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Reimbursement of Digital Health Solutions

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Profil



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Market Access & Reimbursement

- Expert for Biophysics, Medical Technology, Market Analysis and Strategic Business Development
- Evaluation of new Products and Technologies and Development of Go-To-Market Strategies
- Project Management
- Planning and Execution of complex reimbursement cases including all relevant reimbursement applications
- Health Economic Analysis,
- Planning and Execution of Product Launches
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Reimbursement of Digital Health Solutions

Examples:

DiGA -Digitale Gesundheitsanwendungen -Digital Health Applications

DiPA – Digitale Pflegeanwendungen – Digital Care Applications

Alternative Reimbursement

Revenue Streams for Manufacturers of Medical Software

- General usage as part of existing structures (investment budget, hospital reimbursement, out-patient reimbursement) due to economic advantages.
- Specific Reimbursement: DiGA, DiPA
- Selective reimbursement: selective contracting, Innovation Funds
- B2B-White Label-Solutions
- Direct sales to private health insurers / self-payers
- B2B sales to clinics or MVZs (out-patient medical care centers)
- License and subscription models
- Research and data cooperations
- Corporate health management

Reimbursement = Reimbursement? Who is paying for my software?

Reimbursement

DiGA / DiPA

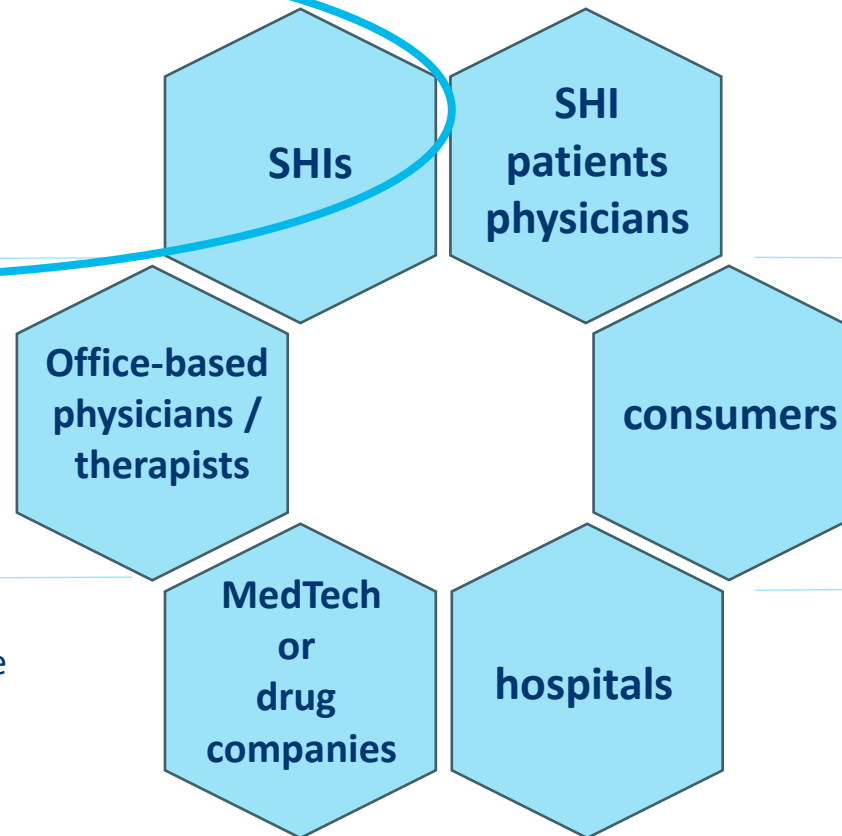
- Medical devices
- Medical purpose (Subject to MDD/R)

Practice software / medical practice

- Management systems
- Administrative systems §291a SGB V interface obligation

Research Use Only (RUO) tools

- No intended medical purpose or objective
- Mostly in collaboration with drug companies for study conduct



Telemedicine platforms

- Doctor-patient communication
- Video consultation
- KV approval required

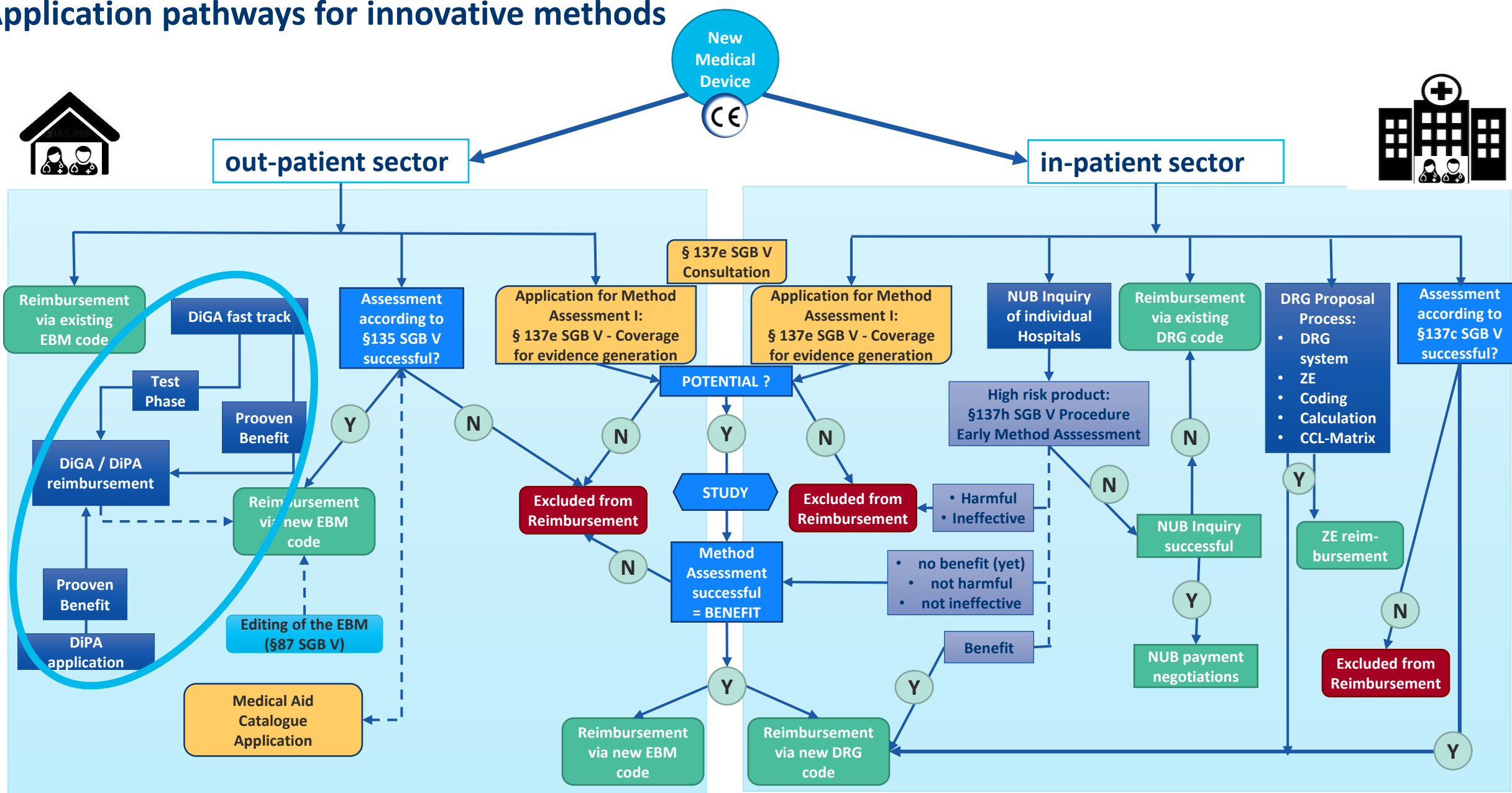
Health apps (consumer)

