standard may specify that a patient ID must be given at a certain position in a data set without specifying which IDs are permitted. A German adaptation of this standard would require that the health insurance number be specified at this point.

Definition: profiles

- Adaptations that concretise a standard for a specific country and / or a specific field of application are called **profiles**.
- The combination of profiles into an overall package covering a specific use case is called a guide, often also an implementation guide, as these are precise and complete “instructions” for interoperable integration (implementation) in digital applications.

Definition: guide



It is stated that the health insurance number is to be used as the patient ID. Does this mean that the health insurance number must always be collected and stored if a database based DiGA is implemented?

The mention of the health insurance number (see above) is given only as an example to explain the implementation of standardisation. The use of the health insurance number is not specified in the DiGAV. Use of the insured person number is only required within the scope of the regulations and billing in accordance with Section 302 SGB V.

3.5.1.1 Vesta and MIOs as the Basis of an Interoperable e-Health Infrastructure

For many issues there is more than one standard or more than one profile, e.g. because different organisations have dealt with the same issue or because similar solutions have been developed from different perspectives. Other questions, on the other hand, can be so specific that there is not yet a standard that can be used within the German healthcare system, or solutions that are in principle suitable internationally exist, but have not yet been profiled for use in the German healthcare system.

In order to achieve an interoperable e-health infrastructure in Germany, structures and processes are needed that create transparency about existing standards and profiles and promote the targeted development of required profiles across all stakeholders. Essential elements in this regard are the vesta standards directory of gematik (vesta-directory) and the procedure for the development of medical information objects (MIOs) for the personal health record (ePA) as laid down Section 291b paragraph 1 clause 7 SGB V:

- In Germany, the online platform vesta, managed by gematik, aims to be the central and independent directory for IT standards in the German healthcare system. It not only lists the standards, profiles and guidelines known in the German healthcare system, but in cases of competing specifications, it also aims to provide recommendations as to which standard, profile or guide is to be preferred under which conditions. Providers of electronic applications in the healthcare system that are financed by SHI funds and that use relevant standards, profiles and guidelines must have them included in vesta standards. The online-platform vesta is publicly available via <https://www.vesta-gematik.de/>

- In future, the personal health record (ePA) will be the central data hub for the exchange of medical documents between healthcare providers. It will be in control of the insured persons. The content of the ePA must be interoperable so that the data can be used across institutions and sectors. In addition, the documents transmitted via the ePA should ideally be structured and coded in order to allow machine evaluation, analysis, classification and further processing. The definition of these interoperable formats is the task of the Federal Association for Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV), which draws up the necessary specifications for MIOs, that will be exchangeable via the ePA. This happens in consultation with other actors named in Section 291b paragraph 1 SGB V and with an open commentary procedure. The MIOs that have been agreed upon and are in progress can be viewed via the URL: <https://mio.kbv.de/>.

3.5.2 The Cascade of Section 6 DiGAV

The specifications in Sections 5 and 6 of the DiGAV concerning the interoperability of DiGA support the consolidation of data formats that can be found in practice, which is pushed by vesta and the standardisation of MIOs under consideration of the market events. Decisive for DiGA manufacturers is the cascade defined in Section 6 DiGAV, which prioritises which standards are to be used in preference to others:

1. If an interoperable interface of a DiGA demanded in the DiGAV can be implemented via a MIO defined by the KBV or a standard or profile marked as recommended in the vesta directory, this MIO or this standard or this profile must be used. Since there will be no recommendations in the vesta directory for standards or profiles competing with MIOs, there cannot be a situation where both a MIO and a standard or profile recommended in the vesta directory are available for selection (or then the recommended profile is exactly the MIO).
2. As far as there is no MIO and no standard / profile / guideline recommended in the vesta directory, over which the demanded interoperable interface could be realised, the manufacturer of the DiGA has three options, which stand equivalently side by side:
 - The manufacturer implements the required interoperable interface in the DiGA via an existing open, internationally recognised interface and / or semantics standard. This can be, for example, a FHIR profile definition defined by HL7.
 - The manufacturer implements the required interoperable interface in the DiGA via a self-defined profile using one or more existing open, internationally recognised interface and / or semantics standards. This can be, for example, the combination and extension of several HL7-FHIR profile

definitions. To use this option, the manufacturer must apply for the inclusion of the resulting interface specification in the vesta directory at the gematik.

- The manufacturer implements the required interoperable interface in the DiGA via a self-defined profile over one or more specifications already listed in the vesta directory. Again, to use this option, the manufacturer must apply for the inclusion of the resulting interface specification in the vesta directory at the gematik.

The works of the national standardisation and profiling organisations (e.g. HL7 Germany) and the Interoperability Forum make an important contribution to the efforts outlined above to establish a cross-sectoral German e-health infrastructure. Accordingly, when evaluating the implementation of the specifications from the Sections 5 and 6 DiGAV, the BfArM will interpret the term “open, internationally recognized interface and semantics standards” in such a way that the characteristic of international recognition is essentially derived from an open, regulated, non-discriminatory development process and does not necessarily mean that a standard or profile is in use worldwide. Thus, the following are considered open, internationally recognised interfaces and semantics standards in any case:

- all standards of HL7, ISO, NEMA and their profiling by HL7 and IHE,
- all semantics standards listed on the website of the former DIMDI, now BfArM office Cologne, (www.dimdi.de) as well as LOINC and SNOMED CT,
- Profiles of open, internationally recognised standards that have undergone a proper consensus procedure at a national Standards Developing Organization (SDO) with a focus on healthcare or at the interoperability forum. The German FHIR basic profiles are explicitly mentioned here.

Standards developed without an open consensus procedure, such as the key tables of the KBV, should not be used. Exceptions are possible, but in this case the manufacturer of the DiGA must justify why this standard is the preferred choice in order to achieve interoperability with existing systems in the care scenarios typically addressed by the DiGA. This may be the case, for example, if a DiGA must exchange data with certain IT systems in a hospital and therefore must use common interface standards in the hospital environment.

! If a DiGA manufacturer uses a profile of a national organisation or the interoperability forum, which has been agreed upon by an open consensus procedure, at the interfaces to be implemented as interoperable without further profiling, he does not have to register it himself in the vesta directory. A reference to the online source where interested parties can view the profile is sufficient. The registration of the profile is the responsibility of the organisation responsible for the profile.

3.5.3 Interoperability Requirements for DiGA

In order to be listed in the DiGA directory, the manufacturer of a DiGA must prove that it is interoperable regarding three selected issues:

1. The DiGA allows the insured person to export therapy-relevant extracts of the data collected via the DiGA in human-readable and printable form, so that he can use them for his own purposes or pass them on to a physician.
2. The DiGA allows the insured person to export the data collected from the DiGA in a machine-readable, interoperable format so that the insured person or a third party authorised by the insured person can further process these data via other digital products. In future, it should also be possible to connect this interface to the ePA.
3. If the DiGA obtains data from medical devices used by the insured person or sensors worn by the insured person for the measurement and transmission of vital signs (wearables), it may also address these devices via an interoperable interface.

The following figure shows the interoperability interfaces to be implemented as green arrows. The dotted arrows represent future enhancements already set, which, however, are only to be implemented after the ePA has been established in the healthcare system. The interfaces shown with grey arrows are optional, i.e. a DiGA can include them, but they are not subject to any specifications or restrictions by the DiGAV. The manufacturer can also provide redundant, additional implementations for all interfaces shown with green arrows in the DiGA. It is only important that at least one option is implemented here for

exporting data or interacting with connected devices, which corresponds to the interoperability specifications formulated in Annex 2 of the DiGAV.

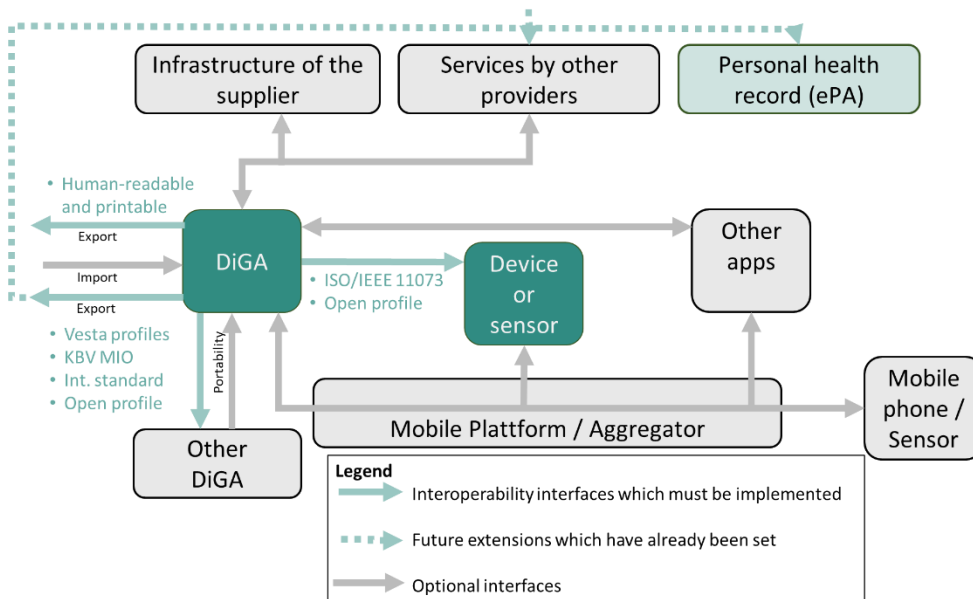


Figure 7: IOP for DiGA.
Source: BfArM.

What can be said about data portability (Article 20 GDPR)?

The obligation to implement Article 20 GDPR is applicable law. A corresponding criterion is included as question 20 in Annex 1 of the DiGAV. Here, in conformity with the GDPR, a common, machine-readable format is required, without specific requirements for the use of certain standards being made. From Article 20 of the GDPR, the requirement can be deduced that it must be possible to transfer data from one DiGA directly to another DiGA, provided this is technically possible. In the absence of agreements on secure communication between DiGA, the BfArM assumes that this is currently not yet technically possible. Accordingly, the DiGAV does not require solutions for direct communication between DiGA either in the requirements for data protection or in the requirements for interoperability.

3.5.3.1 Export of Data into an Interoperable Format



ATTENTION: The functionality described in this section for the interoperable export of data from a DiGA (requirement 1 in the checklist “Interoperability” in Annex 2 of the DiGAV) must not be implemented in the DiGA until 01.01.2021. However, the manufacturer must answer the corresponding question with “yes” when submitting the application and thus commit to the implementation of this functionality by 01.01.2021 at the latest.

The manufacturer must provide a feature for the DiGA which allows data to be exported from the DiGA in an interoperable format regarding syntax and semantics. The term “interoperable” refers specifically to Section 6 DiGAV, which was explained above under the heading “The Cascade of Section 6 DiGAV”. The corresponding question in Annex 2 of the DiGAV contains a supplementary formulation that MIOs or standards, profiles and guidelines recommended in the vesta directory must have been published for at least one year. This formulation is to be understood as follows:

- The manufacturer of DiGA can use MIOs and standards / profiles recommended in the vesta directory even if they are not public for at least one year.
- If a MIO or recommended standard / profile from the vesta directory fits but has been published for less than one year at the time of application for the inclusion of DiGA in the DiGA directory, then the manufacturer of DiGA is not obliged to use this MIO or standard / profile. The only reason for this is that manufacturers should not be forced to reimplement their interfaces by relevant current MIO publications shortly before the planned application is submitted.

For the implementation of interoperable data export, all data processed in the DiGA whose collection or processing is based on Section 4 paragraph 2 clause 1 number 1 DiGAV must be considered (intended use of the DiGA). This includes in particular

- data entered by the users
- data collected via devices and sensors
- data on the user and the context of use (if available)
- information on DiGA and meta data for data export

Derivations on entered or recorded data (e.g. analyses), statistical procedures applied to this data as well as logs and protocols do not have to be exportable as independent objects, as long as they only serve to establish safe operation or are stored exclusively for purposes according to Section 4 paragraph 2 clause 1 numbers 2 to 4 DiGAV or to meet legal requirements.




Description

Diabetics can record information about their measured blood sugar, food intake and insulin units injected in a blood sugar diary:

- Blood sugar measurements are read out from a glucometer, while all other data must be entered manually.
- the DiGA can display blood glucose curves and calculate characteristic values (e.g. number of hyperglycemic and hypoglycemic events).
- In addition, the user can configure limit values for hyperglycemia and hypoglycemia, which influences the way the blood glucose curves are displayed.
- Data on use frequency and user navigation through the DiGA are collected, processed and evaluated to prove a positive healthcare effect (here: increase of adherence) and to optimise the user's experience.

Good Practice: Notes on the requirements

- ✓ In this case, in order to implement the requirements for an interoperable export interface, it must be possible to export all blood sugar measurement data, nutritional data, insulin doses (each with date and time), the key figures that can be displayed to the user as well as the configuration of the limit values and the master data that may have been captured during user registration in an interoperable format. This includes per blood sugar measurement data, nutritional data, insulin delivery etc., as well as the origin of the information, for example whether it is a device measurement or entered by the patient etc.
- ✓ It is not necessary to export the use data as raw data, i.e. the logs showing which user has accessed the DiGA and at which time has accessed the DiGA.
- ✓ Data derived from the use data for the purposes of evaluation, performance measurement and device improvement do not have to be exported either, as these purposes (Section 4 paragraph 2 clause 1 numbers 2 to 4 DiGAV) are not relevant for interoperable data export.
- ✓ Data used for billing, only, also do not have to be exported a, since billing is a legal requirement.

 **Rule of thumb:** The requirement for interoperable, machine-readable export is a requirement for interoperability, exclusively. Interoperability comes before completeness. If a MIO or a standard / profile / guideline recommended in the vesta directory is known, which covers 80 percent of the content that should be exported, then it must be used.

Example

The KBV publishes a MIO for the exchange of diabetes diaries for insulin-dependent diabetics. At the latest one year after the publication all DiGA, which are diabetes diaries by their function or purpose, have to support this MIO as an interoperable export interface when applying for listing in the DiGA directory.

A manufacturer can implement an interface that contains extensions to the MIO used and to the standard / profile / guideline recommended in the vesta directory, respectively, provided that these extensions do not impair interoperability and only use the extension mechanisms explicitly provided in the MIO specification. An application for the inclusion of these extensions in the vesta directory is recommended, but not mandatory in this case.

