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Digital health applications – an evidence-based-approach?

Evaluation and reimbursement process of digital health applications (DiGA) in Germany

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Introduction - Legal framework

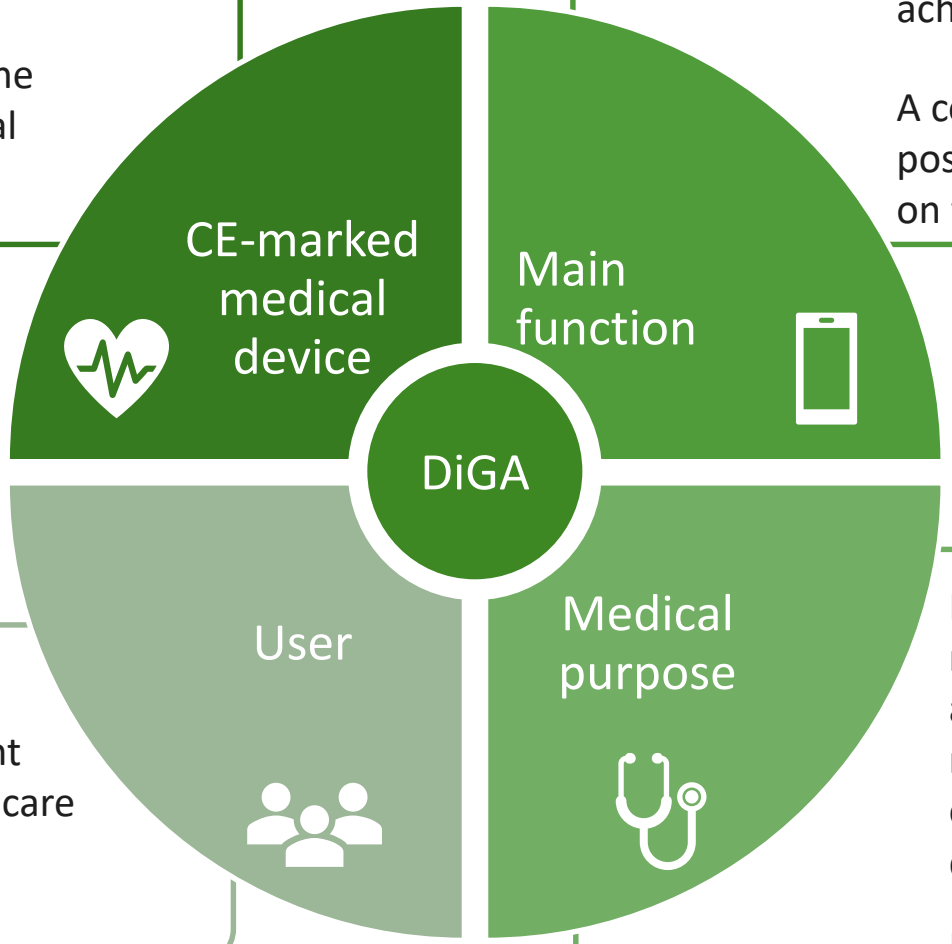
- Digital health applications (**DiGA** – in German: “Digitale Gesundheitsanwendungen”) are **mobile apps or web applications that may be prescribed for medical purposes**.
- With the **Digital Healthcare Act** (Digitale-Versorgung-Gesetz, DVG) coming into force on December 19, **2019** the sometimes called "app on prescription" for patients were introduced into German healthcare
- This means that around 73 million people with **statutory health insurance** (SHI) in Germany can use a medically indicated DiGA at the expense of the SHI.
- The **prerequisite** for this is that the DiGA has successfully passed a testing procedure at the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte**, BfArM**) and is listed in a specific directory
  - The BfArM is an independent federal higher authority within the portfolio of the Federal Ministry of Health.
- **Aim:** To promote digitalisation in healthcare, to create low-threshold access to care services (regardless of time and place of residence), to involve patients in the control and treatment of their illness, and to facilitate communication and coordination between patients and healthcare professionals.

Definition of the term DiGA within the legal framework

Medical device of the risk class I or IIa (according to the Medical Device Regulation (MDR) or the transitional regulation Medical Device Directive (MDD)).

The medical purpose is mainly achieved by way of its digital function.

A combination with hardware is possible if the main function is based on the digital technology.



The DiGA is used by the patient alone or by patient and healthcare provider together

DiGA supports the recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment, alleviation or compensation of injuries or disabilities.

DiGA does not serve primary prevention

How do patients obtain a DiGA?