- Prevention, fitness, lifestyle (without reference to illness)

Control and organization software / Operating software

- Control of processes in hospitals
- Shift planning
- Possibly HIS (hospital information system) integration

Application pathways for innovative methods



DiGAs – Digital Health Applications (Digitale Gesundheitsanwendungen)

Institutions for DiGA reimbursement

Legislation and supplementary jurisdiction

DiGA fast track

Overview of currently listed DiGAs

Positive Healthcare Effects

DiGA Entitlement to Benefits for Insurees (Leistungsanspruch)

- BfArM holds positive list for reimbursable DiGAs according to §139e SGB V.
- DiGAs can be prescribed by treating physician (§73 Abs 2, Satz 7a SGB V) / psychotherapist or hospital (discharge management, §39 Abs 1a, Satz 7 SGB V) (benefit in kind principle – Sachkostenprinzip) or reimbursed after approval of health insurance (cost reimbursement principle – Kostenerstattungsprinzip).
- In April 2020, the BMG published the DiGA ordinance (DIGAV), in which the positive healthcare effects and their provision were outlined.
- A guidance document was published thereafter which explains the legal requirements in a clear way illustrated with examples. Current version is 3.5 (28th December 2023), unfortunately just version 1.0 (7th August 2020) guide is available in English
- The application portal for the DiGA-directory is German-only. Applications are (only) submitted online.
- BfArM offers advice pre-submission (fee) on all relevant topics regarding the fast track.
- Pricing: Evaluation Phase: free, after final listing prices will be re-negotiated with complex modalities
- Latest Update with “DigiG”- law on March 26th, 2024 included Risk Class IIb products into the DiGA space with some restrictions.

DiGA Definition

DiGA according to DVG (§33a SGB V)

- MD with a therapeutic intended use (inclusion of diagnostic instruments allowed)
- Patient centered functionality: detection, (monitoring), treatment, alleviation, (compensation) of diseases, injuries or disabilities
- CE mark >> Risk class I or IIa and b (MDR only) according to MDR or MDD (within the transitional provisions)
- DiGAs are providing always individualized specific feedbacks but may include telemonitoring
- Standalone software or **digital product** (main function is digital)
- Proof of **positive effects** in health care provision / **Test phase only for risk class I and IIa**
- No exclusion of the intended use according to SGB V or G-BA (§§92 or 137c SGB V)
- “Method” can be a new diagnostic and treatment method without respective directive by G-BA
- Continued data collection to measure positive outcome in health care provision after DiGA list

No DiGA according to DVG

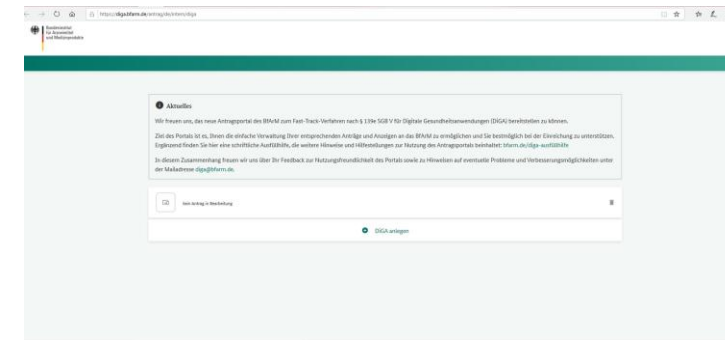
- Intended use in the field of primary prevention, as intended use restricted to detection, **monitoring** and treatment of diseases!
- No CE mark
- Risk class III
- Services excluded by SGB V or G-BA according to §§92 or 137c SGB V

Legislation and Supplementary Jurisdiction

- Digital Healthcare Act (Digitale Versorgung Gesetz (DVG))
- Digital Health Applications Ordinance (DiGAV)
- Digital Act (DigiG)
- Guidance documents