- ✓ The information which standard or profile the manufacturer has used for the implementation of the interoperable export interface must be published by the manufacturer on the application website of the DiGA together with a reference to the specification used. The URL to this section of the DiGA application website must be specified in the application for inclusion in the DiGA directory.



How must the user be able to gain access to interoperable export?

The DiGAV specifies that the user can trigger the interoperable export from the DiGA. This means that the DiGA must provide a corresponding menu item, button etc. at a suitable location. Due to the wide range of technical implementation options of a DiGA, from the web application to the app to the voice application, the DiGAV does not specify how the exported data is to be transferred to the user. The specification that the export must be triggered from the DiGA does not imply that the export must also be executed by the DiGA. For example, it is certainly possible to generate an encrypted data package after triggering the export request, which the user can then retrieve in a secure way from a server of the manufacturer. Push solutions to secure contact data are also conceivable.

3.5.3.2 Export of Data in Human Readable Form



ATTENTION: The functionality described in this section for the human-readable export of data from a DiGA (requirement 2 in the “Interoperability” checklist in Annex 2 of the DiGAV) must not be implemented in the DiGA until January 1st 2021. However, the manufacturer must answer the corresponding question with “yes” when submitting the application and thus commits to the implementation of this functionality by January 1st 2021 at the latest.

The manufacturer must provide a function for the DiGA that can be triggered from the DiGA, which allows the user to continue using the data processed by the DiGA for his own purposes (e.g. documentation of a treatment case) or to pass on treatment-relevant information generated by the DiGA to a healthcare provider. In contrast to the interoperable export interface, the focus here is on human readability and relevance for a DiGA-typical care context:

Requirement 2 on interoperability: [...] the insured person can export extracts of the health data processed via the digital health application relevant to his or her care and pertaining in particular to the course of therapy, therapy planning, therapy results as well as data evaluations [...]. The export shall be implemented in a human-readable and printable format taking into consideration the context of care in which the digital health application is typically used according to its intended use.

The aim of this requirement is to enable insured persons to show, print or send summarising reports on the course of therapy, therapy planning, therapy results and data evaluations carried out from the DiGA to their attending physicians via secure communication channels. The use and storage of the data by the insured persons themselves should also be supported in this way.



Which data does this concern?

The focus of this requirement is on the usability of the exported data in the context of healthcare, i.e. raw data should not be exported here - as is the case with interoperable data export - but rather summarised and prepared data, e.g. in the form of tables, reports, plans or passports. The manufacturer of a DiGA is basically free to decide how to structure and prepare the output summarised data. An implementation that is particularly suitable for healthcare and therapy support can certainly be seen as a competitive factor, since it is physicians as potential users of the data thus output from the DiGA who prescribe the DiGA to the patient and thus also potentially make the choice between different functionally similar DiGA.

**Description**

Diabetics can record information about their blood sugar measurements, food intake and insulin units injected in a blood sugar diary: (see example for data portability). The DiGA can be personalised by the user with his therapy goals and carries out various evaluations to support the user in the individual adjustment of his insulin therapy.

Good Practice: Notes on the requirements

- ✓ The patient can display an overview of his individual settings (basal rate, correction factor etc.) from the DiGA.
- ✓ The patient can display various curves on the blood glucose level as well as selected key figures (number of hypoglycemic events, measurements per day, etc.) to inform his treating doctor.



Rule of thumb: Export the information from the DiGA in a compact form that can be usefully incorporated into healthcare scenarios in which the user of the DiGA typically finds himself. Offer the user the option of exporting / saving settings made for his therapy so that he can restore them if he has accidentally deleted or changed something.

**How should this be implemented technically?**

The DiGAV specification is “readable and printable by humans”. A printed copy is readable by humans. A PDF view is printable. According to the interpretation of the BfArM, both options meet the requirements of the DiGAV. More complex implementations are conceivable but are not required.

3.5.3.3 Data Acquisition from Medical Devices, Wearables and other Sensory Devices



ATTENTION: The functionality described in this section for data acquisition from medical devices and wearables (requirement 3 in the checklist “Interoperability” in Annex 2 of the DiGAV) must not be implemented in the DiGA until 01.01.2021. However, the manufacturer must answer the corresponding question with “yes” when submitting the application and thus commit to the implementation of this functionality by 01.01.2021 at the latest.

If a DiGA uses or can use a medical device or wearable to record data, the insured person should be given the opportunity to use hardware of his choice for this purpose. This requires that manufacturers of medical devices, wearables and other sensor technology can develop their devices in accordance with the interface of the DiGA, which in turn means that the corresponding technical specifications must be disclosed and usable without discrimination.

For DiGA that do not collect data from medical devices, wearables or other sensors, the manufacturer may answer requirement 3 in the “Interoperability” section of Annex 2 of DiGAV with “not applicable”.

Otherwise, the manufacturer has three options for implementing an interoperable interface for reading data from medical devices, wearables and other sensor technology:

1. The DiGA implements a disclosed and documented profile of the ISO/IEEE 11073 standard (Medical Device Communication)
2. The DiGA uses a standard or a profile listed in the vesta directory.
3. The manufacturer develops its own profile or standard for the interface for reading data from medical devices, wearables and other sensor technology and applies for the inclusion of this specification in the vesta directory


! The manufacturer is free to choose which of these options he uses. However, in order to ensure the greatest possible interoperability and standardisation, it is advisable to examine the options in the following prioritisation to determine their feasibility:

1. If there is a current device specification for the type of device in question (e.g. a blood sugar measurement device) within the ISO / IEEE 11073 standard, this should be used. You can search for available ISO / IEEE 11073 device specifications via the ISO websites: <https://standards.ieee.org/search-results.html?q=11073>
2. If a Health Device Profile specified by the Bluetooth SIG already exists for the type of device being addressed (e.g. a heart rate monitor or a scale), this should be used. A list of all defined Health Device Profiles can be found under


<https://www.bluetooth.com/de/specifications/assigned-numbers/health-device-profile/>.

3. If a profile via ISO / IEEE 11073 or HL7 FHIR is already registered in the vesta directory for the addressed type of device, this should be used.
4. The manufacturer develops his own specification and applies for its inclusion in vesta standards. Alignment with the FHIR Personal Health Device Implementation Guide, which is currently under development and based on ISO / IEEE 11073, is recommended: <http://hl7.org/fhir/uv/phd/2019May/toc.html>


- ✓ The information which standard or profile the manufacturer has used for the implementation of the interoperable interface for reading data from medical devices, wearables and other sensor technology must be published by the manufacturer on the application website of the DiGA together with a reference to the specification used. The URL to this section of the DiGA application website must be specified in the application for inclusion in the DiGA directory.

 **Currently, my DiGA reads the blood sugar data via the interface of the blood sugar measurement device I support. If I change my interface to ISO/IEEE 11073 now, the device should be able to do this, so that it still works. What do I do if the manufacturer of the blood sugar measurement device does not implement this interface?**

The interoperable interface for reading data from medical devices, wearables and other sensor technology can be implemented redundantly to an existing proprietary interface. The motivation is that hardware manufacturers can build new, interoperable devices to the app. This does not mean that the “old”, proprietary devices can then no longer be used in parallel.

 **My app processes data from wearables, but reads them from Apple Health, not directly from the device. Do I still need to implement an ISO/IEEE 11073 interface or other interoperable interface to access this wearable?**

No. This only applies if the DiGA directly accesses the medical device or the wearable. If the access via Apple Health or a similar Device Aggregator is decoupled, then “not applicable” can be checked at statement 3 for interoperability in Annex 2 of the DiGAV.


 **The ISO/IEEE-11073 standard is subject to a fee and protected by copyright. If I define a profile about it now, am I allowed to publish it freely or register it in vesta, or do I violate the rights of ISO or DIN?**

As long as only the difference between a profile and the standard are described, this is a permissible application of the standard. However, you may not copy

complete text sections, tables or graphics from the standard into the profile. *“The creator is also permitted to provide appropriate guidance material in the solution collateral (IFU (Instructions for Use), Implementation Guide, etc.) which would allow a system integrator adequate information to interface with that solution. The creator should not directly copy tables, figures, text, etc. without requesting permission from the IEEE.”* (from <http://11073.org>)

3.6 Further Quality Requirements

In addition to interoperability, DiGA must meet further quality requirements. These are listed in Section 5 paragraph 2 to 9 DiGAV and are specified in Annex 2 of the DiGA by means of checklists to be completed by the manufacturer as part of the application for inclusion in the DiGA directory.

 **Annex 2 sets out requirements for the publication of certain information on the “distribution platform” and/or the “application website”. Insured persons can download my DiGA from my website after medical prescription or approval by the SHI fund. Can I also display the information required for the “application website” via this page or do I have to set up a second website?**

The distribution platform designates the source through which insured persons can obtain a DiGA and install it on a suitable terminal device. In the case of apps, for example, this will be the app store of the platform provider. Manufacturers who operate their own distribution platform must also ensure that the information to be provided on the distribution platform is always displayed before loading and installing a DiGA in such a way that insured persons cannot miss it when downloading the DiGA. An “application website” within the meaning of the DiGAV is a website (or an entire website) offered by the manufacturer for the digital health application, which serves to provide user information and primarily addresses the concerns of active users, but also offers comprehensive information for interested parties, potential users, physicians, healthcare providers. If the manufacturer succeeds in serving both target groups (interested and active users) equally via a website, then the distribution platform and application website can be combined.

3.6.1 Robustness

DiGA should be able to be used by insured persons as far as possible without interference, loss of data, transmission errors or difficulties in connection with devices. Incorrect data entry or transfer must not lead to avoidable falsification of the data basis and / or restrictions of the utility value of a DiGA.

3.6.1.1 Robustness Against External Events

The manufacturer must take technical measures in order to exclude typical causes of malfunctions for the platform basis used and the specific type of DiGA

- for example, power failure, interruptions in the internet connection or unintentional disconnection of paired devices - or to treat these malfunctions in such a way that no loss or falsification of data results. For example, automatic switching off of a mobile phone when the battery is empty must not result in data being requested several times by a connected sensor and then being present in duplicate.

Insured persons should be able to reset the DiGA to a safe state, for example to resolve problems of incorrect, incomplete or inconsistent system settings. For example, when connecting a new sensor, a user should not be forced to adapt the configuration of an old sensor but should have the possibility to go through the installation and configuration of a connected device completely new.

Is offline usability a must-have?

No. The DiGAV only requires that no data be lost when the internet connection is interrupted. If the DiGA saves data on a server, data entered by the user but not yet saved by the DiGA must be securely cached on the device until the internet connection is restored.

3.6.1.2 Robust Connection of Devices and Sensors

DiGA that use external devices or sensors must include functions to determine and secure their proper functioning. An example of such measures is the test processing of reference images in DiGA using a camera: the user photographs a reference image of the manufacturer and the software checks whether colors, contrasts etc. have been captured as expected. This could be used, for example, for a DiGA for wound control or for a DiGA for skin cancer screening.

To what extent must my DiGA detect disturbances at connected hardware?

The “best effort” principle applies: If the hardware supports self-test functions or even sends error messages on its own initiative, then this must be considered by the DiGA as far as possible and within the framework of maintaining interoperability. If there are no such functions on the hardware side, then the DiGA should at least recognise when the communication connection falls below a certain minimum quality (availability, throughput etc.) and react accordingly.

3.6.1.3 Robustness Against Operating Errors and Malfunctions

Operating errors and malfunctions are to be minimised as far as possible by the DiGA subjecting all values included in a data processing to a plausibility check. These checks should be comprehensive as far as possible and consider the consistency with other recorded values and the current status of the application.

How do I have to implement the consistency checks queried in Annex 2 of the DiGA? Is a note to the user sufficient, for example, if he gives a very

improbable value or such a value is output from a connected device? Or does the processing of the value then have to be refused? Are static limits sufficient for checking the consistency?


There are improbable and impossible values. For example, a daily food intake of 10,000 calories is unlikely and one in 100,000 calories is impossible. The first one implies a note to the user, the second one should not be accepted. As far as technically feasible and professionally reasonable, plausibility checks beyond simple limit values should always be carried out in the context of other patient data, dependent or related to the checked date. If the patient's weight measurements from Monday to Thursday fluctuate between 80 and 82 kilograms, then a measured value of 95 kilograms on Friday is at least unlikely.

3.6.2 Consumer Protection

The starting point for consumer protection with DiGA is fairness in dealing with the insured persons; users of DiGA find themselves in a special life and / or illness situation simply because of their motivation to use a particular DiGA, which must not be exploited by the manufacturer to take advantage of the users or lead them to make irrational decisions. The potentially positive improvements of structures and processes (e.g. increase in health literacy) potentially associated with DiGA may also already imply an information gap between the manufacturer and the persons using DiGA. Such a gap can also be assumed for IT and media competence and the handling of digital business models.

3.6.2.1 Transparency Regarding the Purpose and Functionality of the DiGA

The manufacturer of a DiGA must supply healthcare providers and insured persons with transparency regarding the purpose and functionality of the DiGA. It must also be clearly recognisable on the sales platform or application website which features are available with the download or use of the application and which features can be purchased at what price, for example as in-app purchases or function transfers.

 **The consumer protection checklist in Annex 2 to the DiGAV states that information on the scope of services of the DiGA must be provided on the distribution platform – e.g. an app store – or on the application website. As a manufacturer, can I choose whether to publish this on the distribution platform or the application website?**

In principle, yes, although in the case of apps for iOS or Android, the scope of what must or may be displayed in the App Store and to what extent is usually severely restricted by the App Store operator. In any case, it is also possible to display this information on the distribution platform and on the application website.

3.6.2.2 Confirmation of Compatibility

Before installing a DiGA or using it for the first time, insured persons must be able to determine to what extent the application fits their own requirements, ideas and (technical) circumstances. For hard- and software, confirmation of compatibility assurances must be given, i.e. it must be stated on the application website maintained by the manufacturer for the DiGA for which mobile devices, web browsers, operating systems, additional hardware, etc. the application has been successfully tested and thus released by the manufacturer. This is to prevent insured persons from being unable to install a prescribed DiGA or from installing the DiGA and then finding that they must make additional purchases in order to use it.

The section of the application website in which the manufacturer discloses and continuously updates the list of hardware and software tested as compliant must be referenced in the application for inclusion in the DiGA directory and will be published in the same directory after listing in the directory.