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Insured persons have **two options for obtaining a listed DiGA** at the expense of the health insurance company

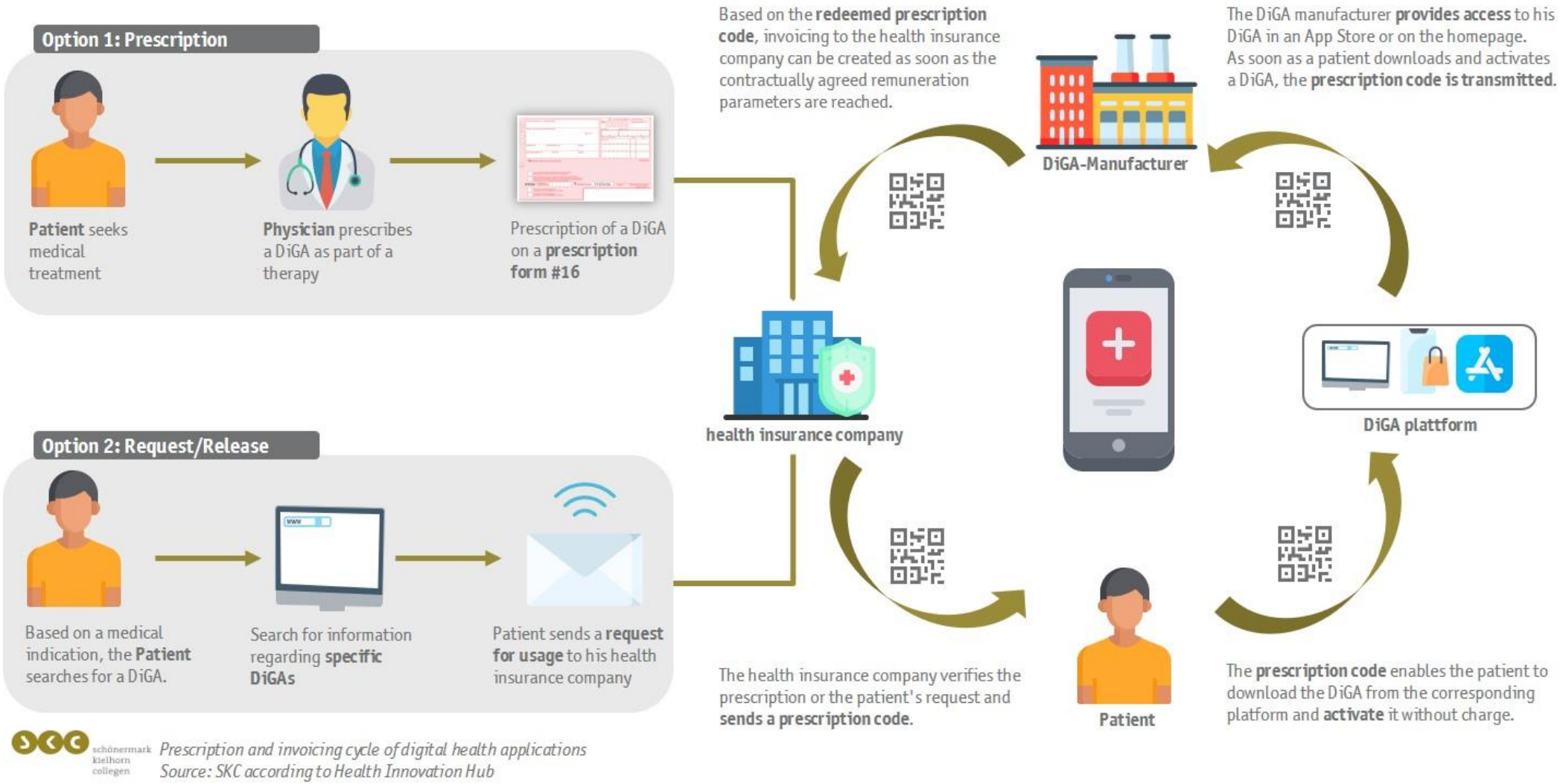
1. Prescription via the physician or psychotherapist

- Physicians and psychotherapists can prescribe DiGA for their patients if it is **medically appropriate**.
- The prescription is made in **exactly the same way as for a drug**
- Once a patient has received the prescription from their doctor or psychotherapist, they submit it to their health insurer
- The patient then receives an activation code or a QR code that can be used to download and activate the DiGA in an app store or on the manufacturer's website.

2. Prescription via the health insurance company

- The insured person can submit an application to his or her health insurer for coverage of the costs of a desired DiGA.
- If there is a corresponding indication, the patient receives an activation code or a QR code (see above)
- The insured person does not have to submit any certificates from the doctor or psychotherapist.

How do patients obtain a DiGA?



Prescription and invoicing cycle of digital health applications
Source: SKC according to Health Innovation Hub

https://skc-beratung.de/insights/blog/2020/08/Prescription_Digital_Health_Applications.php