Portal

<https://antrag.bfarm.de/de>

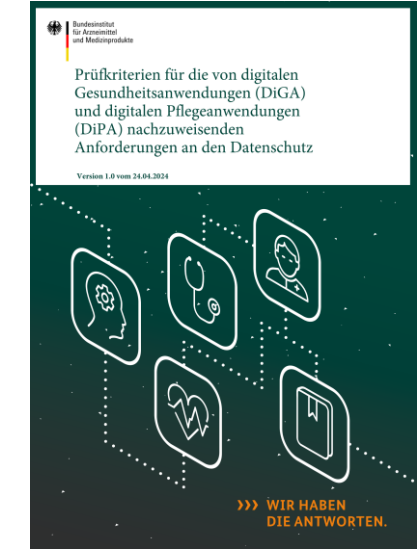


DVG DigiG DIGAV

Guide DE/EN

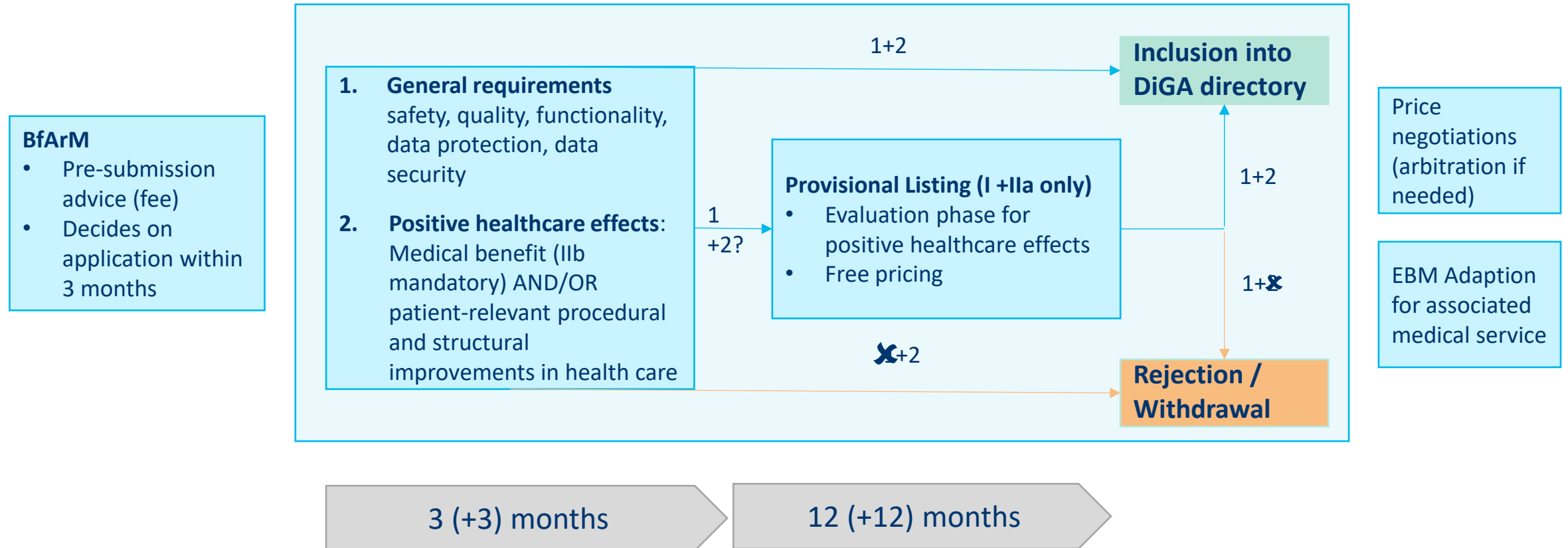
Application Guide

Data protection criteria

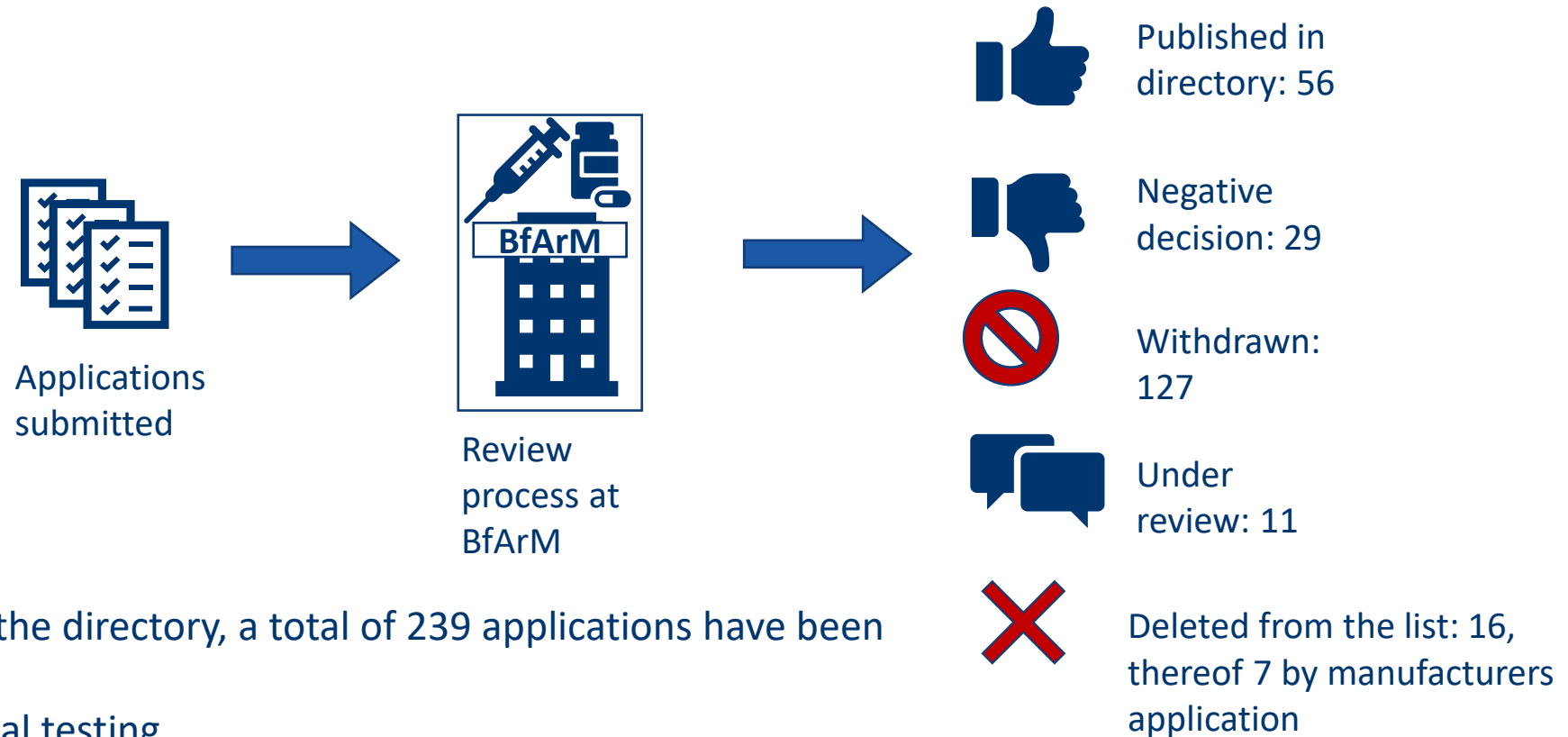


All documents and the portal can be downloaded / approached here:
https://www.bfarm.de/DE/Medizinprodukte/Portale/DiGA-DiPA/_node.html

Fast Track for DiGAs



Statistics on DiGA Applications (October 29th, 2025)



Since the launch of the directory, a total of 239 applications have been submitted:

- 185 for provisional testing
- 54 for permanent inclusion

https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/DiGA/_node.html (Wissenswertes/Zahlen und Fakten)