Is requirement 4 on consumer protection in Annex 2 of the DiGAV to be understood to mean that I should show which hardware and which operating systems / browsers my DiGA has been tested with? Do I also have to state the version of the operating system?

The information on the confirmation of compatibility refers to the mobile hardware, operating systems, browsers, additional devices, etc. with which the functionality of the DiGA has been tested extensively and successfully and is tested for each change to the DiGA. In the case of operating systems and browsers, the major release number must be indicated (e.g. google Chrome Version 80).

3.6.2.3 In-App Purchases

Section 33a paragraph 1 SGB V allows manufacturers to provide medical devices that go beyond the scope of the DiGA, whereby in this case the costs exceeding the reimbursement amounts for the DiGA must be paid by the insured persons themselves:

Section 33a paragraph 1 clause 4 SGB V: If insured persons choose medical devices that exceed the functions or areas of application of the digital health application listed in the directory for digital health applications according to Section 139e [...], they must bear the additional costs.

One way the manufacturer can make use of this option is that users can book and pay for these extended functions or application areas directly from DiGA. One example are in-app purchases that are quite common in mobile applications.

If manufacturers offer in-app purchases or similar procedures in a DiGA, they must comply with the following requirements from Annex 2 of the DiGAV:


- These in-app purchases may not be advertised in the DiGA (see next subchapter).
- The sales platform and / or application website must clearly show which additional functions or application areas can be purchased by the insured person at what cost.
- In-app purchases shall not be automatically renewable subscriptions or limited-time special offers.
- An in-app purchase by mistake must be precluded.

3.6.2.4 Advertising


Section 5 paragraph 4 DiGAV defines that a DiGA may not be used as a vehicle for advertising:

Section 4 DiGAV: Digital health applications must be free of advertising

The term “advertising” does not differentiate whether it is the manufacturer's own advertising for his own products or third-party advertising for third-party offers. Both are prohibited.

 **DiGA should be free of advertising. May I refer to DiGA extensions (which can be subject to a charge) in the DiGA, e.g. additional support services? May I inform the user at the end of the prescription period about offers for further, privately financed use?**

Extensions that are subject to a charge are provided for in the SGB V, therefore it cannot be forbidden to make objective references to them and to open a way to obtain the corresponding extension. The manufacturer may point out, but not actively advertise. More details can be found in the explanation to Section 5 paragraph 4 DiGAV: *The term advertising is immanent in this context, i.e. the promotion of a product or a service with the aim of promoting sales. This also includes practices of courting or addressing on an emotional level with the aim of bringing about an irrational decision.*

 **What exactly does the text of the ordinance mean by “digital health applications must be free of advertising”? Does this mean that no pop-ups or advertising banners may be used within the DiGA or that no manufacturer logos (branding) may appear in the entire DiGA?**

DiGA may not contain any self-advertising for products of the same manufacturer or third-party advertising for the offers of third parties. The form of the advertising is irrelevant. The use of one's own logo is of course permissible according to this standard.


See Section 5 paragraph 4 DiGAV for reasons:

Financing of a digital health application from funds of the statutory health insurance excludes financing through advertising. The insured person should be protected to a large extent from inappropriate influence on its behaviour during use. The term advertising refers to the promotion of a product or service


with the aim of promoting sales. This also includes practices of courting or addressing customers on an emotional level with the aim of bringing about an emotional decision. The concept of advertising in paragraph 4 does not differentiate between self-advertising by the manufacturer for its own products or third-party advertising for offers from third parties. In contrast, merely enabling the purchase of a product supplement not covered by the claim to benefits under Section 33a paragraph 1 SGB V in the context of an in-app purchase is unobjectionable, as offering a service for sale without further promotion efforts does regularly not constitute advertising.

 **If I am not allowed to advertise in DiGA as a manufacturer, can I at least inform the user of my DiGA by direct advertising with other means (mail, e-mail, etc.) about products and services that are potentially interesting to him?**

No. This would require user consent. However, consent may only be obtained for the purposes specified in Section 4 paragraph 2 clause 1 of the DiGAV.

 **Within the framework of the DiGA, consent may only be obtained for the purposes of Section 4 paragraph 2 clause 1. Does this mean that consent may not be obtained anywhere, e.g. for the receipt of a newsletter? Not even if this is done separately from other consent in the DiGA or on the homepage?**


The restriction concerns the processing of data in and via the DiGA and thus also consents given in the DiGA. The offering of newsletters independent of the use of DiGA – e.g. on the homepage of the manufacturer – is not restricted by DiGAV.

 **As a manufacturer, am I allowed to use forms of mass advertising (TV spots, advertisements in professional journals, billboards, etc.) to draw attention to my DiGA?**


DiGA are (digital) medical devices. Advertising of the device is permitted within the limits of the regulations of the German Advertising in the Healthcare System Act which exist for medical devices.

3.6.2.5 User Support

Manufacturers must provide measures for their DiGA in order to be able to answer user inquiries promptly.


 **What measures must I take to support the insured persons? Is an e-mail address that is checked daily sufficient?**

The DiGAV requires that the manufacturer responds to requests within 24 hours and provides the requesting person with feedback (and ideally an answer) to the request.

 **Is an automatic e-mail reply sufficient on weekends and holidays? If telephone support is offered, must it be available continuously? Are a few hours on Sundays enough?**

There must be a response to the patient's request within 24 hours. In which format is not specified in principle, but the format should be appropriate to the content of the request and the function of the DiGA.

	Example: Patient Asks for Information on the Effectiveness of the App
Format of the response	Automatic e-mail within 24 hours with announcement of prompt reply possible
	Example: Patient Reports a Loss of Data, on the Basis of Which He or She Independently Makes Insulin Dose Adjustments
Format of the response	The loss of data must be addressed within 24 hours by e.g. telephone support and, if possible, resolved if necessary. An automatic e-mail within 24 hours is not sufficient.

 **Is the condition “German-language support” fulfilled if I answer incoming e-mail inquiries in German, but continue to offer my telephone hotline only in English?**

Yes, the manufacturer must allow requests in German for at least one communication channel and provide feedback in German. The provisions of the DiGAV do not specify which communication channel this is, if the requirements of free access and a reply within 24 hours can be implemented (which excludes, e.g. the postal service).

3.6.3 Ease of Use

The requirements of the DiGAV regarding the ease of use of a DiGA aim at an intuitive usability and learnability of the DiGA for the target groups addressed. In principle, the specifications of the usability style guide of the respective platform apply. When implementing alternative solutions, a particularly high degree of ease of use must be demonstrated in the user tests.

The DiGAV demands an alignment with the usual look & feel of digital applications for persons used to dealing with applications guided by the implementation of platform-specific style guides. The demand for focus group-tests targets primarily on people who have been newly won over to the use of digital applications via DiGA. When conducting focus groups, manufacturers should therefore ensure that the participants have different previous experiences in handling digital media.



Attention: The DiGAV requirement for support for people with disabilities described below must be implemented in every DiGA from 01.01.2021. DiGA listed in the directory before this date must provide corresponding technologies with an update by 31.12.2020 at the latest, unless requirements were already met when they were included in the DiGA directory. By confirming this requirement in Annex 2 of the DiGAV, manufacturers give the BfArM a commitment to implement or support operating aids to assist people with disabilities.

From January 1st .2020 all DiGA listed in the register must either

- include operating aids for people with disabilities or
- support the operating aids offered by the platform.

Mixed implementations, in which the manufacturer implements individual operating instructions himself and otherwise uses the operating aids already offered by the platform, are permissible. The operating instructions implemented or supported in the DiGA must consider the areas of vision, hearing and motor skills. Exceptions are only permitted if this can be justified on the basis of the target group or the purpose of the DiGA.

If the manufacturer chooses the option of supporting the operating aids offered by the platform in his DiGA, the following requirements apply:

- In each of the above categories of disability (hearing, vision, motor skills), the DiGA must actively support at least one of the operating instructions offered by the platform, i.e. it must be fully effective for the DiGA when activated.
- Other operating instructions must not cause any disturbances or impair the use of the DiGA when activated (e.g. illegible texts when changing the font size).

In order to implement accessibility, the manufacturer can orientate himself to the specifications and instructions of organisations such as the Federal

Accessibility Agency. The implementation of accessibility must always be examined in terms of target groups and usage.

3.6.4 Support for Healthcare Providers

The DVG also allows the listing of a DiGA in the DiGA directory that involves physicians and other healthcare providers in the usage of the DiGA by the insured person. For such a DiGA, the manufacturer must provide clear guides aimed at the desired positive healthcare effect, which role the healthcare provider fulfils in the overall context of the DiGA and its use, how it is to be structured in practice and which legal requirements are to be observed in the process - with the aim, among other things, that the healthcare provider can explain the interaction of the roles to the insured person and explain the use of DiGA in the context of therapy to him. The manufacturer must provide suitable information for this purpose.

3.6.4.1 Information According to Section 2 paragraph 1 Number 16

According to Section 2 paragraph 1 number 16 DiGAV, the manufacturer must already provide information on the user roles provided for in the digital health application when applying for listing in the DiGA directory. The information to be given by the manufacturer on the role model of healthcare supported by the DiGA must be structured in such a way that insured persons and healthcare providers can gain an idea of the healthcare approach associated with the use of the DiGA and the tasks assigned to them. Here it is useful to first describe the individual roles with their tasks and responsibilities and then, based on this, to outline a prototypical process of a care scenario using the DiGA. Information provided by the manufacturer here forms the basis for the implementation of more detailed explanations, which can be found under the heading "Support for Healthcare Providers" in Annex 2 of the DiGAV.


3.6.4.2 Additional Information for Healthcare Providers

For each role described in the information on Section 2 paragraph 1 number 16 DiGAV (with the exception of the insured person), the DiGA manufacturer must provide supplementary information specifically addressing the tasks of this role. This information must address the following issues:


- What are the tasks and responsibilities of this role?
- What is the legal framework for the actions of this role in the context of DiGA, and what regulatory requirements must be met?
- From the perspective of this role, how is the interaction with the insured person and other roles?
- How can the use of the digital health application be explained to the insured person in the context of therapy?

Structuring the information according to the questions outlined above ensures that all the content required to confirm the statements in the section "Support

for Healthcare Providers” in Annex 2 of the DiGAV (numbers 1 and 2) is addressed.

 **How do physicians and other persons involved in the use of the DiGA receive these role-specific information materials?**

The manufacturer shall make these information materials available via the application website and shall provide these materials within the application portal according to Section 2 paragraph 1 number 16. The materials will be then uploaded in the DiGA directory.

 **As a manufacturer, am I allowed to proactively send such materials to physicians and at the same time promote the use / prescription of my DiGA?**

Yes, as long as this takes place within the framework of the provisions of the German Advertising in the Healthcare System Act.

3.6.4.3 Transfer of Data to Healthcare Providers

To the extent that other roles beyond the insured person are involved in the use of the DiGA in care, data processed or reports created in the DiGA may have to be made accessible to persons in these roles. The manufacturer of the DiGA must confirm under the heading “Support for Healthcare Providers” in Annex 2 to the DiGAV that this is done under the control of the insured person and in compliance with the specifications for data protection and information security. These conditions are fulfilled, e.g. with the human-readable export function to be provided by the manufacturer in the DiGA, provided that the transfer of the exported data takes place via a secure transport route. The transfer of a paper printout by the insured person is a secure transport route.

3.6.5 Quality of Medical Content

The procedure implemented by DiGA and the content presented must be based on sound medical knowledge and take into account recognised professional standards. Health information provided to the insured must be up-to-date and appropriately prepared for the focus group.

3.6.5.1 Assured Medical Knowledge

The DiGAV demands that the medical professional basis of DiGA must be derived from accepted and reliable sources such as medical guidelines, established textbooks, comparable recognised sources or at least published studies. In order to be able to check the bases used and their adequate implementation, it must be disclosed in the DiGA which sources form the professional basis of the application. If studies conducted for the DiGA are advertised or referred to in the justification of the medical quality claim, these studies must be specifically named.

! The sources should be listed in a bibliography as part of the submission. This should be presented in accordance with the citation style of the National Library of Medicine Samples of Formatted References for Authors of Journal Articles (https://www.nlm.nih.gov/bsd/uniform_requirements.html).

The manufacturer must have defined and established processes for the DiGA with which the actuality and adequacy of the medical and technical basis of the DiGA is continuously ensured. New developments in medicine or other areas of knowledge that have been incorporated into DiGA must be recognised, evaluated and considered in the further development of DiGA.

 **My DiGA pursues a completely new approach to care, for which there are no publications yet for reasons of patent protection. How do I deal with the checklist regarding the quality of the content?**

This can only be clarified in individual cases. Advice from the BfArM prior to submission of the application is recommended.


3.6.5.2 Providing Appropriate Health Information

DiGA can contain or refer to explanatory or instructive content on diseases, symptoms or therapies. These content can influence the understanding of the affected person of his situation and his options for action and his health behaviour and must be carefully selected and prepared accordingly. In addition to the substantiation of the content, for example on current and recognised professional standards, this includes in particular the orientation of the content and forms of presentation to the target group, the use of tried and tested didactic methods and the appropriate embedding of content in the course of use of the application.

The sources on which the health information presented is based must be identified in order to allow an examination of its adequate implementation.

3.6.6 Patient Safety

The manufacturer of a DiGA must ensure by appropriate organisational and technical measures that the risks of use of the application are as low as possible. While the CE marking ensures the basic technical safety of the DiGA, the measures required here are aimed at conscious handling of existing residual risks for the insured person. In addition to the recognition of potentially risky conditions, this includes above all the appropriate sensitisation of users, who must be able to recognise when it is necessary to consult a physician or even discontinue the use of a DiGA. A DiGA must also not mislead users to take ill-considered actions or false ambition.

 **My DiGA is a diabetes diary. Do I have to point out again with every hypoglycemic event, how dangerous a low blood sugar level is and what can happen? Diabetics usually know this very well.**

The note is for patient safety, so yes. To make this user-friendly, however, a checkbox can be added to the warning message, with which users can switch off this note for the future (“Do not display note again” etc.). Also, different content and explanations can always be displayed in the warnings, e.g. if the DiGA also aims at improving health literacy.