BfArM assessment procedure

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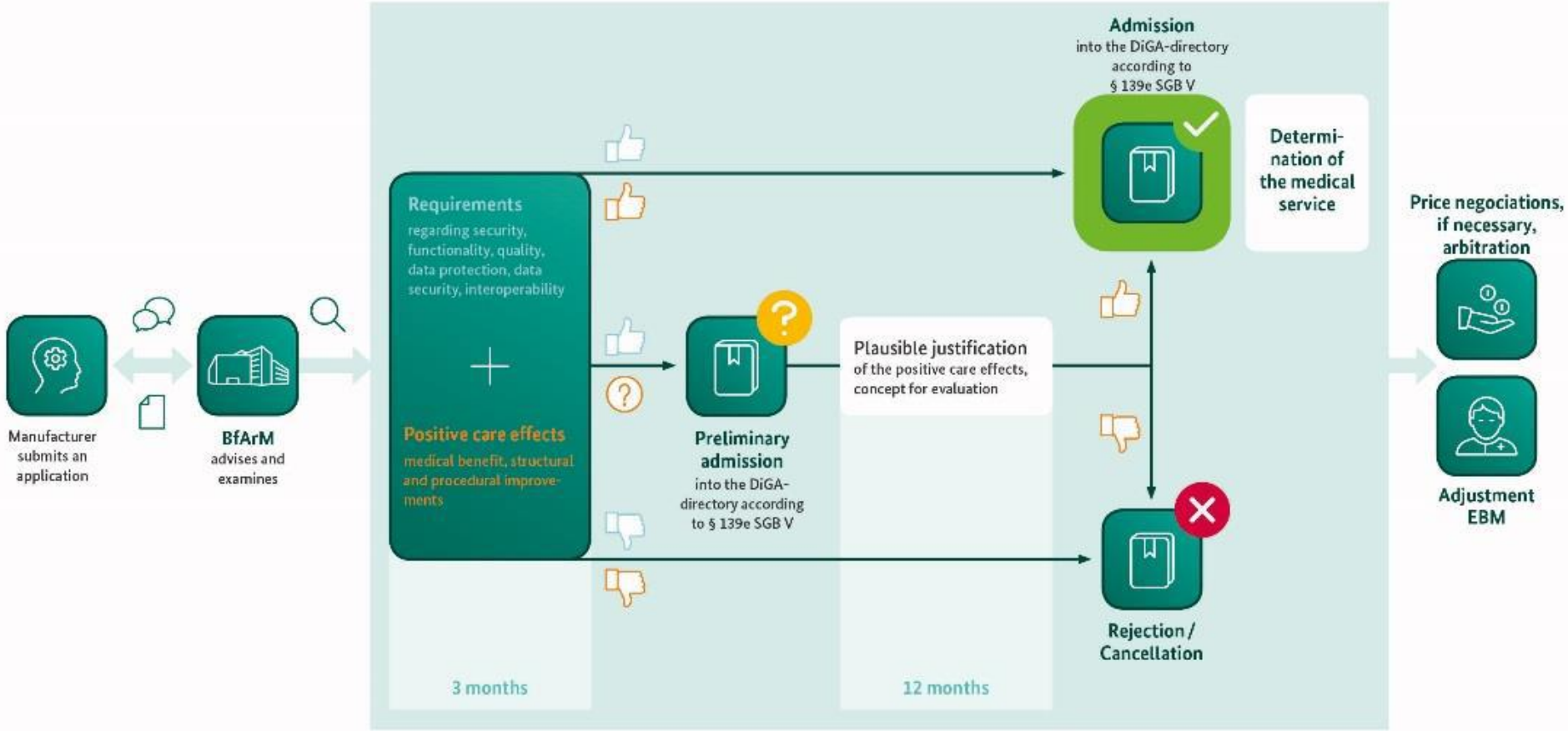
- The procedure is designed as a **fast-track process**:
  - Within a **three-month period** at the most, starting with the filing of the complete application, the BfArM has to assess the DiGA.
- Once a DiGA has **successfully passed the evaluation process**, it is **listed in the DIGA directory** and can be prescribed at the expense of the SHI.
- The **essence of this assessment** is the examination of :
  - the manufacturer's statements about the **product quality**
    - Safety and suitability for use
    - Data protection and information security
    - Quality, especially interoperability.
  - the **evidence of the positive healthcare effect** of the DiGA provided by the manufacturer.

BfArM assessment procedure

- 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 (in exceptions of up to two years).
  - An evaluation concept is the prerequisite of a provisional listing followed by a 1-year trial phase.
  - The evaluation concept must include a study protocol and a statistical analysis plan.
- The Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) has regulated the **details of this procedure** in the supplementary legal regulation, the **Digital Health Applications Ordinance** (Digitale Gesundheitsanwendungen-Verordnung, **DiGAV**).