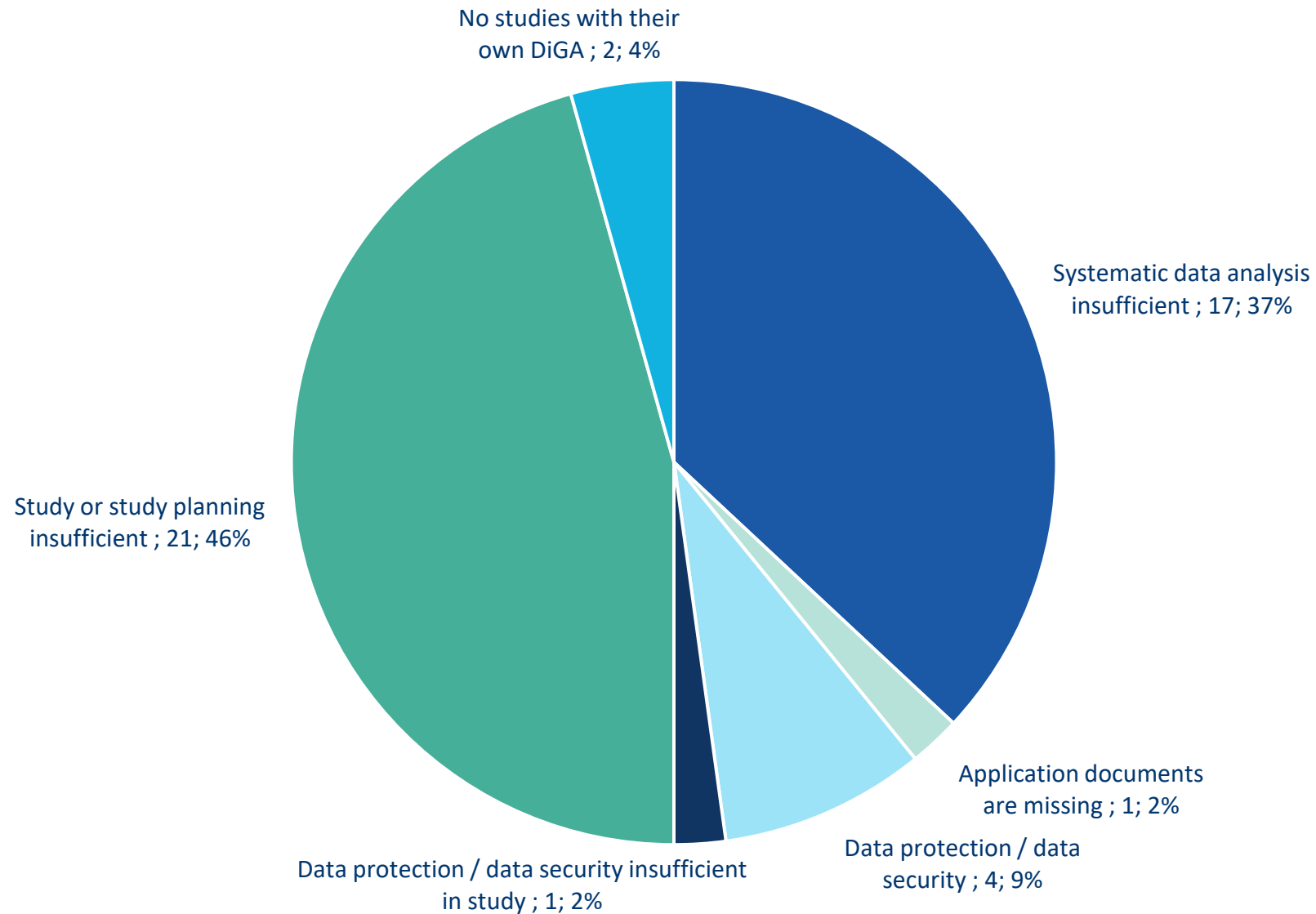
DiGA Directory (October 2025)

Category	Amount	DiGAs
Respiratory tract	0	
Genitals, kidneys and urinary tract	3	<ul style="list-style-type: none"> Kranus Edera Kranus Lutera Kranus Mictera Endo-App
heart and blood circulation	1	<ul style="list-style-type: none"> ProHerz
hormones and metabolism	6	<ul style="list-style-type: none"> glucura Diabetestherapie HelloBetter Diabetes Una Health für Diabetes Oviva Direkt für Adipositas Vitadio Zanadio
cancer	3	<ul style="list-style-type: none"> PINK! Coach Untire Uroletics
muscles, bones and joints	7	<ul style="list-style-type: none"> Kaia Rückenschmerzen - Rückentraining für Zuhause companion patella powered by medi - proved by Dt. Kniegesellschaft Companion shoulder eCoverly – Therapie bei Schmerzen im unteren Rücken HelloBetter chronische Schmerzen Mawendo Vivira
nervous system	5	<ul style="list-style-type: none"> Elevida HelloBetter Schlafen Levidex sinCephalea – Migräneprophylaxe somnobia

Most DiGAs for mental health, but also those for other target indications are based on cognitive behaviour therapy.

Category	Amount	DiGAs
ears	2	<ul style="list-style-type: none"> Kalmeda Meine Tinnitus App - Das digitale Tinnitus Counseling
psyche	29	<ul style="list-style-type: none"> attexis - die digitale Therapie bei ADHS im Erwachsenenalter Deprexis edupression.com® elona explore – für die mentale Gesundheit elona therapy Depression HelloBetter Schlafen HelloBetter Panik HelloBetter chronische Schmerzen HelloBetter Vaginismus Plus hiToco®: ADHS Elterntraining Invirto- Die Therapie gegen Angst Mindable: Panik & Agoraphobie Mindable: Soziale Phobie My7steps App NeuroNation MED NichtraucherHelden-App Novego: Depressionen bewältigen Novego: Ängste überwinden ORIKO ADHS-Therapie priovi - digitale Unterstützung der Borderline-Behandlung Selfapys Online-Kurs bei Depression Selfapys Online-Kurs bei Generalisierter Angststörung Selfapys Online-Kurs bei Binge-Eating-Störung Selfapys Online-Kurs bei Bulimia Nervosa Somnio velibra Vorvida Smoke Free - Rauchen aufhören Somnobia
digestion	1	<ul style="list-style-type: none"> Cara care für Reizdarm
trauma	2	<ul style="list-style-type: none"> companion patella powered by medi - proved by Dt. Kniegesellschaft
other	2	<ul style="list-style-type: none"> HelloBetter Stress und Burnout Neolexon Aphasie

Reasons for withdrawal or rejection of applications



Source: BfArM, August 2021

Evidence Criteria for DiGAs

Demonstration - positive healthcare effects (§9 DiGAV)

- In the application, the **positive healthcare effect** according to the definition of the term **must be stated**, as well as the **corresponding patient group**.
- **Intended use must be consistent** with positive healthcare effect.
- If several indications are given, **positive healthcare effects must be proven for all indications**. This proof can be provided for all indications together or separately.

Positive Healthcare Effects

Medical Benefit >> Mandatory to be proven upon application for risk class IIb:

- Patient relevant effects in particular with regard to:
 - Improvement of health status
 - Reduction of the duration of illness
 - Prolongation of survival
 - Improving quality of life

Patient relevant Structural and procedural improvements (pSVV). Most recent additions:

- Better coordination of treatment processes
- Alignment of treatment with guidelines and standards
- Increase adherence
- Facilitating access to care
- Increasing patient safety, health literacy, patient sovereignty
- Coping with illness-related difficulties in everyday life or reducing therapy-related efforts and burdens on patients and relatives

Latest Developments in DiGAs

DiGA – changes in 2024 and 2025

- Changes from „DigiG“ Law and „GDNG“ (06/23)– in force since 03/24:
 - Inclusion of IIb - devices
 - Prolongation of timelines
 - Changes in period of proof
 - Higher data security requirements (certification)
- Planned Changes from 2. Regulation of DiGA, January 2025 (not yet in force):
 - Introduction of „anwendungsbegleitende Erfolgsmessungen“, obligatory from 2026.
 - Manufacturers must submit anonymized and aggregated data
 - covering the duration and frequency of use,
 - patient satisfaction, and
 - the health status of patients during use.
- Open:
 - Complex service models (Telemonitoring, Diagnostic components) needs support from DiGA Team @ BfArM

DiGA – Perception from Payers

- 4th report from Payers regarding usage and development of DIGAs
- No positive review on procedure to include DIGAs in reimbursement system, even though the potential of DIGAs is acknowledged
- Most DIGA show no benefit, but incur high costs, especially during the first year of testing, which is then ended with negative testing results.
- Average price in 2024: 585€
- If testing comes out positive, and is prolonged for another year for the high price, a retroactive change of the price after the second year to the negotiated prices creates many insolvencies of DIGA producers
- Statistics: In total since 2020 (4 years): 1 mio prescriptions, costs of 234 mio €. Most usage in psyche (30%), followed by hormones and metabolism (28%) and orthopedics (16%)

Source: <https://dserver.bundestag.de/btd/21/001/2100110.pdf>

DiGA - Perception from Manufacturers

- 1/3 of all listed DiGAs are attributable to 3 manufacturers (GAIA (8), HelloBetter (6) and Selfapy (4)).
- Companies that rely solely on DiGA revenues are dependent on the listing of several DiGAs in order to operate economically due to the high development costs (especially studies).
- From the manufacturer's point of view, the evaluation phase is necessary in order to finance the comparatively high development costs.
- Some DiGAs have been removed from directory due to the manufacturer's insolvency (not lack of benefit).