The DiGAV requires that the DiGA defines consistency conditions for all values taken from external sources, which are checked before this value is used. External sources are not only connected devices, but also the insured person who, for example, makes manual entries in a diary. Consistency conditions can address both the type of a value taken from an external source and its scope or content. For example, it may be required that certain values are always entered with one decimal place to force any necessary accuracy. Also, values read from a measuring device, for example, should be checked against the value ranges specified by the device manufacturer, in which the manufacturer assures reliable measurements.

4 Evidence of Positive Healthcare Effect

- 4.1 Definition of Positive Healthcare Effect
- 4.2 Definition of Positive Healthcare Effect
- 4.3 General Requirements for Studies to Prove Positive Healthcare Effect
- 4.4 Publication of the Complete Study Results
- 4.5 Application for provisional listing
- 4.6 Specific Requirements for Study Types and Study Design

The concept of positive care effect was introduced into the social law framework of SGB V with the Digital Healthcare Act (DVG). According to the definition in DVG and DiGAV, positive healthcare effects (positive Versorgungseffekte, pVE) are either a medical benefit (medizinischer Nutzen, mN) or a patient-relevant improvement of structure and processes (patientenrelevante Struktur- und Verfahrensverbesserungen, pSVV) in healthcare.

When a manufacturer applies for listing in the DiGA directory, he must prove one or more positive healthcare effects for his DiGA. The positive healthcare effect he chooses to prove may derive either from the area of medical benefit or from the area of patient-relevant improvement of structure and processes.

4.1 Definition of Positive Care Effects

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.

4.1.1 Medical Benefit

The medical benefit (medizinischer Nutzen, mN) is defined in the DiGAV (based on the corresponding standards for the evaluation of drugs) as patient-relevant effect(s), particularly regarding

- the improvement of the state of health,
- the reduction of the duration of a disease,

Definition:
medical benefit

- the prolongation of survival or
- an improvement in the quality of life.

Those who claim a medical benefit for a DiGA must show that patient-relevant endpoints, in particular morbidity, mortality or quality of life, are positively influenced.

4.1.2 Patient-relevant improvement of structure and processes

The concept of patient-relevant improvement of structural and processes (patientenrelevante Struktur- und Verfahrensverbesserungen, pSVV) as a basis for reimbursement of a product in the SHI system is based on the fact that DiGA offer good and new possibilities for improving care, especially with regard to processes in the patient. The DiGAV defines in Section 8 paragraph 3:

Definition:
patient-relevant structural
and procedural improvement

pSVV are

- seen as part of the detection, monitoring, treatment or alleviation of disease or
- the detection, treatment, alleviation or compensation of injury or disability, and are
- aimed at supporting the health behaviour of patients or integrating the processes between patients and healthcare providers, and
- include in particular the areas of
 1. coordination of treatment procedures,
 2. alignment of treatment with guidelines and recognised standards,
 3. adherence,
 4. facilitating access to care,
 5. patient safety,
 6. health literacy,
 7. patient autonomy,
 8. coping with illness-related difficulties in everyday life, or
 9. reduction of therapy-related efforts and strains for patients and their relatives.

This concept is based on the assumption that DiGA can provide the necessary resources and structures to substantially strengthen the role of patients in health care, to improve their position through information, participation and co-decision making, and to support their contribution to therapy in a structured way and in accordance with the guidelines. Their health behaviour can be supported by DiGA, closely interlocked with the processes of the healthcare providers and flexibly aligned to a commonly defined therapy goal. The decisive factor here is the support in all aspects of therapy, which patients can experience directly through DiGA, which is close to everyday life and geared to individual needs.

DiGA are strengthening the
position of patients

The areas in which positive healthcare effects (pVE) can be demonstrated:

1. Coordination of Treatment Procedures

DiGA can support the coordination of treatment processes between one or more healthcare providers on the one hand and the patient on the other. Improvements in care can result, e.g. from a therapy that is particularly well adapted to the acute support needs of the patient, from a better organised therapy process or from communication possibilities that are low-threshold and event-related.

2. Alignment of Treatment with Guidelines and Recognised Standards

Guidelines and other recognised treatment standards not only cover the actions of the healthcare providers, but also describe how the patient can or must contribute to the success of the therapy. For various diseases such as diabetes mellitus, for example, patient guidelines have been drawn up which not only make the guidelines, which were originally addressed to physicians, easy for laypersons to understand, but also explain what patients themselves can do. DiGA can translate such instructions into concrete formats that are suitable for everyday use and can be individually adapted, and help to ensure that treatment is based on guidelines and other recognised standards throughout - i.e. even when the patient is not sitting opposite the physician. For example, by reminding patients of necessary visits to the physician, explaining and motivating them to perform exercises at home on a regular basis, or by supporting them in achieving a sustainable change in their lifestyle.

3. Adherence

“Adherence” refers to the implementation of parts of the patient's therapy that have been agreed between patient and physician, or parts of the therapy necessary within the framework of treatment in accordance with guidelines. Adherence thus requires the cooperation of the patient and underlines his active role in the implementation of a therapy. DiGA can support in fulfilling this active role, for example by enabling a better integration of health behaviour and everyday activities. The relevance of the improvements that can be achieved in this way is enormous, to international studies, 30 to 50 percent of chronically ill patients on long-term medication are not adherent to the agreed therapeutic measures.

(Source:

https://www.who.int/chp/knowledge/publications/adherence_full_report.pdf?ua=1).

4. Facilitating Access to Care

Similar to telemedicine services, DiGA can help to improve patients' access to care and support equal and reliable access to health services, regardless of place of residence and other factors.

5. Patient Safety

Patient safety is a priority objective of healthcare and a guiding principle for the further development of health system. The extensive quality and safety specifications, which were developed to reduce risks and avoid treatment

errors, can be strengthened by DiGA and extended from the events in clinics and medical practices to the patients' home environment. They can enable patients to recognise and even react to increased risks in a treatment, errors in the application of a therapy or undesirable individual effects. For example, DiGA with a medication management function can effectively support patients in safe drug therapy.

6. Health Literacy

According to the majority of the population in Germany, it is difficult to find, understand, correctly classify, evaluate and use health-related information. Health literacy is important in order to be able to make decisions in everyday life that facilitate maintaining health or to support the success of a therapy. In the context of a therapy, DiGA can provide patients with relevant health information that is important for their own actions and support them in understanding and implementing the therapy by means of an individualised performance that is adapted to the needs of the target group, in order to strengthen and ensure its success.

7. Patient Autonomy

Patients are important contributors to their own health. Their experience and knowledge hold great potential for improving all areas of the healthcare system, which must be used. Through patient orientation and participation, the prevention of diseases, but also the health status and quality of life of patients can be improved. DiGA can enable and strengthen the patients' autonomous health behaviour and effectively support their involvement in decision-making processes concerning his or her health.

8. Coping with Illness-Related Difficulties in Everyday Life

DiGA can support patients in reducing and coping with everyday illness-related difficulties. For example, digital health applications can use sensor technology or data evaluation to warn of seizures at an early stage or to detect an imminent increase in symptoms, so that patients can better prepare for them. They can facilitate care and monitoring by relatives, e.g. making it possible to monitor a patient even at a distance, and they can also help to develop individual strategies for dealing with a disease to enable a better social participation.

9. Reduction of Therapy-Related Efforts and Strains for Patients and Their Relatives

Likewise, DiGA can organise the treatment procedures and the daily handling of a disease more effectively for the patients and their relatives. This saves time and effort or reduces avoidable physical or psychological stress for those involved. Examples of this are the simplification of measurements and recordings, support in deciding whether a visit to the physician is necessary, for example through the correct classification of side effects, or the strengthening of the feeling of safety under therapy. In addition, data analyses can be used to plan visits to the physician in a more targeted manner if necessary.

4.2 Declaration of Positive Care Effects in the Application

4.2.1 Specification of the Patient Group

In order to indicate the positive healthcare effect, the patient group, i.e. the indication, must first be specified. Evidence that a DiGA has a pVE can only be provided for a defined patient group or several defined patient groups. Only for these patient groups can the DiGA be prescribed and reimbursed in case it is listed in the DiGA directory. It is possible to perform subgroup analyses to detect pVE as long as the implementation and evaluation still meets the requirements for a study as defined by the DiGAV. The BfArM reserves the right to assess individual cases.

A positive healthcare effect can only be proven for one or several defined patient groups

The definition and delimitation of this patient group must be based on one or more indications according to ICD-10, whereby only either three- or four-digit codes are admissible. This makes it possible to differentiate, for example, whether all type II diabetics belong to the DiGA target group or whether the pVE should only be detected for type II diabetics in whom diabetes mellitus has gotten out of control or in whom certain complications are present.

	Example for a Three-Digit Code
Specified patient group	Patients with diabetes mellitus type II
Indication in the application	Diabetes mellitus type II, ICD-10 code: E11

	Example for a Four-Digit Code
Specified patient group	Patients with diabetic foot syndrome with diabetes mellitus type II
Indication in the application	Other more closely defined diabetes mellitus: With multiple complications, ICD-10 code: E13.7

In the German ambulatory care, i.e. in medical practices, ICD-10 codes are provided with an additional identifier A, G, V, Z (excluded diagnosis, confirmed diagnosis, suspected diagnosis and (symptom-free) condition after the diagnosis in question) as a mandatory indication of the degree of diagnostic certainty. If the additional identifier is relevant for determining the target or

user group, it must also be specified. The additional identifiers do not count as additional digits in the coding.

Generally, the manufacturer can determine and specify several indications for his DiGA. But the evidence of positive healthcare effects must always be provided separately for each patient group defined by an ICD-10 code in order to register the DiGA under this diagnosis in the DiGA directory. However, the manufacturer can also perform the evidence for several indications together if these indications are essentially comparable regarding the pVE to be proven and a summary seems to make sense. The investigated study group must then cover the entire spectrum of indications given. The manufacturer submits a justification for this in the application, the decision is up to the BfArM.

Evidence of positive healthcare effect can be provided for several indications together, if these indications are comparable with regard to the pVE to be proven

	Example for the Combination of Several Indications
Specified patient group	Patients with glucose metabolism disorders
Indication in the application	Diabetes mellitus type I and II, ICD-10 code E11 and E12, (in a broader sense also E13 and E14)

Currently, it is only possible to specify patient groups within the ICD-10 framework in an application for listing in the DiGA directory. However, in the explanatory memorandum to the DiGAV, the perspective of further development is already opened: If necessary, the inclusion of further nomenclatures such as SNOMED CT or, with regard to rare diseases, Alpha-ID-SE and the associated ORPHAcode number can be included at a later date.

The indication or diagnosis is per se always a medical or psychotherapeutic task. It is a requirement for any form of providing a DiGA - whether it is a prescription by a physician or psychotherapist or an approval by a SHI.

4.2.2 Specification of the Positive Care Effect

The manufacturer must prove at least one positive healthcare effect, which can be either from the mN or the pSVV area. The evidence of several pVE, also from both areas, is not necessary for the listing in the DiGA directory, but may, under certain circumstances, have a positive effect on the remuneration amounts achieved later. The decision to provide evidence of more than one pVE lies solely with the manufacturer.

As a first principle, the postulated pVE must be consistent with the following:

- the intended use according to medical device law
- the functions of the DiGA

- the content of the DiGA
- statements on DiGA published by the manufacturer, for example in advertising statements and sales material

A DiGA is a medical device that the manufacturer has designated for a medical purpose. Even after the application has been included in the DiGA directory, it remains valid and determines the possible areas of application for DiGA. The pVE to be proven must therefore be within these application areas. This excludes, for example, an extension of the indication or target group, whereas a restriction within the scope of the medical purposes is permissible.

	Example for the DVG's Requirement of Consistency for the Intended Use and the Specification of the pVE
Not permissible	<p>A DiGA was introduced into the market with the medical purpose of treating adult knee joint arthrosis and is now also used to treat wrist arthrosis.</p> <p>Explanation: DiGA is used as a medical device outside its intended use as declared by the manufacturer and is therefore not consistent with the medical purpose.</p>
Permissible	<p>DiGA was introduced into the market with the medical purpose of treating adult headache disorders and is now only used for the treatment of tension headache and is being investigated in studies.</p> <p>Explanation: DiGA is consistent with the medical intended use of the marketed medical device because it addresses only a subpopulation within the intended use declared by the manufacturer in the intended use.</p>

Both the medical benefit (mN) and the patient related improvement of structure and processes (pSVV) refer directly to the insured persons and have to prove through study endpoints that the patients directly benefit of the application.



Are economic aspects considered in the evaluation by the BfArM?

No, economic factors are not included in the assessment for inclusion to the DiGA directory. However, these may be considered in later price negotiations, if necessary.



The wording in the DiGAV indicates with the phrase “in particular” for both mN and pSVV that it is not an exhaustive list of all possible positive effects that can be shown. The statements above rather give some important examples that can be extended with further aspects with appropriate justification according to the medical purpose and scientifically recognised standards and methods.

4.3 General Requirements for Studies to Prove a Positive Care Effect

In order to prove a positive healthcare effect, a manufacturer must present the results of a comparative study which shows that the application of DiGA is better than not applying it. This means: In the patient group using DiGA as part of therapy, pVE must be demonstrated using DiGA in comparison to another patient group not using DiGA.

The “non-application” of DiGA, i.e. the comparison group, can either be


- treatment without the use of a DiGA or
- non-treatment or
- treatment with another, comparable DiGA, which is already finally listed in the DiGA directory at the time of application.

Comparison group: “non-application”

The choice of the comparison group must be oriented on the reality of healthcare. For example, if a DiGA offers care for patients who would otherwise remain untreated in the majority and would e.g. wait for a therapy place, the appropriate comparison is non-treatment.

The comparison against a treatment without DiGA should also be based on and include the reality of healthcare practice. In particular, when retrospective data sources such as billing data of a health insurance fund are used, the comparison with a “historical” control group can be made depending on the reality of care. Due to the recommendations of the healthcare providers and the choice of patients, this can include different therapy modalities up to “unspecific” therapy or non-treatment. A comparison with standard treatment, the so-called “standard of care”, is also possible.

A comparison with (one of) the other DiGA in the list is also useful, provided that comparable products have already been finally listed and have therefore in turn demonstrated a positive healthcare effect in a comparative manner. This will become more important as the supply of DiGA increases.

 **May an evaluation of already “sold” DiGA be used for the evaluation study in the trial phase?**

Yes.

 **Can studies also be carried out within the framework of the Innovation Fund or together with SHI funds in a DMP context?**

In principle, yes. However, it should be noted that the necessary study criteria regarding design and implementation must be observed.