The Fast Track at the BfArM – overview of the procedure



https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html

The Fast Track at the BfArM – overview of the procedure

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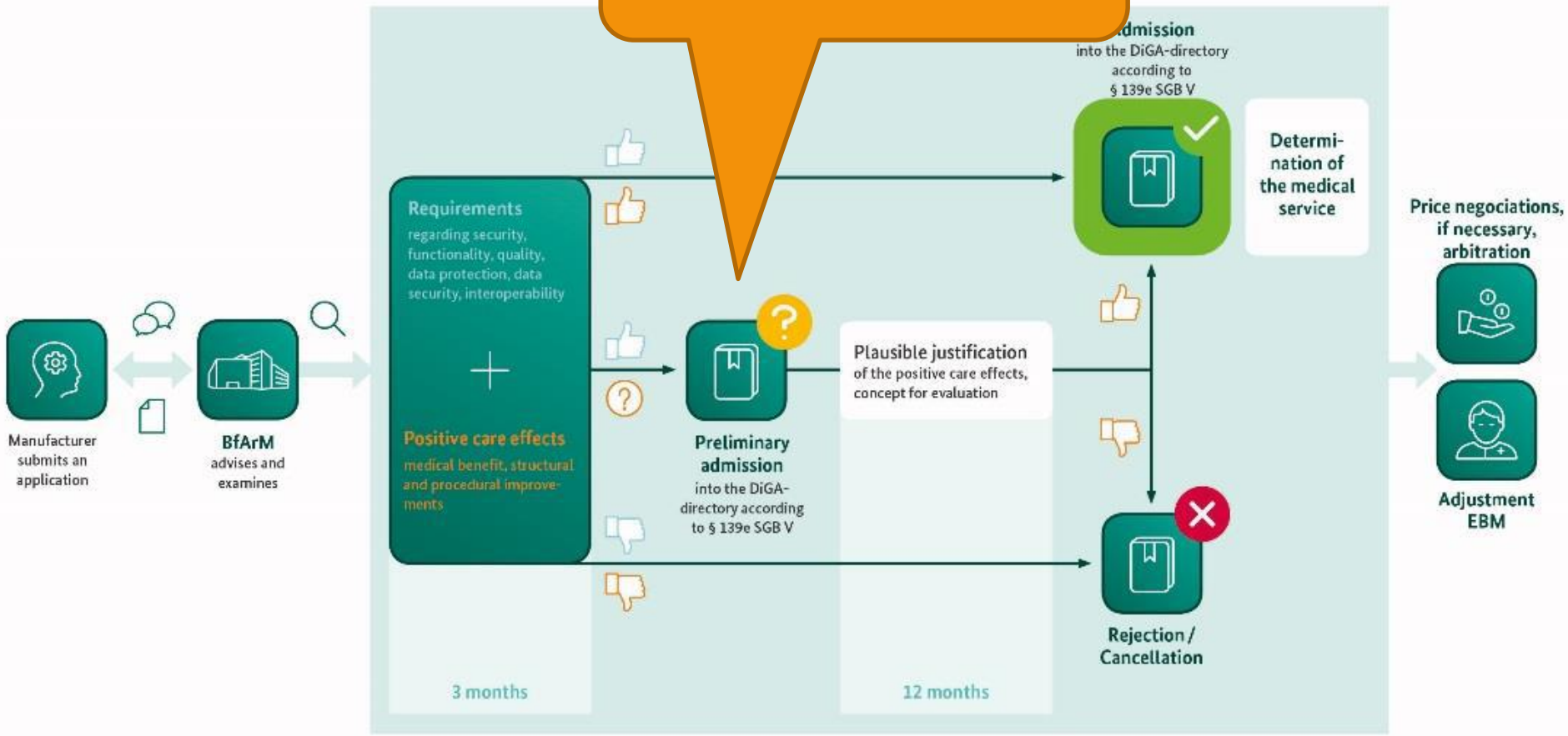
DiGAs in the trial phase are also prescribed at the expense of the health insurance funds.



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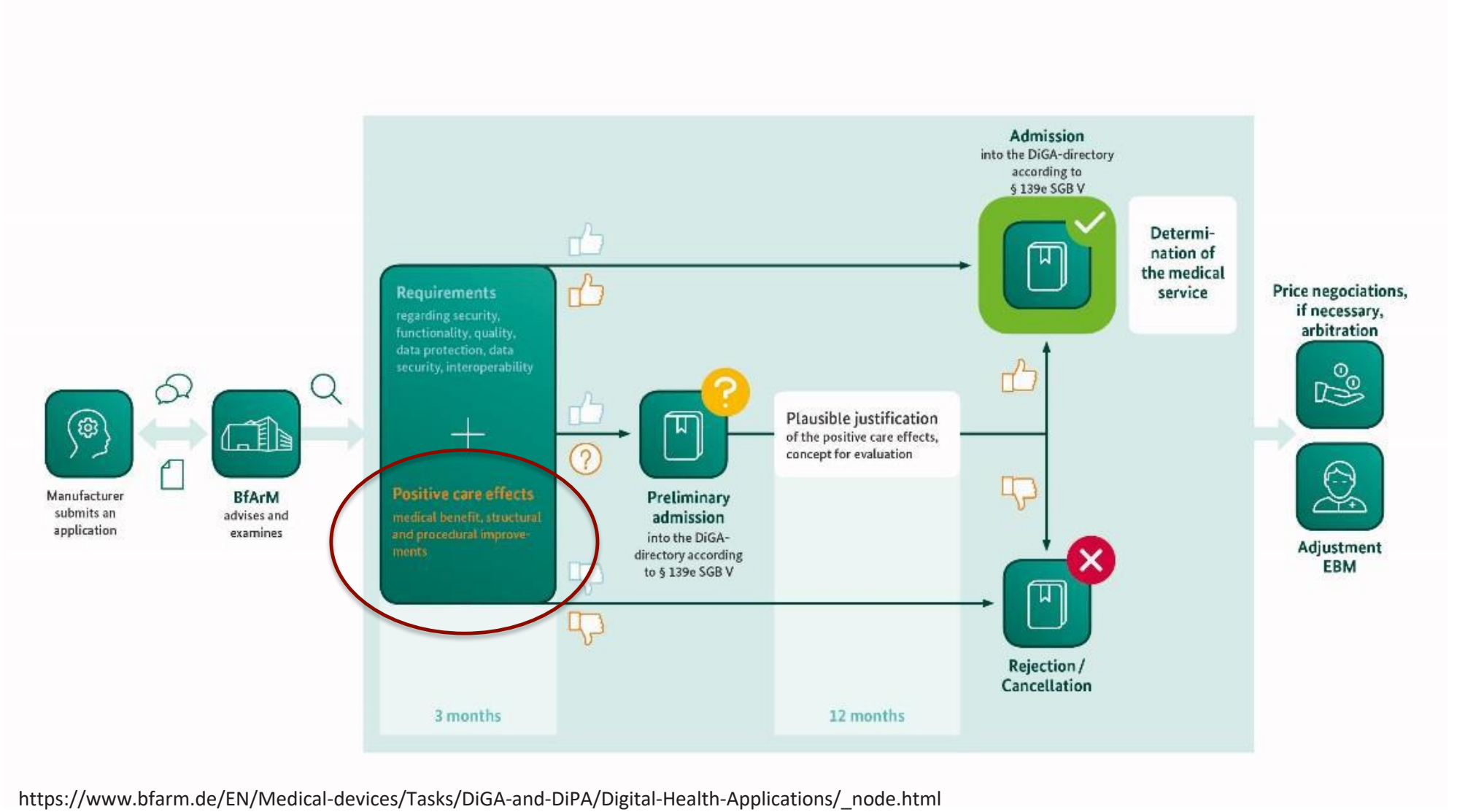
The Fast Track at the BfArM – overview of the procedure