DiPAs – Digital Nursing Applications (Digitale Pflegeanwendungen)

Institutions for DiPA reimbursement

Legislation and supplementary jurisdiction

DiPA application process

Nursing benefits

DiPA Definition

DiPA according to DiPAV and § 40a SGB XI

- May be, but must not be a Medical Device
- Intended users: **persons in need of care** in care levels 1-5 with home care, or in interaction of care recipients, relatives and authorised outpatient domestic care facilities (§ 64j SGB V)
- **If medical device: Risk class I or IIa according to MDR**
- Safety and functional requirements can be fulfilled with CE mark but being a MD (Medical device) is not mandatory
- Non-medical devices especially need to implement a QMS and a Risk Management System
- Application with main digital technology (main **function is digital**)
- Proof of nursing benefits for a defined group of care recipients and other users (e.g. mobility, self-care)
- When using DiPAs, persons in need of care are entitled to supplementary support services (“ergänzende Unterstützungsleistungen”) acc. to §39a SGB XI.

No DiPA

- Intended use **not** in the field of impairments of autonomy, need for care reduced or counteracting the worsening of need for care
- Digital application for **general necessities of life, work organisation** of outpatient care facilities, **applying** for or **managing benefits, social benefits** or other **support services**.
- Risk class >IIa

Exclusion Criteria DiPAs (§40a (1a) SGB XI)

NO
Digital Nursing
Applications

Knowledge transfer, information or communication

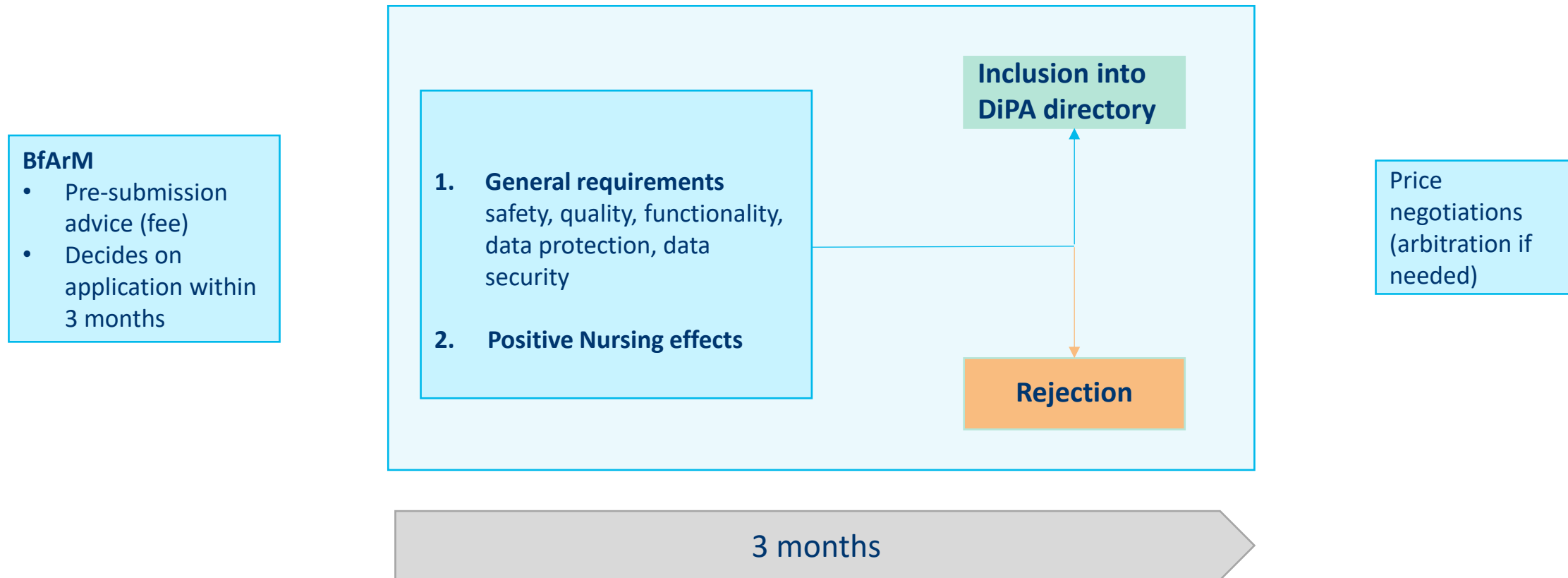
General necessities of life or general living

Application for or administration of services

Work organization of approved outpatient nursing facilities

Information/ advice on selection & utilization of services (social/ assistance)