 **To what extent can collected data and study results from the conformity assessment for medical devices be used to prove positive healthcare effects?**

The clinical evaluation of the MDD / MDR conformity procedure must initially be considered separately from the DiGA Fast Track. The conformity assessment first proves the safety and suitability of the medical device. However, study results that have been included in the conformity assessment can also be cited in the fulfilment of the DiGAV criteria for the evidence of pVE.

4.3.1 Choice of Methods

Depending on the research question and the endpoints investigated, studies that are presented to prove positive healthcare effects can be clinical or epidemiological studies, but they can also be designed and conducted using methods from other scientific fields such as healthcare research, social research or behavioural research.

! The prerequisite is that they are quantitative comparative studies and that the chosen methodology is adequate for the chosen object of investigation.

4.3.2 Realisation in Germany

The studies must be conducted in Germany. The limitation to Germany ensures that the study results are sufficiently meaningful. DiGA are often designed to connect patients and healthcare providers and thus to specifically include processes in healthcare and to support and complement them from the patient's perspective. The care situation in which DiGA are used cannot be separated from the question of which positive effects they can have. Moreover, the comparison against a treatment without DiGA is only meaningful if a treatment in the German healthcare system is addressed here. If, in individual cases, evidence for a comparability of the care situation can be provided, studies that were conducted in whole or in part in countries outside of Germany will also be recognised. In principle, the comparability of the population must be demonstrated and argued for all pVE. In the case of pSVV, comparability of the healthcare reality in Germany (regarding the parameters relevant for the validity of the study) must be presented.

4.3.3 Entry in the Study Registry

The studies must be registered in a public study registry. The study registry must be a primary registry or a partner registry of the World Health Organisation International Clinical Trials Registry Platform or a data provider of the World Health Organisation International Clinical Trials Registry Platform. This ensures the quality and comparability of the data collected. The WHO (World Health Organisation) brings the information together and makes it available at a central location worldwide.

The recognised primary registry for Germany is the German Register of Clinical Studies (DRKS) at the BfArM. Studies that have already been completed can also be subsequently registered there.


4.4 Publication of the Complete Study Results

The publication of study results strengthens the confidence of the insured and healthcare providers in the DiGA test procedure. Research also benefits from access to the data. It is important that negative results are also published. For this reason, study results must be submitted before admission to the register, but not yet published. This must be done no later than twelve months after the completion of the study and therefore no later than twelve months after submission of the evidence of studies to the BfArM.



How must the evidence of benefit be published? In a peer-reviewed publication or is publication on one's own website also sufficient?

Initially, publication on one's own website is sufficient; later, the entry in the register must be made. An additional publication in a peer-reviewed journal is not necessary but can be advantageous in terms of professional reputation and acceptance.

 **What if my study results allow conclusions to be drawn about business and trade secrets?**

Respective passages may be blacked out for the publication of the full results.


4.4.1 International Standards for Study Reports

Reports on studies must be as comprehensive as possible: Study and report quality are inseparably linked, as an incomplete report does not allow to distinguish between the shortcomings of the report and those of the study. Precise information on details of planning and implementation is important in order to assess quality and identify deficiencies. Therefore, the study reports to be generated in the course of conducting, the studies must be prepared in accordance with the relevant internationally recognised standards for the presentation and reporting of studies. The Consort Statement (<http://www.consort-statement.org/>), for example, provides guidelines for the correct presentation and reporting of studies.


4.5 Application for Provisional Listing

4.5.1 Justification of the Improvement of Healthcare

DiGA manufacturers who apply for provisional listing must plausibly demonstrate that their DiGA can achieve one or more pVE for a specific patient group. For this purpose, they are required to submit a systematic evaluation of data on the use of the DiGA. The systematic data evaluation includes a systematic literature search and evaluation as well as the inclusion of own systematically evaluated data obtained in the application of DiGA. The evaluation is intended to provide initial indications, prepare the execution of the study in the course of the trial. This includes, in addition to the intervention effects to be demonstrated, e.g. case numbers, measuring instruments, recruitment methods and other relevant issues.

 **Can Real-World-Data also be submitted for provisional listing?**

Yes, systematic data analyses from the DiGA, among other things, should be submitted when applying for provisional listing. These can also include real-world-data.

 **In case of provisional listing in the directory: How is it ensured that a DiGA does not have a negative care effect? How is liability regulated?**

Basically, the safety of the medical device is ensured by the medical device law. The DiGA manufacturer is liable according to general principles of civil law and product liability law.



Many DiGA are aimed at behavioural changes. So, what is the plan for DiGA, which benefit can only be measured after more than two years?

In principle, of course, a study can be started before applying for the listing of DiGA to the DiGA directory and its results can be included. Even in the case of longer-term effects, at least clear indications in a systematic data analyses must be obtained for provisional listing. In this case, during the trial phase of initially twelve months, an application for an extension of the trial phase can be submitted before the trial phase expires (specified in the BfArM decision) if it is plausibly explained why the evidence is not yet available.

4.5.2 Evaluation Concept

In addition, the manufacturer shall submit with the application an evaluation concept drawn up in accordance with generally accepted scientific standards, which takes appropriate account of the results of the data evaluation. The study protocol of the intended study should be part of the evaluation concept. Furthermore, at least one accompanying document should be prepared that explains the choice of outcomes and study design of the chosen comparison and the reality of healthcare practice and explains why and how the evidence of the intended pVE is derived from the chosen evaluation concept. This document must have been provided by a manufacturer-independent scientific institute. “Manufacturer independent” means that it is an institution that is not particularly financially, organisationally or disciplinary connected with the manufacturer. Furthermore, there should be no conflicts of interest. A market-standard remuneration of the expenses of the manufacturer-independent institution is of course permissible.

The procedure described in the evaluation concept must be suitable to provide evidence for pVE. The guidelines of the British Medical Research Council (Craig et al., 2008; Moore et al., 2015), but also national recommendations such as the method memoranda of the Deutsche Netzwerk für Versorgungsforschung (DNVF; Pfaff et al., 2009) as well as recommendations on good epidemiological practice (Ahrens et al. 2007) and on good practice in secondary data analysis (Swart et al., 2015) can be used to create the evaluation concept.

4.5.3 Extension of the Trial Phase

The trial phase of a maximum of twelvemonths may be extended once for up to further twelve months at the request of the manufacturer.

With the application for an extension of the trial phase, the manufacturer must provide a justification explaining why, at the end of the granted trial phase, the evidence of the pVE cannot yet be provided. Furthermore, in the context of a further extension, it must be explained why it can be assumed that the missing evidence can actually be generated.

An extension can only be granted once and only upon early application, at least three months before the end of the trial phase.

It is recommended to contact the BfArM at an early stage, i.e. in the context of a consultation, if there are indications that the granted trial phase is not sufficient to generate the required evidence.

The BfArM may refuse an application for an extension of the trial phase if the necessity for an extension is not sufficiently plausibly demonstrated or if the manufacturer cannot credibly demonstrate that the successful evidence can be generated by an extension of the trial phase.

- Craig et al., 2008: <https://www.bmj.com/content/337/bmj.a1655>
- Moore et al., 2015: <https://www.bmj.com/content/350/bmj.h1258>
- Pfaff et al., 2009: <https://www.netzwerk-versorgungsforschung.de/index.php?page=memoranden>
- Ahrens et al., 2007: https://www.dgepi.de/assets/Leitlinien-und-Empfehlungen/Leitlinien_fuer_Gute_Epidemiologische_Praxis_GEP_vom_September_2018.pdf
- Swart et al., 2015: <https://europepmc.org/article/med/25622207>


4.6 Specific Requirements for Study Types and Study Designs

Due to its characteristics and mode of operation, the positive effects resulting from a DiGA often result from improvements in everyday healthcare practice, from better communication and information or, i.e. from individual therapy support for patients close to everyday life. For this reason, studies to prove positive healthcare effects of DiGA should, if possible, be based in the reality of healthcare practice and carried out with the help of the collection and processing of data closely related to healthcare. It should be possible to draw on existing data in retrospective studies, where such data are available. Digitalised medical data are becoming increasingly available, e.g. from digital patient files or from billing data of health insurance funds. The documentation of clinical information and thus the usability of data for retrospective studies is also increasing in disease-related registers.

Accordingly, an application for listing in the directory requires at least the submission of a retrospective comparative study: case-control studies, retrospective cohort studies or intra-individual comparisons are possible.

Evidence of pVE: at least one comparative study

Irrespective of this, the manufacturer is always free to submit a prospective comparative study, i.e. a study with a fundamentally higher evidence level, instead of the minimum required retrospective comparative study.

 **Is it possible that patients with digital consent (in the DiGA) can be enrolled in a study to demonstrate pSVV?**

Yes, this is explicitly provided for in Section 4 paragraph 2 cl. 1 number 2 DiGAV.

However, the respective standards and regulations, for example the Declaration of Helsinki for a study participation or the GDPR for data protection consents for study participants of the individual consents must be observed.

! If DiGA contain diagnostic instruments, i.e. a measurement and interpretation of vital data, a survey of users on physical or mental conditions, a survey of pain sensation, etc., additional studies on test quality must be submitted. (see [Chapter 4.6.2 Studies on Diagnostic Quality](#)) These determine the sensitivity and specificity in relation to the indications given for the positive healthcare effect.

If DiGA contain diagnostic instruments, additional studies on test quality must be submitted

4.6.1 Study to Verify Positive Care Effects

In order to achieve a final listing in the DiGA directory, it is necessary to prove at least one pVE through own data evaluation for the use of DiGA as described above. Sole references to other primary literature and studies, even from other similar DiGA, are not permitted.

Which study or evaluation design can be chosen also depends on the type of DiGA and the targeted pVE. In principle, the manufacturer is free in the choice of the study design and the selection of the pVE to be demonstrated.

Choice of study or evaluation design depends on the type of DiGA and the targeted pVE.

In general, it should be noted that the study designs and the selection of data sources must be methodologically valid. Suitable statistical methods must be used to ensure that any distortions that could significantly affect the quality and significance of the evidence are minimised. In order to ensure this, quantitative studies must be submitted, regardless of the selected pVE to be verified. Purely qualitative research results are not sufficient.

Scientific merit

 **How is the risk of bias and reliability of results of studies treated in the Fast Track?**

Reliability of results and avoidance of bias should be ensured as far as possible by implementing a suitable study design and evaluation methods.

If several indications, e.g. comparable pVE, can collectively be managed, the study population must also cover the specified indications. If the results are not sufficient, the evidence is generally deemed not to be provided. If the subgroup analysis shows that individual study groups do benefit according to indications, evidence may be provided for the individual indication in individual cases after consideration by the BfArM.

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

As a rule, the evidence according to Section 10 DiGAV can be provided by a retrospective comparative study. “Retrospective” in this context means that data can be analysed that relate to events that occurred in the past. It is therefore a retrospective study. “Comparative” implies that comparisons are made against a control group. A special case is the intra-individual comparison, which can also be suitable as evidence: here a before-after comparison is carried out over one group of patients.

Evidence through a retrospective comparative study

The feasibility of retrospective studies depends on whether the available data sources already contain the necessary data in the required quality. Sources for valid data for retrospective analysis can be, i.e. billing data from health insurance funds or data from disease-related registers.

Feasibility of retrospective studies

If a retrospective approach is chosen to demonstrate a positive healthcare effect, it must be ensured that the characteristics to be investigated have been collected completely and correctly in terms of type and scope.

It is important to achieve comparability of the study groups, e.g. regarding the composition of the study population (age, gender, disease severity, socioeconomic status, etc.) and the respective healthcare context. Progress in medicine and changes and adaptations of guidelines and healthcare processes may make retrospective comparisons in individual cases impermissible. The

same also applies, i.e. if the characteristics of the “historical” data to be investigated have not been not or not sufficiently documented; furthermore, if i.e. a characteristic is recorded which is made possible for the first time by DiGA and which did not previously exist with the available classical therapy / diagnostic approaches.

If it is not possible to the necessary extent, the BfArM may also demand the submission of a prospective comparative study in individual cases.

	Possible Retrospective Study for the Evidence of Positive Care Effects
permissible	<ul style="list-style-type: none"> – Compare data from a DiGA to support breast cancer patients against complete and high-quality historical data from a breast cancer registry
not permissible	<ul style="list-style-type: none"> – 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)
not permissible	<ul style="list-style-type: none"> – 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
not permissible	<ul style="list-style-type: none"> – Compare data from a DiGA for monitoring patients with Parkinson's disease with historical data from a monitoring system in which the movement of the patients was not measured and evaluated using 3D camera technology as with the DiGA

A prospectively planned study may be easier to realise in terms of scope than the use of data that are retrospectively made comparable for the purposes of the research question. For example, comparability must be constructed arithmetically (by means of a model-based adjustment of a suitable matching of e.g. age, gender or comorbidities or a propensity score) if healthcare data are used as a data source for therapy effects.

Prospective study

If a (methodological) comparability, e.g. of the patient population(s) to be examined or of the survey of characteristics cannot be established even mathematically, the positive healthcare effect must be demonstrated by means of a prospective comparative study.

In principle, the characterisation of the groups regarding comorbidities and main diagnosis is based on recognised scientific standards. The selection and, if necessary, conception of the comparison or control group is of importance. In principle, the control group can be used for inter- as well as intra-individual comparison. This means, for example, that both the inter-individual two-arm comparison (e.g. group A: application of DiGA and group B: control group) and the intra-individual one-arm comparison (e.g. before and after DiGA application) can provide evidence. In intra-individual comparison, the examined group therefore simultaneously represents its own control group.

The choice of an appropriate comparison is initially the responsibility of the manufacturer and is verified by the BfArM. Decisive for the appropriateness of the choice is not only the respective real application and healthcare context of the DiGA but also the suitability of the chosen concept from a scientific point of view.

The manufacturer must give the evidence that his DiGA is better than the control group. It is therefore not sufficient to prove that DiGA is equivalent to a DiGA already finally admitted to the directory. If such a comparison is made, the patient group treated with the comparable DiGA should have the same indication, structure, observational parameters and treatment.

	Possible Prospective Study for the Evidence of Positive Care Effects
permissible	<p>A DiGA supports patients with mild depression, who have received an indication in a psychotherapeutic consultation and who are treated with a time delay due to waiting for a psychotherapy treatment.</p> <p>The comparison against non-treatment is admissible, as patients are usually not treated during the waiting period if there is no urgent need for treatment.</p>

not permissible

A DiGA supports patients with a supine position dependent sleep apnea syndrome and gives acoustic signals when lying on the back to prevent breathing stops.