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Positive healthcare effect (§ 8 DIGAV)

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- The term "**positive health care effects**“ (Positiver Versorgungseffekt) was introduced into the social law framework of SGB V with the Digital Healthcare Act (DVG) in 2019.
- According to the definition in DVG and DiGAV, positive healthcare effects are either
  - a **medical benefit** or
  - a patient-relevant **improvement of structure and processes in healthcare**
- Both medical benefits as well as patient-relevant improvements of structure and processes refer directly to the patient and shall be demonstrated by appropriate **patient-relevant endpoints.**
- For inclusion in the the DIGA directory, a manufacturer must demonstrate one (or more) positive health care effect(s) for the respective DiGA
  - The manufacturer can choose whether to show a positive health care effect from the area of medical benefit or from the area of patient-relevant structural and procedural improvement, or from both.
  - It is not necessary to provide evidence of several pVEs, possibly from both areas.

Positive healthcare effect (§ 8 DIGAV)

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Medical benefit

- Improvement of the state of health
- Reduction of the duration of a disease
- Prolongation of survival
- Improvement in the quality of life

Structural and procedural improvement (not conclusive)

- Coordination of treatment processes
- Promotion of guideline-based care
- Adherence
- Facilitating access to care
- Patient safety
- Health literacy
- Patient empowerment
- Coping with disease-related difficulties
- Reduction of therapy-related expenses and burdens

General Requirements for Studies

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- 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**.
  - According to the DIGAV, it is **generally acceptable** to submit **retrospective comparisons** or **intraindividual comparisons**.
  - The conduction of a **prospective (randomised) comparative study** is described there as an **alternative**.
  - However, in the **BfArM guidelines**, which are intended to support manufacturers in the application process, this weighting is set differently and the focus is placed on conducting "classic" comparative studies.
- The **“non-application” of DiGA** 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.
- The choice of the comparison group must be oriented on the reality of healthcare.

General Requirements for Studies

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- In order to achieve **permanent inclusion in the DiGA directory**, it is necessary to provide evidence of at least one positive health care effect through a **study on the use of the specific DiGA**.
  - Simple references to other primary literature and studies of other DiGAs of the same type are not accepted.
- The studies **must be conducted in Germany** to ensure that the results are applicable to the German health care context
  - If the comparability of the health care situation can be proven in individual cases, studies that were conducted completely or partially in countries outside of Germany will also be recognised
- The studies must be **registered in a public study registry**
- The study **results must be published no later than twelve months after completion of the study**
  - For entry into the DIGA directory, study results must be submitted, but not yet published.
- The **study reports** to be prepared **must meet internationally recognised standards** of study presentation and reporting.