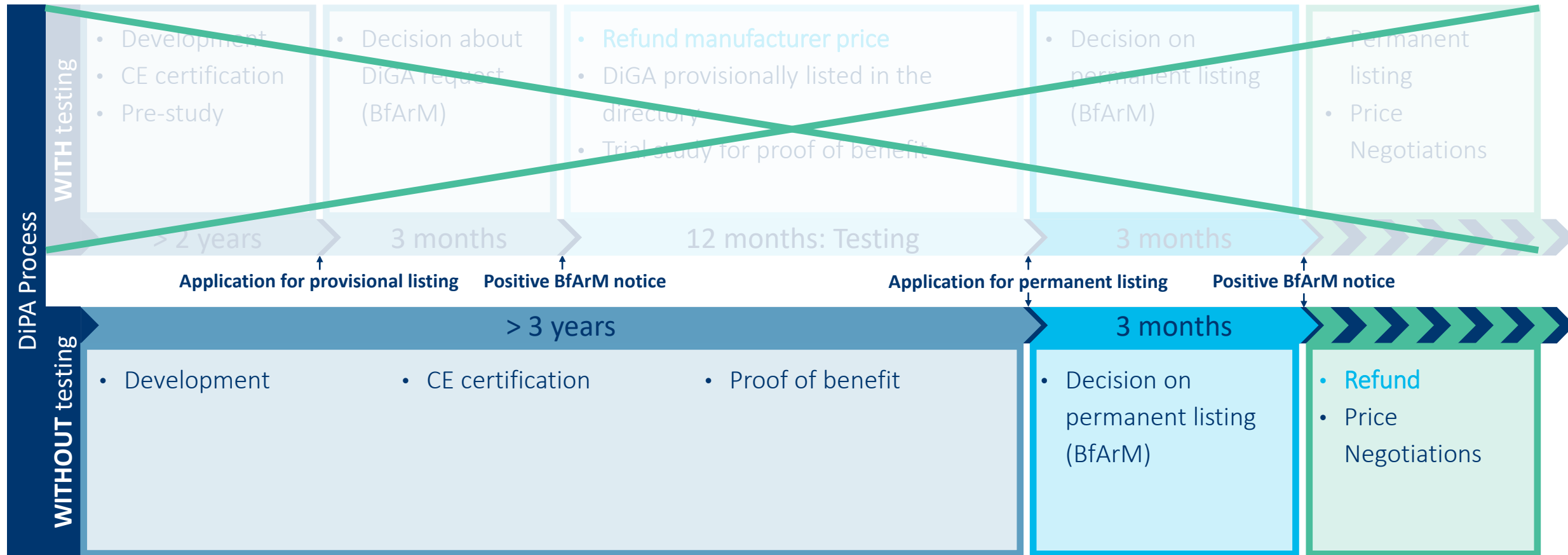
DiPA Process



DiPA - Overview Evidence of Use/ Evidence Generation

Procedure for **DiPA** (1)

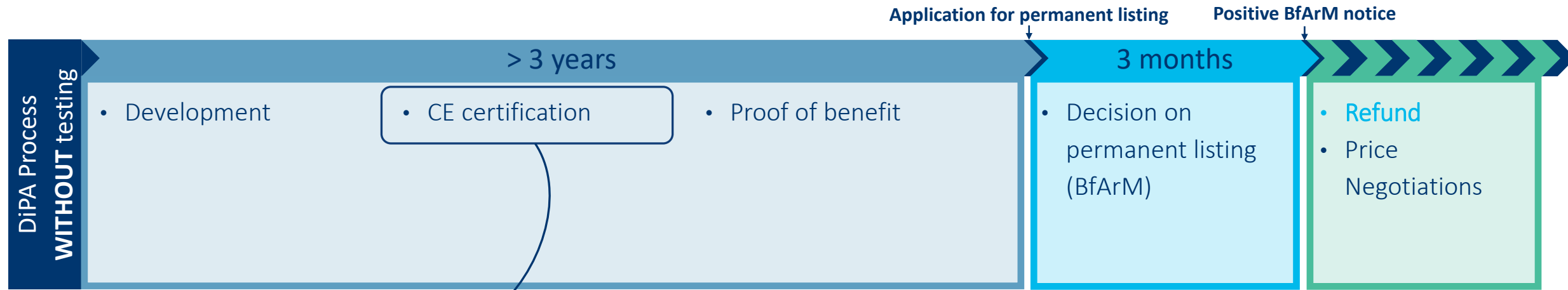
There is no fast-track procedure for DiPA



DiPa - Overview Evidence of Use/ Evidence Generation

Procedure for **DiPA** (2)

It is expected that the DiPA procedure will differ only slightly from the DiGA Fast Track procedure without testing



DiPAs do not have to be medical devices

- If applicable, facilitation of market access
 - **But:** implementation of a QMS and a Risk Management System is mandatory for non-medical devices ≈ medical device requirement!
- Certification of a DiPA as a medical device creates more trustworthiness with a comparable effort (BUT: cost for certification by Notified Body are added)

Conceivable examples of nursing benefits

(on the background of the digital main function)

Mobility

- **Mobility analysis via app** to determine fall risk
- Recommendations for fall prevention and preservation of mobility

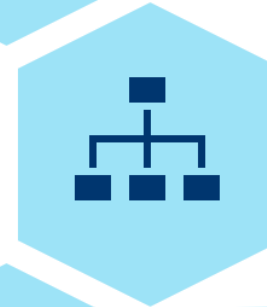


Self-care (& household management)

- **App**, which supports with a guide and intelligent assistant in the **organization of care**, or further measures for self-care

Cognitive and communication skills

- **Training concept** with exercises to increase cognitive performance in order to enable the person in need of care to perform everyday tasks independently again



Coping with illness- or therapy-related requirements and stresses

- **Electronic medication plan**, and scheduling assistant for doctor visits, to help reduce the burden of therapy-related planning efforts

Behavioral and psychological

- **Cognitive behavioral therapy via app** to counteract mental health issues (e.g., anger and despair outbursts)



Organization of everyday life and social contacts

- **Chatbot for caregivers and family caregivers** to practice, schedule, and encourage further social interaction

Comparison DiGA and DiPA

	DiGA	DiPA
Aim	Detection, monitoring, treatment, or alleviation of disease , or to support the detection, treatment, alleviation, or compensation of injury or disability	To reduce impairments in the independence or abilities of the person in need of care and to counteract a worsening of the need for care
Payer	Statutory Health insurance (SGB V)	Long-Term Care Insurance (SGB XI)
Provision	Prescription by physicians or psychotherapists / direct approval by SHI.	Application of the person in need of care to long-term care insurance fund (no prescription provided).
Type of application	Certified low-risk medical device whose main function is essentially based on digital technologies .	Application based essentially on digital technologies. → Medical Device certification not mandatory!
Price cap	Defined in framework contract between GKV-SV and manufacturer organizations	53 € per month (for all DiPAs) per patient.
Application procedure / directory	Elaborated and in operation	Elaborated and in operation.
Proof of benefit	Provisional and final listing in DiGA directory possible. Medical benefit can be provided according to pilot data upon application in provisional phase.	Care benefits must be available at the time of application (no fast-track!).