The comparison against non-treatment alone is not admissible, since patients are treated with a supine position prevention vest as standard and in the reality of care this is also used extensively by patients.

An evidence based solely on expert opinions or expert reports is excluded. Even observational, purely descriptive studies such as case reports, case series or cross-sectional studies are not suitable for proving a positive healthcare effect according to DiGAV.

Excluded studies: proof is based on expert opinions or expert reports as well as purely observational, descriptive studies

Table 1: Examples of study design

	feasible as a comparative study	feasible as a retrospective study	feasible as a prospective study	
expert opinions or expert reports				⇒ excluded
observational, purely descriptive studies e.g. case series / case reports, cross-sectional studies				⇒ excluded
observational analytical studies e.g. case / control studies, cohort studies				⇒ permissible
experimental intervention studies e.g. non-randomised / randomised controlled intervention study				⇒ permissible
meta-analyses also including evaluation of own primary data				⇒ permissible

	feasible
	not feasible

Observational analytical studies, such as case / control studies or cohort studies are acceptable study designs since they provide for a control group and can be conducted retrospectively or prospectively, depending on the research question. Before and after comparisons are also permitted. Furthermore, experimental intervention studies such as non-randomised or randomised controlled trial (RCT) are also suitable for demonstrating positive healthcare effects. Theoretically, it is also possible to present meta-analyses that meet the required criteria and specifications of the DiGAV. However, these must also include the manufacturer's own data and studies.

In addition to the above-mentioned study designs, other alternative study designs and methods such as Pragmatic Clinical Trials (PCT), Sequential Multiple Assignment Randomised Trial (SMART) or Multiphase Optimisation Strategy (MOST) may also be useful, depending on the care context of the DiGA and the evidence sought. The inclusion of other data sources in the sense of real-world-data can also be useful in proving the pVE. It is up to the BfArM to check such a procedure in individual cases using the alternative study designs and to approve it, if necessary. An early exchange with the BfArM in the planning phase of the evaluation concept is advantageous at this point.


Alternative study designs are permissible in individual cases

The manufacturer may also submit his own studies that he has carried out in the past when submitting his application. These must meet all the above criteria and must be reviewed in particular with regard to the timeliness of the underlying healthcare context.


The BfArM carries out a discretionary decision for each application. The assessment as to whether evidence of the pVE was provided on basis of study results is made on a case-by-case evaluation. In the case of particularly vulnerable patient populations or applications that may involve an inherently high risk due to the actual therapeutic approach, the study data must be methodologically robust to a particularly high degree.

The other additional examples are intended to show which considerations should play a role in the planning of a study according to Sections 10 to 12 DiGAV and which points the BfArM prioritises in the application procedure. These are selected examples that are intended to illustrate the spectrum of possible study objectives and parameters and should by no means be regarded as conclusive and complete.


Example 1

	DiGA-Supported Physiotherapy for Patients with Anterior Knee Pain
Feature(s)	Established and validated physiotherapeutic exercises are performed at home and instructed by the DiGA.
Target positive healthcare effect	<ul style="list-style-type: none"> - medical benefit
Research question / Study objective	Does the morbidity parameter "validated pain score" improve by using the DIGA compared to the control group, which does not use the DiGA? (intervention vs. control group)?
Parameters to be collected	<ul style="list-style-type: none"> - Numerical Rating Scale (NRS) for pain - KOOS (Knee Injury and Osteoarthritis Outcome Score) - Health-related quality of life (e.g. SF-36)
Method of data collection	<ul style="list-style-type: none"> - validated questionnaires - socio-economic data - billing data from health insurance funds
Possible data sources	<p>retrospective: data already collected by the DiGA, health insurance data, data from the electronic patient file, data from another DiGA that is finally listed in the directory</p> <p>prospective: validated questionnaires, medical findings</p>


Example 2

	Support DiGA for Mental Illness (e.g. Depression, Anxiety)
Feature(s)	Support of everyday life through know-how and diary keeping in the app, support through a structured digital care approach with guidance on behavioural therapy exercises
Target positive healthcare effect	<ul style="list-style-type: none"> - patient-relevant improvement of structure and processes: <ul style="list-style-type: none"> o Facilitating access to healthcare - medical benefit
Research question / Study objective	<p>Does the DiGA create a new or improved care situation for patients?</p> <p>Is an improvement of the mental disorder achievable by the use of DiGA compared to the usual care situation in Germany (intervention vs. control group)?</p>
Parameters to be collected	<ul style="list-style-type: none"> - Symptom Checklist SCL-90, including GSI (Global Severity Index, PSDI (Positive Symptom Distress Index), PST (Positive Symptom Total) - average waiting time until the start of therapy - therapy discontinuation rates - drug administration
Method of data collection	<ul style="list-style-type: none"> - validated questionnaires - clinical parameters - healthcare data
Possible data sources	<p>retrospective: data already collected by the DiGA, health insurance data, data from the electronic patient file, data from another DiGA that is finally listed in the directory</p> <p>prospective: validated questionnaires, medical findings</p>


Example 3

	Digital Pain Diary for Patients with Chronic Pain
Feature(s)	Documentation of the pain by the patient (pain intensity, pain duration, type of pain, frequency of pain)
Target positive healthcare effect	<ul style="list-style-type: none"> - patient-relevant improvement of structure and processes: <ul style="list-style-type: none"> o patient autonomy o health literacy o adherence
Research question / Study objective	Can pain be better documented with DiGA than without digital support?
Parameters to be collected	<ul style="list-style-type: none"> - validated adherence-score (e.g. Morisky-Score) - health literacy (e.g. HLS-EU-Q-questionnaire) - patient or user satisfaction
Method of data collection	- validated questionnaire
Possible data sources	retrospective: data already collected by the DiGA, data from the electronic patient file, data from another DiGA which is finally listed in the register prospective: validated questionnaires


Example 4

	Accompanying DiGA in Patients After Stroke
Feature(s)	Documentation of everyday activities, memory/motor status, further cognitive tests, information for patients on disease and therapy
Target positive healthcare effect	<ul style="list-style-type: none"> - patient-relevant improvement of structure and processes: <ul style="list-style-type: none"> o health literacy o adherence
Research question/ Study objective	Does the DiGA improve the health literacy and adherence of patients after a stroke?
Parameters to be collected	<ul style="list-style-type: none"> - validated adherence-score, when taking medication (e.g. Morisky-Score) - health literacy (e.g. HLS-EU-Q-questionnaire) - patient or user satisfaction
Method of data collection	- validated questionnaires
Possible data sources	retrospective: data already collected by the DiGA, data from another DiGA which is finally listed prospective: validated questionnaires

Example 5

	DiGA for Patients with Chronic Sleep Deficiency
Feature(s)	Instructions for exercises from the spectrum of cognitive behaviour therapy and relaxation
Target positive healthcare effect	<ul style="list-style-type: none"> - patient-relevant improvement of structure and processes: <ul style="list-style-type: none"> o patient autonomy - medical use
Research question/ Study objective	<p>Does the information from the DiGA improve patient autonomy?</p> <p>Does the DiGA improve the subjective sleep quality?</p>
Parameters to be collected	<ul style="list-style-type: none"> - Pittsburgh Sleep Quality Index (PSQI) - patient or user satisfaction
Method of data collection	<ul style="list-style-type: none"> - validated questionnaires - clinical parameters - healthcare data
Possible data sources	<p>retrospective: data already collected by the DiGA, health insurance data, data from the electronic patient file, data from another DiGA that is finally listed in the directory</p> <p>prospective: validated questionnaires, medical findings</p>

Example 6

	DiGA for Patients with Chronic Sleep Deficiency
Feature(s)	Documentation about pain conditions / neural events, information about disease pattern, reminder of appointments / medication, motivation, e.g. for sports activities
Target positive healthcare effect	<ul style="list-style-type: none"> - patient-relevant improvement of structure and processes: <ul style="list-style-type: none"> o adherence o health literacy
Research question / Study objective	<p>Does the use of DiGA improve the adherence in this group of patients?</p> <p>Does it increase health literacy?</p>
Parameters to be collected	<ul style="list-style-type: none"> - validated adherence-score, when taking medication (e.g. Morisky-Score) - health literacy (HLS-EU-Q-questionnaire) - patient or user satisfaction
Method of data collection	<ul style="list-style-type: none"> - validated questionnaire - clinical parameters - healthcare data
Possible data sources	<p>retrospective: data already collected by the DiGA, health insurance data, data from another DiGA that is finally listed in the register</p> <p>prospective: validated questionnaires, medical findings</p>

As a guideline for planning a study with medical devices, the DIN EN ISO 14155 “Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice” and the FDA guide “Design Considerations for Pivotal Clinical Investigations for Medical Devices” can be used. The planning and execution of the study towards the objective of the study is the responsibility of the manufacturer. In case of physician's involvement, the ethical principles of the Declaration of Helsinki apply and at least one professional consultation with an ethics committee must be carried out. Other possibly applicable medical device regulations must also be observed. The manufacturer is initially responsible for checking the requirements and ensuring that they fit into the regulatory context. If necessary, it can also be discussed within the framework

of the consultation by the ethics committee or a consultation by the BfArM. The study must be conducted in Germany. If studies are conducted outside Germany, the transferability to the German healthcare situation must be proven.

The study report shall be prepared according to internationally accepted standards for the presentation and reporting of studies. The results must be published in full by the manufacturer on the internet in a public register that is a primary or partner register or a data provider of the WHO International Clinical Trials Registry Platform (ICTRP). Negative results are not exempt from the obligation to publish. See also [Chapter 4.4.1 International Standards for Study Reports](#).



If studies and meta-analyses already exist, is a study report even necessary or would an introductory summary be appropriate?

A study report must be submitted in every case - regardless of whether the studies have already been published.

4.6.2 Studies on Diagnostic Quality

A diagnostic function can be an essential and important component of a DiGA and can record treatment-relevant parameters by individual or serial measurements. The measurement can, i.e. be performed by external sensors such as cameras, microphones, position sensors, etc., but also by user input on validated scales such as the Numerical Rating Scale (NRS) or by completing validated questionnaires such as the Center for Epidemiological Studies Depression Scale. Thus, a wide range of parameters can be measured, monitored and, if necessary, evaluated.


Examples for a DiGA with diagnostic function




Using 3D camera technology, a DiGA records movement patterns and determines the probability of falls in patients with walking disabilities.




A DiGA uses position sensors to detect trembling movements of the arms (tremor) and evaluates the medication settings of patients with Parkinson's disease.


	<p>A DiGA records the pain values by regularly querying the numerical rating scale and provides information on untreated pain peaks in tumor patients.</p>
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	<p>By filling out the Epworth Sleepiness Scale (ESS), a DiGA records the sleepiness of patients with sleep apnea syndrome and instructs the patient in case of abnormalities to have their home therapy settings checked by their doctor and adjusted if necessary.</p>
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In order to assess the quality of a diagnostic instrument in a DiGA, the test accuracy with sensitivity and specificity has to be demonstrated in a dedicated study. The evidence must refer to the patient group defined by the ICD-10 coding. The test accuracy study may also be part of the study to demonstrate positive effects of care.

If the diagnostic tool is a recognised and scientifically validated test procedure such as a validated questionnaire, studies that determine the test quality can be submitted as evidence. However, if the diagnostic instrument is used in combination with other test procedures, also validated ones if applicable, and the results influence or condition each other, proof of test quality must be provided for the whole construct.

	<p>The DiGA contains the validated NRS for pain documentation for a pain diary in chronic inflammatory bowel disease</p>
<p>Evidence</p>	<p>Evidence of test quality possible via literature references</p>

	<p>The DiGA contains the validated NRS for pain documentation as well as the “Kiel Headache Questionnaire” and indirectly estimates a headache probability that recommends medication when a threshold is exceeded.</p>
<p>Evidence</p>	<p>Although validated questionnaires are used, the hypothetical overarching test procedure for determining the “likelihood of headache” must be examined in a study of test quality.</p>

5 Course of the Procedure

5.1 Deadlines for Applicants and the BfArM

5.2 Life Cycle of a DiGA in the Directory

5.3 Changes to the DiGA

5.4 Advice by the BfArM

5.5 Application Fees and Expenses of the BfArM

The entire application procedure is conducted via the BfArM application portal. This portal allows, among other things, to submit an application for listing in the DiGA directory, submitting documents on the expiration of the trial phase for final listing or applying for an extension of the trial phase and notifications of significant changes to the DiGA in accordance with Sections 18 and 19 DiGAV. Further details on the practical application procedure and on how to fill out the forms in the portal can be found in the application guideline.

This chapter is primarily covering practical, administrative topics related to the application and the application portal. This includes, i.e. deadlines and fees to be observed.

In addition, an outlook is given on what happens when a DiGA is included in the directory: What rights and obligations are involved, and what exactly does the manufacturer have to do if he makes changes to the DiGA?

5.1 Deadlines for Applicants and the BfArM

The application procedure begins when the manufacturer has submitted the application for listing a DiGA in the DiGA directory to the BfArM. In practice, the application procedure begins when the manufacturer has filled out all the mandatory information in the application portal and attached the necessary attachments, clicked on the button that triggers the transmission of the application to the BfArM who receives the application online.

Start of the application procedure

Once the application procedure has begun, the BfArM first conducts an initial formal review in which the formal completeness of the submitted documents and evidence is checked:

Initial formal check

- In any case, the applicant receives a reply from the BfArM within 14 days.
- If the documents and verifications are complete, the BfArM will confirm receipt of the formally complete application documents to the applicant within 14 days, stating the corresponding date of receipt as the start of the processing period.

- If, however, the BfArM determines during the incoming inspection that the application documents are incomplete, it will ask the applicant to complete the application within a period of up to three months and submit the changes or additions via the application portal. It is, of course, also possible to submit the missing documents or information earlier at any time within the set deadline in order to speed up the procedure.
- If the document is complete after the addition, the BfArM will inform the applicant of the corresponding date of receipt of the complete application documents as the start of the processing period.
- If the application documents have not been completed within the set deadline, the BfArM must refuse the application and will notify the applicant accordingly.
- If the manufacturer is unable to supply the demanded information, he may withdraw the application. To do so, he must submit a written declaration of withdrawal of the application via the electronic application portal.