Current status of the BfArM assessments

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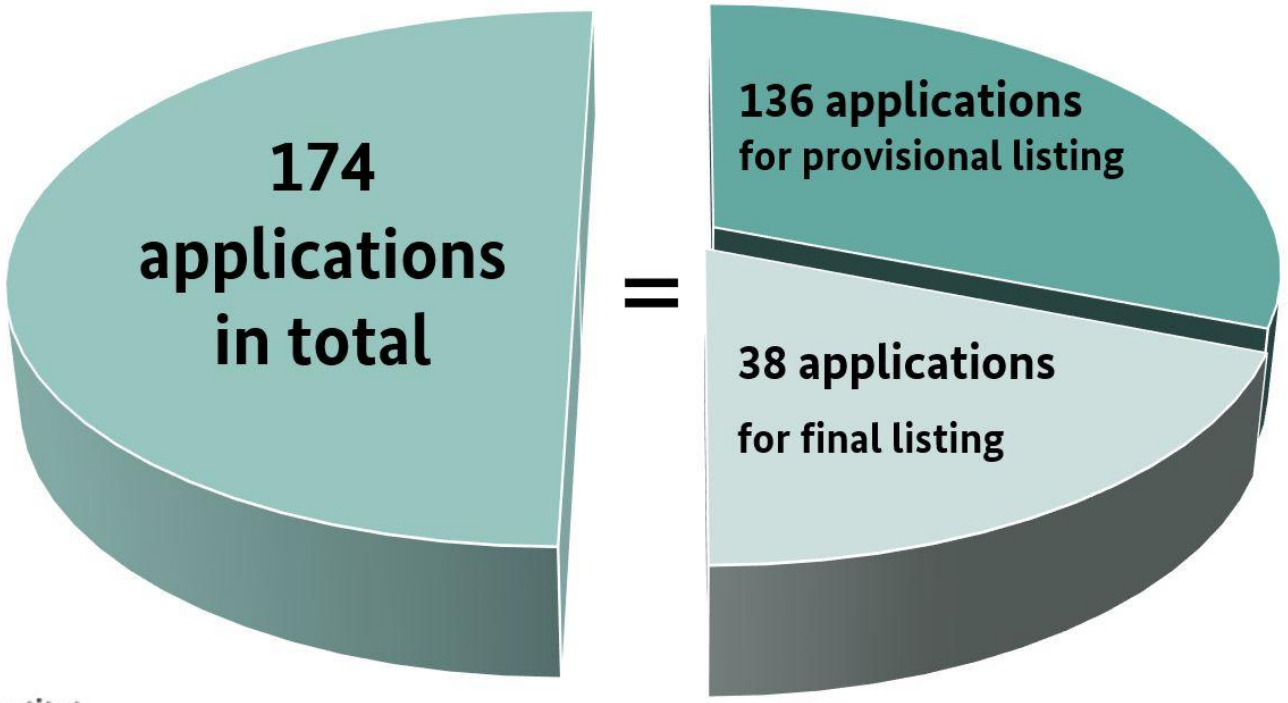
How many applications have been submitted to the BfArM for assessment since the start of the DiGA application portal?



Bundesinstitut für Arzneimittel und Medizinprodukte

Graphic updated on: 05/31/2023

https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html

Current status of the BfArM assessments

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18 permanently listed, 7 of them from provisional listing

Results of the assessment by the BfArM up to now

Applications submitted by manufacturer

Assessment by the BfArM

- Positive decisions: 47
- Negative decisions: 16
- Withdrawn: 94
- Currently being processed: 11
- Deleted from Directory: 6*

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*of which 2 DiGA on application of the manufacturer

Graphic updated on: 05/31/2023

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Indications and therapeutic concept

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- The most frequent indication group for which DiGAs were developed is mental illness.
- Of the **18 DiGAs** that have been **permanently listed**:
  - 11 were developed to treat mental illnesses or symptoms
  - 2 for the treatment of back pain
  - 2 for the treatment of sexual dysfunction
  - 1 for the treatment of fatigue
  - 1 for the treatment of obesity
  - 1 the treatment of tinnitus
- Most DIGA include elements of cognitive behavioural therapy or mindfulness exercises
- 3 DiGAs implement physiotherapy digitally, one DIGA a digital weight loss programme.

Pricing

- Within the first year after inclusion in the DiGA list, the manufacturer sets the price himself.
- After the first twelve months, the so-called remuneration amount is negotiated between the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband, GKV-SV) and the manufacturers.
- If no price agreement is reached between the manufacturer and the GKV-SV, an arbitration board determines the remuneration amount.
- The price negotiated or determined by the arbitration board applies retroactively, so that repayments may have to be made.
- The prices set by the manufacturers currently range between **119 €** and **952 € for 90 days**
- One manufacturer has set the price for a **one-time license** of its product at **2,077.40 € .**
- Currently, the reduction of the manufacturer's price to the final remuneration amount for the DiGA negotiated is on average < 50 % (manufacturer's price approx. 470 €; remuneration amount approx.: 220 €).