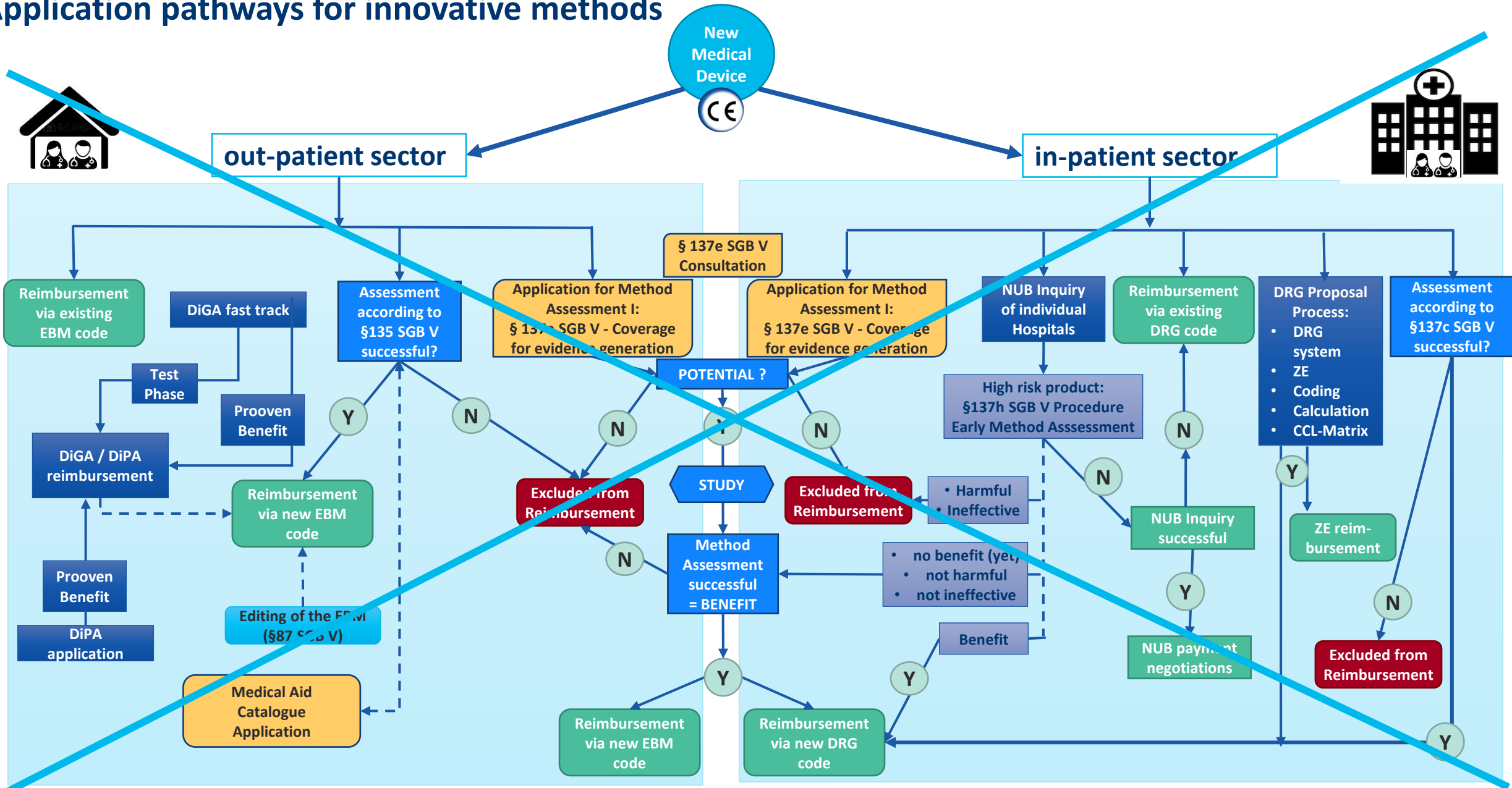
Applications can be DiGA and DiPA at the same time if they meet the requirements from both categories.

DiPA Entitlement to Benefits for Insurees – Current Status

- BfArM holds positive list for reimbursable DiPAs according to §16 VDiPA
- DiPAs are available upon application of the person in need of care to the long-term care insurance fund (no prescription provided).
- In October 2022, the BMG published the DiPA ordinance (DiPAV), in which the nursing benefit and their provision are stated.
- In December 2, 2022, the BfArM published version 1.0 of the DiPA guide. In this current version, the feedback from the survey on version 0.9 of the guideline published at the beginning of November was considered.
- The latest version is version 1.2 from October 2023
- The application portal also went live in 2023.
- Since then, no DiPA listed and reimbursed by payers.

Alternative Reimbursement Options

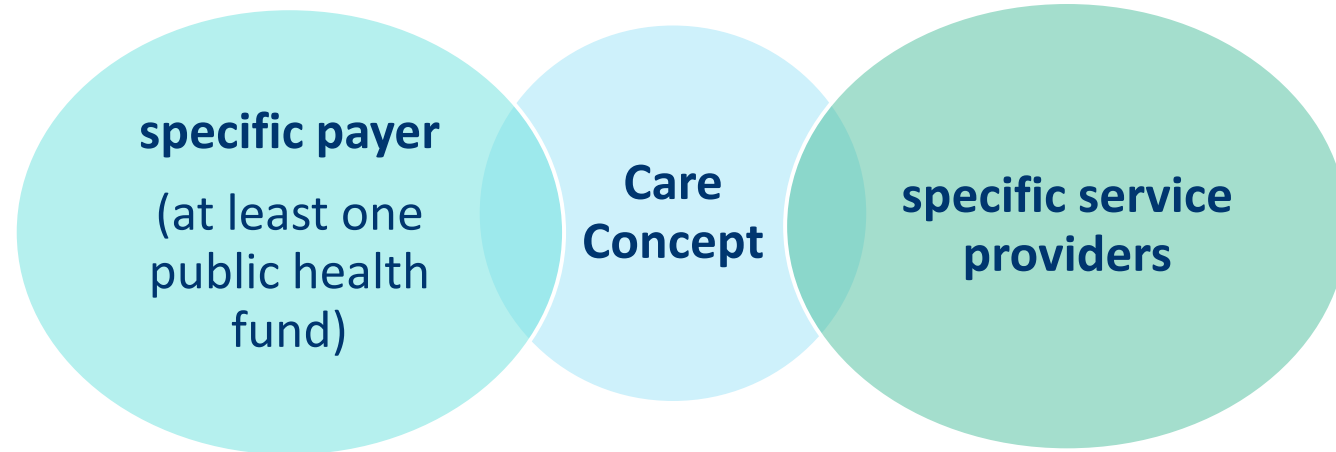
Application pathways for innovative methods