On the day of receipt of the complete documents by the BfArM, the legally prescribed maximum three-month evaluation period of the application by the BfArM begins. At the end of this period, the application is either included in the directory (provisional or final) or refused and a corresponding notification is issued.

Start of the processing period



How and within what period can I object to a decision?

An objection may be lodged against the decision within one month of notification. The appeal must be lodged with the BfArM. The notification will contain instructions on how to appeal.

During the three-month processing period, the BfArM may demand that the manufacturer makes changes or additions to the application details or documents. This is the case, i.e. if an explanation of a “not applicable” answer in the checklist from Annex 2 of the DiGAV is not comprehensible to the BfArM or if statements in the application do not appear conclusive. In its correspondence, the BfArM usually sets deadlines for the applicant for such additional claims.

If the manufacturer is unable to provide a sufficient response to the requested subsequent deliveries in the form of corresponding information or documents within the set deadline, the BfArM must refuse the application and will notify the applicant accordingly. If the manufacturer is not able to provide the required subsequent deliveries, it may withdraw the application. For this purpose, a written declaration of withdrawal of the application must be submitted via the electronic application portal



After the application procedure officially started and until receipt of the decision of the BfArM, changes or additions to the application for listing a DiGA

in the directory are only possible at the request of the BfArM. The manufacturer cannot subsequently change or complete applications that have been released in the application portal on his own initiative.

The deadline for the subsequent submission of missing information and evidence will be set by the BfArM as a discretionary decision. In individual cases, the deadline may be considerably shorter than three months, i.e. if information that is easy to obtain or only a small amount of information needs to be complemented. The BfArM's subsequent demand does not result in an extension of the processing period. The expiration of the processing period of three months from receipt of the complete application is not impeded by the additional demand.



Can I contact the BfArM by telephone or e-mail to clarify incomprehensible matters with regard to the BfArM's supplementary claim?

The BfArM is available to answer questions on the comprehensibility of supplementary claims at your disposal.



Can I arrange further consultation appointments at the BfArM if my DiGA is listed in the directory after completion of the application procedure?

Yes, this can be useful, i.e. in the case of a DiGA included for trial if the manufacturer intends to extend the trial phase. Advice from the BfArM can also be helpful on the question of whether a change to the DiGA constitutes a significant change within the meaning of Section 18 DiGAV.



As a manufacturer, does it make a difference whether I withdraw an application or receive a refusal (e.g. because I let a deadline pass)?

A withdrawn application can be re-submitted at any time as long as no decision has been taken.

If the BfArM has issued a refusal on the basis of missing or unrecognised evidence of positive healthcare effects, a new application can be made in accordance with paragraph Section 139e paragraph 2 SGB V at the earliest twelve months after the refusal of the BfArM and only if new evidence of positive healthcare effects is submitted.

5.2 Life Cycle of a DiGA in the Directory

A DiGA becomes visible in the DiGA directory as soon as a positive decision on the inclusion in the DiGA directory according to Section 139e SGB V has been issued. All information published and presented in the DiGA directory is automatically taken from the information provided in the original application. The BfArM ensures that all information in the directory is displayed correctly and that a DiGA newly included in the DiGA directory is found by physicians and insured persons using the appropriate search filters.

5.2.1 Obligations of the BfArM after the Listing of a DiGA in the DiGA Directory

The positive healthcare effects proven in the study to be submitted or carried out as part of a test conducted and recognised by the BfArM are entered in the DiGA register in addition to the information from the manufacturer's application.

Entry of proven and recognised positive healthcare effect

On the basis of the completed tests, the BfArM enters the required medical services into the DiGA directory according to the manufacturer's proposal, should the DiGA in question provide for the involvement of a physician. In addition, the BfArM sends a notification of its assessment of the required medical services to the evaluation committee, which compares them with the SHI benefits catalogue and, if necessary, establishes them in the Physicians' Fee Scale (Einheitlicher Bewertungsmaßstab, EBM).

Entry of required medical services in the DiGA directory

After final listing in the DiGA directory, the amount of remuneration for the DiGA must be negotiated between the manufacturer and the National Association of Statutory Health Insurance Funds (GKV-SV). This replaces the actual price ("manufacturer price") twelve months after the decision of the BfArM on the provisional or final listing of the DiGA in the DiGA directory. The BfArM informs the GKV-SV of the need for corresponding price negotiations.

Price update when actual price is available

5.2.2 Manufacturer's Obligations After the Listing of a DiGA in the DiGA Directory

The study submitted with the application or carried out as part of the trial period must be published no later than one year after the completion of the study. This is the responsibility of the manufacturer, who has to provide the link to where the study is published, either with the application or with the submission of the documents for final listing after the end of the trial period – or submit it at the time of publication. This link will be added to the DiGA directory by the BfArM.

Publication of the study

Every time a manufacturer makes changes to the DiGA he has to check whether these are significant changes according to Section 18 DiGAV, which have to be reported to the BfArM. For this purpose, the checklist of the BfArM can be used for an initial orienting self-assessment (see [Chapter 5.3 – Changes to the DiGA](#)). The obligation for notification of significant changes exists regardless of whether a DiGA is included in the DiGA directory permanently or provisionally. Even during the trial phase, any significant change must result in a notification. Safety-relevant changes must be directly implemented and reported within the framework of the Medical Devices Act (MPG). If an additional notification as a "significant change" according to Section 139e SGB V is necessary, the manufacturer is also obliged to provide that. This notification cannot and should not delay the implementation of safety-relevant changes.

Check if changes are significant changes

It is the responsibility of the manufacturer to ensure that all information displayed or linked to the DiGA in the directory is up-to-date and complete. Information displayed directly in the directory can only be updated by the BfArM by means of a notification of a significant change after appropriate evaluation. A direct maintenance of this information by the manufacturer is not intended.

Ensuring that information is up-to-date and complete

All information linked in the DiGA directory in the distribution platform or on the application website must be kept up to date by the manufacturer in an active and independent manner.

Keeping information linked in the distribution platform or the application website up to date

In particular, Annex 1 of the DiGAV imposes various obligations on the manufacturer of the DiGA, which can be derived directly from the processes described there and to be set up by the manufacturer:

Obligations resulting from Annex 1 of the DiGAV

- continuous maintenance, reassessment and further development of the technical and organisational measures of data protection and information security (*Verfahren zur regelmäßigen Überprüfung, Bewertung und Evaluierung der Wirksamkeit der technischen und organisatorischen Maßnahmen zur Gewährleistung der Sicherheit der Verarbeitung* according requirement 28 in Annex 1 of the DiGAV and *kontinuierliche Neubewertung von Bedrohungen und Risiken* according to requirement 30 in Annex 1 of the DiGAV),
- planning and implementation of changes within a framework of change and release management, maintenance of the product configuration as well as the runtime and operating environment via configuration management,
- maintenance of the directory of third-party software in use and monitoring its development and status (e.g. version updates or changes in support),
- deleting or blocking of data that no longer required,
- automated evaluation of logging data in order to detect or proactively prevent safety-relevant events.

Further continuous, DiGA-specific obligations may result from the General Data Protection Regulation, possibly other data protection regulations, the Medical Device Law and the processes and components of IT-data protection) relevant to DiGA.

Further continuous, DiGA-specific obligations

5.2.3 Mandatory Further Development of the DiGA

Various requirements are specified in the DiGAV, which are only to be implemented at a later date. The manufacturer must provide the following DiGA extensions by 01.01.2021 via updates, even for DiGA already listed in the directory:

DiGA extensions to be provided

- support of the authentication of insured persons via NFC-capable health cards

- support of the authentication of healthcare providers via NFC-capable health professional cards (if healthcare providers are intended as active users of the DiGA)
- interoperable export interface and export of selected DiGA content in a human-readable format
- interoperable interface to connected medical devices and wearables (if the DiGA depends on such devices)
- implementation of operating aids for people with disabilities or support of the operating aids offered by the platform

Manufacturers who apply for listing in the DiGA directory after the end of 2021 must have set up and established an information security management system (ISMS).

5.2.4 De-Listing of a DiGA from the DiGA Directory

If a manufacturer wishes to have a DiGA deleted from the directory, he can submit an application for de-listing to the BfArM via the electronic application portal. This deletion is not bound to any preconditions. The de-listing of a DiGA from the DiGA directory is subject to a fee (see [Chapter 5.5 Application Fees and Expenses of the BfArM](#))

[Application for de-listing via the electronic application portal](#)

The BfArM may remove a DiGA provisionally listed in the DiGA directory from the directory if it was initially included for testing and the manufacturer is unable to provide the evidence for a pVE (in time or completely). Furthermore, the BfArM may delete a finally listed DiGA from the register if, upon notification of a substantial change by the manufacturer, there are reasons to believe that the DiGA can no longer be included in the directory, e.g. because the change to the DiGA means that the previously fulfilled test criteria are no longer met.

[De-Listing from the DiGA directory by the BfArM](#)

If the manufacturer consciously or unconsciously makes false statements in the application for listing in the DiGA directory or in the notification of a significant change, the BfArM may delete the DiGA from the directory in accordance with Section 139e paragraph 6 SGB V or withdraw or revoke the listing in the directory for DiGA in accordance with Section 139e paragraph 1 SGB V under general social law regulations.

5.3 Changes to the DiGA

According to Section 18 DiGAV, changes to the DiGA which have a significant influence on the evaluation decision of the BfArM, or which may lead to changes in the information in the directory must be reported as such to the BfArM using the corresponding form in the application portal. Information that is maintained by the manufacturer on the application website and is only linked from the directory does not fall under the term “data and information

published in the directory for digital health applications” from Section 18 paragraph DiGAV. A significant change can be, for example, a change in the location of data storage, a change in prices, etc. The availability of the DiGA for a new hardware or a new operating system version, on the other hand, is not a significant change as it is not the implementation of another or the update of an existing standard at the export interface. Also, pure design changes, necessary updates for error correction, etc. are not counted among the significant changes.

For the self-assessment on the part of the manufacturer as to whether a change to the DiGA is a “significant change” in the sense of Section 18 DiGAV, the BfArM has provided a checklist which can be downloaded from the BfArM website. As soon as one of the questions listed there is answered with “yes”, it can be assumed that the planned change falls under the characteristic of a notifiable significant change. In the event of uncertainty, the BfArM offers advice; the sole independent examination based on the questionnaire does not release the applicant from the obligation to clarify any necessary obligation to notify with the BfArM in order to avoid sanctions.

If in the course of the assessment of the notification of changes by the BfArM it turns out that the information in the notification is not sufficient to decide on the necessity of adapting the directory or on the deletion of the application from the directory, the BfArM may request the manufacturer to complement the information within a period of up to three months.

! If the BfArM becomes aware of changes made which have not been notified to the BfArM or have not been notified in time (three months before the change is made), the BfArM may delete the affected DiGA from the directory.

The notification and assessment of the significant change(s) may result in the BfArM adjusting the details of the DiGA in the directory. The assessment of the change(s) made may also lead to a decision that the requirements for listing in the directory are no longer fulfilled, provided that the notified change is implemented as indicated.

In order to avoid deletion from the directory in such a case, it is recommended to contact the BfArM at an early stage and, if necessary, to refrain from the planned change or to implement it in an adapted form according to the recommendations of the BfArM.

 **Do I also have to fill in the checklist in the case of a change that I as a manufacturer do not consider significant?**

The checklist is only intended to support the manufacturers. The manufacturer can thus check the modifications made against the criteria of Section 18 DiGAV and document the result of this check. There is no obligation to do so and the manufacturer does not necessarily have to keep the completed test form and

be able to show it when requested. However, storage for internal documentation of the changes is recommended on a voluntary basis.

5.4 Advice by the BfArM

The BfArM offers extensive consulting services to manufacturers who wish to apply for the listing of their DiGA in the directory, on issues involved: Starting with simple questions of understanding which cannot already be answered by the guide or further information from the BfArM, through questions e.g. on the requirements for listing in the DiGA directory to questions on the documents and evidence to be submitted. The BfArM provides a form (www.bfarm.de/innovation) for requesting advice. The manufacturer himself or an authorised representative can apply for consultation. Depending on the applicant's wishes, advice can be given in writing, by telephone, by video conference or in the form of a personal meeting at the BfArM in Bonn. The applicant will receive a notification of fees after completion of the counselling process.

Consultation is available either before or after inclusion in the DiGA directory. However, the BfArM cannot offer advice on ongoing proceedings under Section 139e SGB V.

Consultation before or after inclusion in the DiGA directory

5.4.1 Consultation before Inclusion in the DiGA Directory

In a consultation prior to application, information will be provided in particular on the eligibility to apply, the procedure or the information and proof to be submitted with an application for listing in the DiGA directory. The subject of such consultation may, for example be the question of whether the purpose, function or implementation of a digital application may give rise to questions regarding conformity with the definition of a DiGA, which the manufacturer should reconsider as part of the further development of its offer.

In addition, the details of the required proof of a positive healthcare effect, whether for provisional or final listing, can also be discussed in a consultation. For example, it can be discussed together with the BfArM whether the available data are already sufficient for a final listing in the directory or whether an application for provisional listing in the DiGA directory is recommended first. Questions of the evaluation concept in the case of planned provisional listing can also be the subject of a consultation with the BfArM before the application is submitted.



Will I receive binding advice, and can I rely on the advice in the proceedings?

No legal obligation of the BfArM to the legal opinions expressed results from the consultation, especially as this is based on the current state of scientific knowledge and essentially on the information provided by the manufacturer

or applicant. The manufacturer (or his authorised representative for the application according to Section 139e) must prepare a **protocol** of the results of the consultation (according to the draft of the BfArM, available at www.bfarm.de/innovation), which must be enclosed with any subsequent application for listing in the directory.

5.4.2 Consultation after Inclusion in the DiGA Directory

After inclusion in the DiGA directory, questions regarding planned changes to the DiGA may also be discussed, in particular to what extent they meet the criteria of a significant change and are therefore notifiable to the BfArM (see [Chapter 5.3 Changes to the DiGA](#)).

5.4.3 Consulting Fees

Depending on the nature and scope of the issue, the consultation may be subject to fees of between 250 and 5,000 euros (Section 27 DiGAV).

In the case of simple enquiries, which do not require any significant preparatory or follow-up work on the part of the BfArM, fees are generally not charged. This applies in particular to *minor general oral, written or electronic information* referred to in Section 27 paragraph 2 DiGAV.