Pricing process

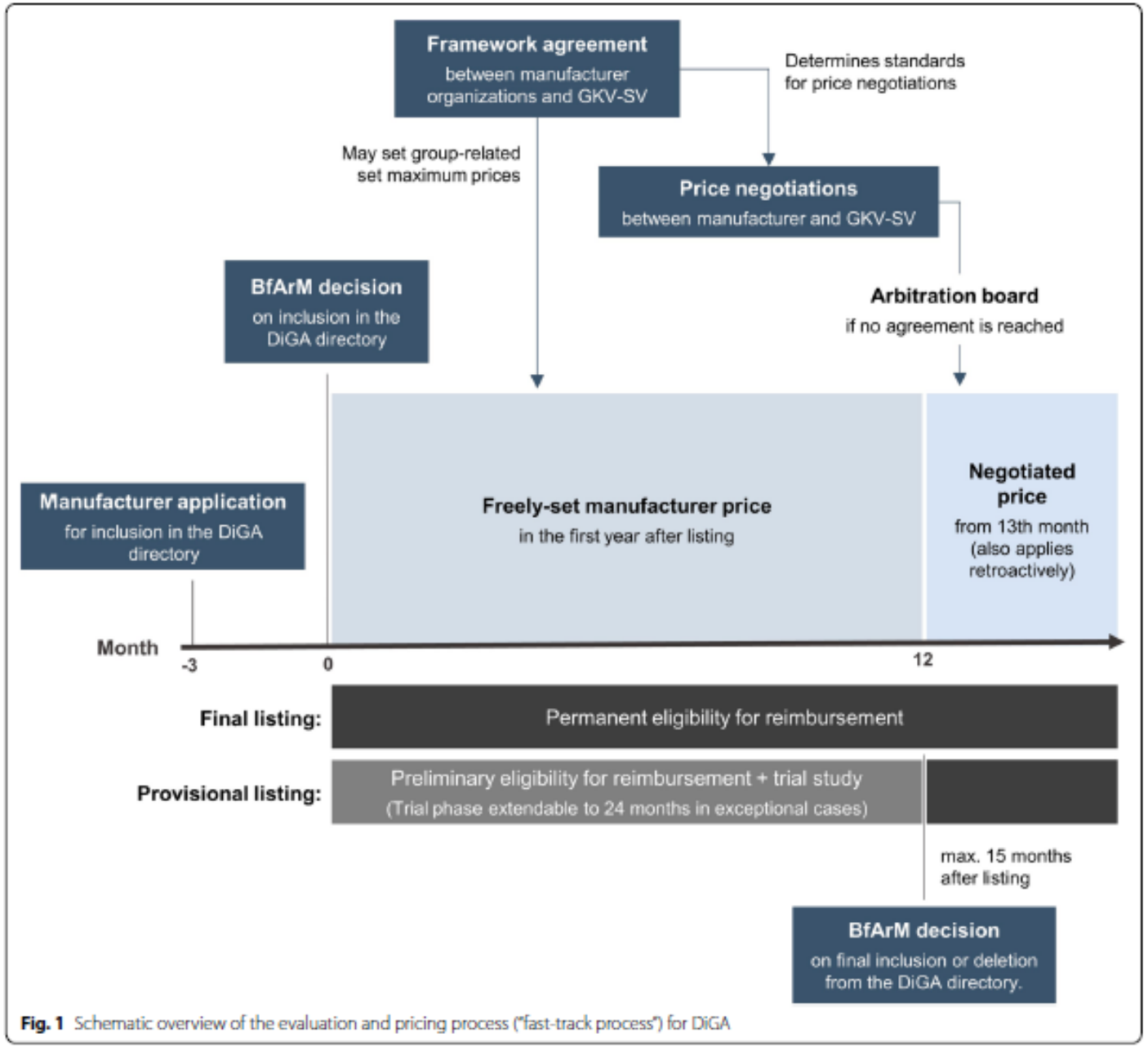

Fig. 1 Schematic overview of the evaluation and pricing process ("fast-track process") for DiGA

Gensorowsky, D., Witte, J., Batram, M. *et al.* Market access and value-based pricing of digital health applications in Germany. *Cost Eff Resour Alloc* **20**, 25 (2022).

Prescriptions and costs in the first two years

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- Since the first inclusion of a DiGA in the DiGA directory of the BfArM in September 2020 until 30 September 2022, a total of 203 thousand DiGAs were prescribed by a physician or psychologist or approved by the health insurance fund.
- The **vast majority** of DiGAs, almost 89 % of all activation codes redeemed, were **prescribed by a physician or psychologist**, whereas 11 % were approved by health insurers.
- The five most frequently used DiGAs accounted for 66 % of all prescriptions
- These **most frequently used DiGAs** in the first two years included: zanadio (obesity), Vivira (back pain), Kalmeda (tinnitus), somnio (sleep disorders) and M-sense migraine.
  - M-sense migraine was removed from the DiGA directory after the trial period because it did not show a positive effect on care.
- The benefit expenditure for the entire period, i.e. from the first inclusion of a DiGA in the DiGA list in September 2020 to 30 September 2022, amounts to € 55.5 million. Thereby, the expenditure in the first year was € 13.5 million, in the second year € 42 million.

Tasks of the Federal Medical Advisory Service in the context of price negotiations

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- In accordance with §134 of the German Social Code, Book V, the determination of the remuneration amounts must take into account whether and to what extent proof of positive health care effects has been provided.
- **Whether:**
  - With the final listing in the DiGA directory and the underlying evaluation procedure by the BfArM, it is considered proven that the digital health application (DiGA) has positive health care effects.
- **To what extent:**
  - The BfArM does not assess the extent of the positive health care effect.
  - Furthermore, the assessment decision does not include any statements on the quality of the evidence.
  - However, this is essential in order to be able to classify the demonstrated extent of the positive health care effect with regard to the certainty of the evidence.

➢ Therefore, we prepare evidence assessments (partly with additional calculations) of the finally listed DiGA and support the GKV-SV in price negotiations.

Rough overview of the results of the evidence assessments

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- On the positive side, randomised controlled trials were conducted for all products, which were intended to establish a patient-relevant benefit.
  - However, the studies show a high potential for bias for most endpoints, so that the quality of the evidence must be downgraded.
  - The studies are all unblinded and mostly use self-reported endpoints.
- Many studies have high drop-out rates, especially in the respective intervention group. Often, there is no adequate handling of the missing data.
- The magnitude of the effects is often rated smaller than it is stated and communicated by the manufacturer. Long-term data are missing in many studies, so that often nothing can be said about the sustainability of the effects.
- We know little about duration and frequency of use and adherence in general.

Conclusion of the advisory activities to date

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- With the evidence assessment reports carried out so far, price negotiations could be supported in a targeted manner.
- The results have been incorporated into the calculations used to determine the negotiated prices.
- With the evidence assessment reports, we were able to contribute to a weighting of the quality of the evidence and the extent of the positive effect on care.

What is special about the introduction of the DiGA?

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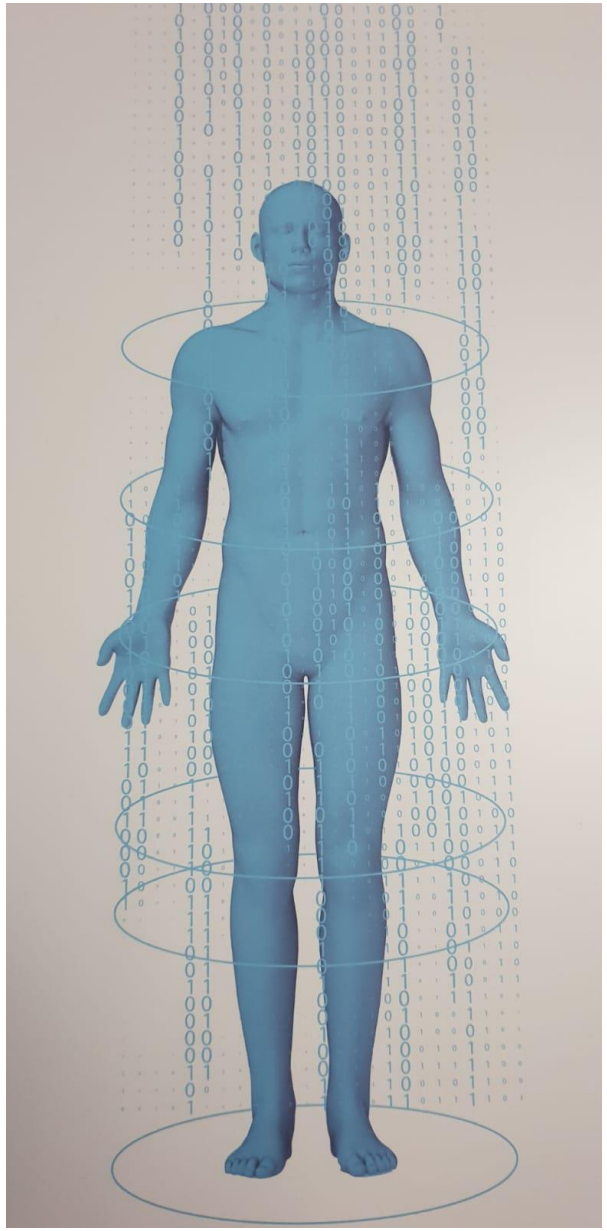
- The way in which certain treatments or examinations in SHI-accredited care are paid for by the health insurance funds is not regulated in detail by the Social Code.
- It is specified in more detail by the Federal Joint Committee (G-BA) in binding guidelines within the self-governing German healthcare system.
- The Federal Joint Committee (G-BA) is a public legal entity comprising the four leading umbrella organizations of the self-governing German healthcare system: the National Associations of Statutory Health Insurance Physicians and Dentists, the German Hospital Federation, and the Central Federal Association of Health Insurance Funds. In addition patient representatives also participate in all sessions.
- Therefore, it has not been common practice so far for a decision on what constitutes a SHI benefit to be made by law and without consultation in the G-BA.
- Even though the procedure requires evidence in principle, the evidence requirements are much lower than for other procedures that are decided in the G-BA.

What does the future hold?

- With the Digital Care and Nursing Modernisation Act (DVPMG), **digital nursing applications (DiPA)** were introduced on June 9th 2021 in the Social Long-Term Care Insurance
- DiPA are "digital assistants" that can be used by care recipients or in the interaction of care recipients with relatives, other voluntary caregivers or outpatient nursing care facilities.
- The procedure for listing DiPA is relatively similar to the DiGA procedure.
- No DiPAs are listed in the directory yet.
- It is not known whether applications have already been submitted and what the status is.
- However, DiPA pricing is somewhat different, so we will first pilot whether a comprehensive evidence assessment by us can usefully support price negotiations.



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Thank you for your attention!