Consulting services that subject to charges are divided into four categories, which are shown in the following table.

Chargeable consulting services

Table 2: Chargeable consulting services

Category	Object of Consultation	Charge
I	- General questions e.g. on the formal requirements of the application procedure or eligibility to apply	€ 250
II	- Inquiries e.g. about more detailed product-related application requirements, documents to be submitted - Requests with similar extent regarding material and personnel expenses.	€ 1,000
III	- Inquiries about methodical and more extensive procedural requirements - Requests for assessment of significant changes	€ 2,000

IV	<ul style="list-style-type: none"> - Inquiries with direct reference to the individual requirements for providing evidence, the suitability of evidence, - the suitability of specific study designs/evaluation concepts for demonstrating a positive healthcare effect - Requests with similar extent regarding material and personnel expenses. 	€ 5,000
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In the run-up to the consultation, the manufacturer can ask the submitted inquiry to be classified into the corresponding fee categories for better orientation and planning. It should be noted here that billing will be based on the actual personnel and material expenses incurred and that changes may still be made depending on any additional consulting services that may be required in advance or during the discussion.



Can I ask general questions also by e-mail, without an application form?

Yes. Simple or more general questions about the procedure according to Section 139e SGB V, about documents, deadlines, etc. or in the run-up to a consultation can also be directed by telephone or e-mail to the Innovation Office of the BfArM or to the corresponding contact persons of the department:

e-mail: innovation@bfarm.de

Questions regarding ongoing application procedures can be sent in writing to the following e-mail address, quoting the reference:

e-mail: diga@bfarm.de

5.5 Application Fees and Expenses of the BfArM

The BfArM charges fees for the processing of applications and notifications (listing of DiGA in the DiGA directory, notification of significant changes, etc.).

The applicable fees can be found in Section 9 of the DiGAV (Fees and Expenses, Section 24 et seq.). Currently (August 2020) the fees for individual applications are set as follows.

Fees for the processing of applications and notifications


Table 3: Fees for the processing of applications and notifications

Application or Notification	Charge
Application for final listing in the DiGA directory	€ 3,000 to € 9,900
Application for provisional listing in the DiGA directory	€ 3,000 to € 9,900
Assessment of the proof of positive healthcare effect after the trial phase (in the case of provisional listing)	€ 1,500 to € 6,600
Application for extension of the trial phase	€ 1,500 to € 4,900
Notification of significant changes to the DiGA	€ 1,500 to € 4,900
Notification of the need for changes to the information published in the DiGA directory	€ 300 to € 1,000
Removing of a DiGA from the DiGA directory	€ 200


The reimbursement of any necessary expenses of the BfArM is made in accordance with the Federal Fees Act (Bundesgebührengesetz).

The applicant will receive a separate notification of fees after completion of an application or notification procedure. Fees may also be charged if an application is refused, an objection is raised against a notice or if the applicant


withdraws the application. Further details are also regulated in Section 9 of the DiGAV.

 **Can I be (partially) exempted from the fees?**

Section 30 DiGAV lists various reasons for which a manufacturer can apply to the BfArM for a fee reduction or exemption from fees. This applies in particular to DiGA with a very small target group, rare use cases and constellations in which the fees are disproportionate to the expected economic benefit of DiGA.

 **If the application is refused, must the fees for the application also be paid?**

Yes, as a full examination has been carried out. The fees are due regardless of the result of the examination.

 **Is a reduction in fees for applications for listing possible if a manufacturer submits individual applications for two devices in different indication areas which are similar in content and relevant criteria and which are certified as individual medical devices?**

The circumstances for a reduction of the fees are set out in Section 30 DiGAV. These do not apply in the given case. Therefore, in this constellation, the full fees must be paid for each application.

Glossary

A B C D E F G H I M N P R S U V W

A

Additional costs	An insured person has to pay the additional costs of medical devices if their functions or areas of application exceed the applications listed in the DiGA directory according to Section 139e SGB V or if their costs exceed the limit of reimbursement according Section 134 SGB V.
Applicant	Manufacturer of a DiGA or their representative, who filed an application to the BfArM in order to list the DiGA in the DiGA directory.
Evaluation of methods	A medical method is a procedure for the examination or treatment of certain illnesses, which is based on its own theoretical and scientific concept. If its benefit has not yet been sufficiently proven, it must be tested in a study and its usefulness evaluated (responsibility: Federal Joint Committee (Gemeinsamer Bundesausschuss / G-BA)).
Authorised representative according to Article 2 Para.32 Medical Device Regulation (MDR) or Sec. 3 Cl. 16 Medical Devices Act (MPG)	Any natural person or legal entity established within the EU who has been commissioned (in writing) by a manufacturer established outside the EU to perform certain duties in his name in order to fulfil the requirements resulting from this regulation and who has accepted this commission.
Authorised representative for the submission of applications	A third person authorised by the manufacturer to file an application to be listed in the DiGA directory according to Section 139e SGB V. This authorised representative for the submission of applications is not necessarily an authorised representative according to Article 2(32) Medical Device Regulation (MDR).

B

BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte)	The Federal Institute for Drugs and Medical Devices is an independent federal superior authority within the portfolio of the Federal Ministry of Health. The BfArM manages the DiGA directory and decides on all applications for DiGA to be listed in the directory.
BMG	Federal Ministry of Health

C

Cohort Study	A comparative observational study in which the sample belongs to the same cohort. A cohort is a group of people who have a similar defining characteristic. It belongs to the longitudinal studies.
Collective Contracts (Kollektivverträge)	Agreed rules on how health care, particularly by licensed physicians and dentists, should be provided. They are agreed at state level between the associations of (dental) physicians and the state associations of health insurance funds and at federal level between the Federal Association of Statutory Health Insurance (Dental) Physicians and the GKV-SV.

D

Data portability (Article 20 GDPR)	An insured person's right to transfer data he or she entrusted to one responsible party to another responsible party.
Declaration of Helsinki	Declaration by the World Medical Association (June 1964) committing to ethical principles for medical studies conducted on humans.
Diagnostic tool	One use case of digital health application that can support medical diagnoses, e.g. by measuring and interpreting of vital data, by questioning users on physical or psychological conditions, by tracking levels of pain perception etc.
Digital Health Application (Digitale Gesundheitsanwendung - DiGA)	A DiGA is a medical device of Class I or IIa that achieves its designated main function via digital technologies and is used either by a patient or a patient and a healthcare provider mutually.
Digital Healthcare Act (Digitale-Versorgung-Gesetz - DVG)	Law for the improvement of medical care by the means of digitalisation and innovation (DVG). Among other things, the law introduced a right of prescription of digital health applications.
Digital Health Applications Ordinance (Digitale-Gesundheitsanwendungen-Verordnung – DiGAV)	Ordinance concerning the procedure and the requirements for deciding on the reimbursability of Digital Health Appliances within the statutory health insurance.
DiGA directory	The directory of Medical Health Appliances according to Section 139e SGB V. Only DiGA that are listed in the DiGA directory can be prescribed by physicians and psychotherapists or be approved by health insurance companies.
DIMDI (Deutsches Institut für Medizinische Dokumentation und Information)	Former German Institute for Medical Documentation and Information, now BfArM office Cologne

E

EU-US Privacy Shield	The EU-US Privacy Shield is an agreement between the European Union and the USA that regulates the protection of personal data transferred from an EU member state to the
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	USA. Participating US-Companies guarantee to comply with specified data protection rules and publish their policies on the handling of personal data in a freely accessible register. On July 16 th 2020, the Court of Justice of the European Union invalidated the EU-US Privacy Shield (C-311-18), for more information: chapter 3.3.3.
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F

Fast Track	Accelerated procedure by which a DiGA is supposed to be admitted (also for trial period) as a part of regular medical care more swiftly. To take part in the fast track procedure it is necessary for the manufacturer to file an application in order to be listed in the DiGA directory.
Federal Joint Committee (Gemeinsamer Bundesausschuss / G-BA)	The Federal Joint Committee (G-BA) consists of the National Association of Statutory Health Insurance Physicians/Dentists, the National Association of Statutory Health Insurance Funds (GKV-SV) and the German Hospital Federation (DKG). It represents the highest decision-making body within the system of joint self-administration that decides which healthcare services qualify for reimbursement in the statutory health insurance.
FDA	U. S. Food and Drug Administration
Framework agreement	In accordance with Section 134 SGB V, the National Association of Statutory Health Insurance Funds and the relevant federal umbrella organisations of the manufacturers of digital health applications, which are formed to represent their economic interests, reach a framework agreement on the standards for the agreements of the remuneration amounts.

G

GDPR (Datenschutz-Grundverordnung - DSGVO)	General Data Protection Regulation. Regulation (EU) 2016/679 by the European Parliament and the European Council of April 27th, 2016 protecting natural persons concerning the processing of personal data, the free movement of data and the abolition of directive 95/46/EC.
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H

Healthcare providers	Group of persons who provide services for the insured under the Statutory Health Insurance: physicians, psychotherapists, but also a large number of other
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	healthcare providers such as physiotherapists and occupational therapists.
Healthcare providers who can prescribe DiGA	SHI-accredited physicians and psychotherapists
HL7 Deutschland e. V.	Health Level 7 is a communication standard specifically developed for the healthcare system. As an informal group, the German partner organisation of the international standardisation body works closely with the German standardisation bodies.

I

ICD-10	Regularly updated international statistical classification of diseases and related health conditions (ICD).
Interoperability	Interoperability refers to the ability of technical systems to work together on a technical-syntactical, semantic and organisational level.
ISMS	An information security management system defines rules and methods for ensuring information security in a company or an organisation.
ISO / IEEE 11073	A family of standards and norms defining the component of systems used for the exchange of vital data between medical devices and for the remote control of such devices.
ISO 14155 “good clinical practice”	A norm that covers the formal requirements for the conduct of clinical trials for medical devices. It focuses on the protection of the test persons, their informed consent and the quality of the study results.

M

Manufacturer	Manufacturer of a Digital Health Appliance within the scope of the Medical Devices Act (MPG) according to Section 3 paragraph 15 MPG or Article 2 paragraph 30 (EU) 2017 / 745 (MDR, Medical Device Regulation).
Medical benefit	Medical benefit according to DiGAV is the perceptible effect for a patient specifically regarding improvement of the state of health, the shortening of the duration of the disease, the extension of survival or an improvement in the health-related quality of life.
Medical devices	Medical devices are products with a medical purpose which are intended by the manufacturer to be used on humans. They are classified and tested according to their risk class.

N

National Association of Statutory Health Insurance Funds (GKV-Spitzenverband, GKV-SV)	The central association of the German health insurance funds: National Association of Statutory Health Insurance Funds (GKV) at the national level, which primarily regulates the framework conditions for competition for quality and efficiency of care. The contracts concluded by the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and its other decisions apply to its member funds, the regional associations of health insurance funds and to the insured.
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P

Patient-relevant improvements of structure and processes	<p>Patient-relevant improvement of structure and processes in healthcare are aimed at supporting patients' health behaviour or at integrating processes between patients and care providers in the context of the identification, monitoring, treatment or alleviation of diseases or the recognition, treatment, alleviation or compensation of injuries or disabilities. They include particularly the areas of</p> <ul style="list-style-type: none">- coordination of treatment processes,- alignment of treatment with guides and recognised standards,- adherence,- facilitating access to healthcare,- patient safety,- health literacy,- patient autonomy,- coping with illness-related difficulties in everyday life or- reducing therapy-related expenses and strains for patients and their relatives.
Penetration test (also pen test)	Testing the (IT-) security of a network and its components by simulating a hacker attack. Determined attack patterns are used to check for the possibility of unauthorised intrusion into the system.
Positive Healthcare Effect	Positive healthcare effects in the sense of the DiGAV consist either of medical benefits or in patient-relevant improvements of structure and processes in healthcare.
Prevention	Measures and activities to prevent illness or damage to health, reduce the risk of illness or delay its occurrence.

	<ul style="list-style-type: none"> - primary prevention: aims to avoid the development of disease - secondary prevention: aims at the early detection of diseases or at preventing the worsening of a disease - tertiary prevention: aims to prevent complications, alleviate the consequences of a pre-existing, mostly chronic disease or to prevent a relapse
Propensity Score Matching (PSM)	Form of assignment of study participants in pairs to estimate effects of an intervention between different observation groups in non-experimental, non-randomised studies.
Prospective study	Observational study, where data collection takes place after the start of the study and specifically for this study.

R

Retrospective study	Observational study, where data collection takes place before the start of the study.
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S

Scientific evaluation concept	If an application for provisional listing is to be submitted, a scientific evaluation concept must be attached to it. To prove the positive effect of care according to generally accepted scientific standards, this concept must be prepared by an institution independent of the manufacturer according to generally accepted scientific standards.
Selective contracts	Individual contract between one or more health insurance funds, healthcare providers and insured persons, in which services outside the standard care can be agreed upon. With the DVG, health insurance companies can also enter into selective contracts with DiGA manufacturers without involving healthcare providers.
Significant changes	<p>The following changes are considered as significant changes:</p> <ul style="list-style-type: none"> - Modifications of the data and information provided in the DiGA directory - Changes which have a significant influence on the fulfilment of the requirements for safety, functionality and quality of the medical device, - data protection and security or - Proof of positive healthcare effects, including changes in patient groups for which the positive healthcare effects of a digital health application have been or will be demonstrated.

U

User	User of a digital health application (DiGA), usually a patient.
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V

Vesta directory	Interoperability directory of the German healthcare system.
Vulnerable patient population	Patients with the following characteristics: <ul style="list-style-type: none">- under 18 or over 65 years old- people with mental illnesses- people with diseases or disabilities that impair the ability to reason and/or significantly impair the ability to cope with everyday life

W

WHO-ICTRP	International Clinical Trials Registry Platform. This clinical trial registry publishes information on the planning, conduct and management of clinical trials on a publicly accessible website.
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Images

Federal Institute for Drugs and Medical Devices (BfArM)

Notice

This guide (as of August 7th, 2020) is available as a pdf-file (Adobe®) in German language on the website www.bfarm.de/diga.

Disclaimer

This English version of the guide is a service provided by the BfArM, which also includes translations of the German standard texts or references to them.

The corresponding standards in the German version are legally binding; these will also be available in English translation shortly.

Version

1.0

Revision history

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