Selective contracting – Special care

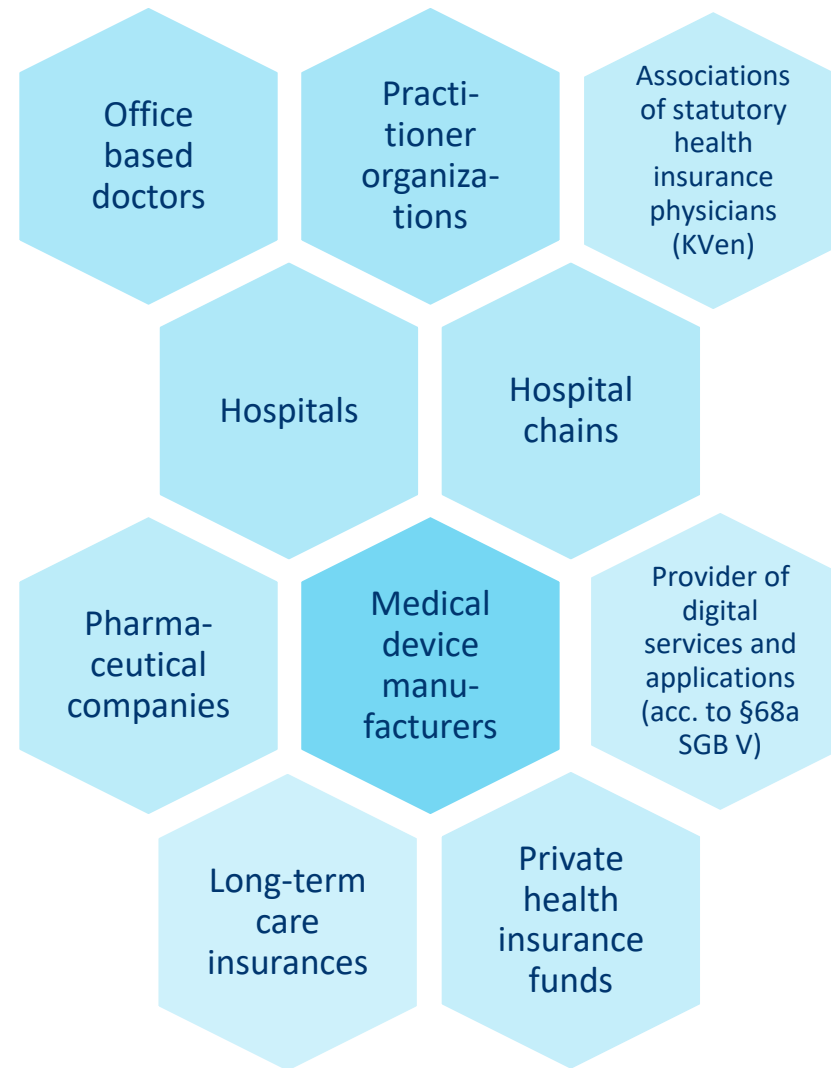
§140a SGB V - Specific Care Solutions

Selective contracts according to §140a SGB V



- Contracts for the special care of insured persons based on
 - A care concept that covers different service sectors, or
 - Interdisciplinary, multidisciplinary care (integrated care) or
 - A special care mandate involving health care providers or their associations.
- (Temporarily) replaces regular reimbursement path for patient insured with a contracting payer.
- „Fast track“ (relatively! >> 6- 24 months) for assessing innovative health care concepts, before potentially introducing into standard care, but no guarantee that it will ever become standard of care.
- Please note: a negative decision of G-BA on a method means that the method cannot be subject of selective contracts.

Contracting partners for Selective Contracts (acc. to §140a SGB V)



Preparing a Selective Contract - What health funds usually ask for...

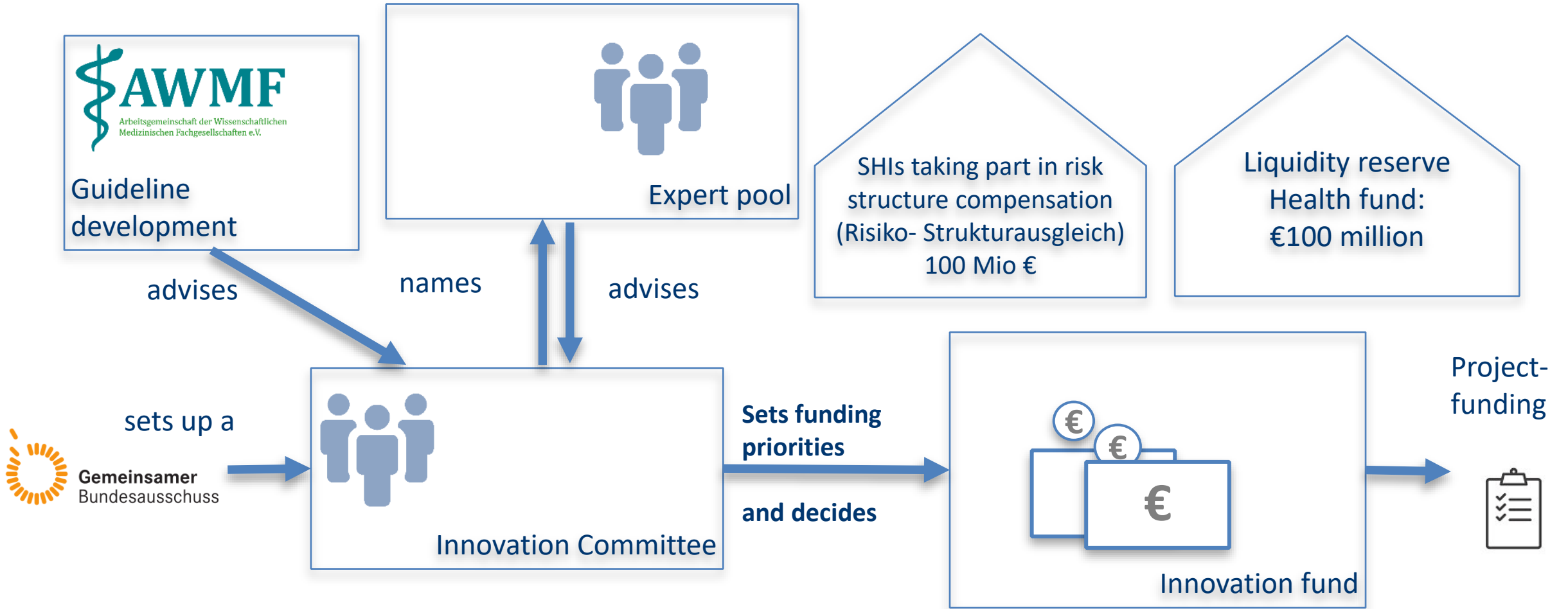
- ✓ **Benefit for this specific health fund**
 - cost reduction
 - marketing/image support
- ✓ **Evidence**
 - at least for potential / substantiating care concept
 - and/or guidelines of medical societies
- ✓ **Cost perspective of new care concept**

Innovation fund

§§92a and 92b SGB V

- 17. Dec 2014: Gesetz zur Stärkung der Versorgung in der gesetzlichen Krankenversicherung (Act to strengthen care in the statutory health insurance system) (GKV-VSG) plus Dec 2019 Digitale Versorgung Gesetz (DVG) decided for 5 years continuation and perpetuate with the Digital Gesetz 2024.
- Project volume 200 million euros (Digital Gesetz): Promoting innovation in care (160 M €) and care research (40 M €), and in this context explicitly developing medical guidelines.
- Usually based on selective contract in accordance with § 140a SGB V or a pilot project in accordance with §§ 63 ff. SGB V
- *Aims (among others)*
 - innovation in care = forms of care that go beyond the current standard care, in particular, cross-sector care models
 - Results shall be translatable into either G-BA guidelines or even changes to the legal framework

Innovation fund: Structure



Innovation fund - Legal basis and eligibility criteria

Legal basis for the work of the Innovation Committee set up at the G-BA, Sections 92a and 92b of the Fifth Book of the Social Code (SGB V)

Eligibility criteria include in particular:

1. Improving the quality of care and efficiency of care,
2. Addressing care deficits,
3. Optimization of cooperation within and between different care sectors, utilities and occupational groups,
4. Interdisciplinary care models,
5. Transferability of the findings, in particular to other regions or indications,
6. Proportionality of implementation costs and benefits,
7. Evaluability.

Only projects that are **not yet in the standard care** can be supported.

A **health insurance fund must be included** in the application.

Source: <http://www.sozialgesetzbuch-sgb.de/sgbv/92a.html>

Project Funding options

- NVF: New forms of care
- VSF: care research
- One step (direct funding of project)
- Two step (concept development, then project)
- long project (up to 48 months, typical 36 months)
- Short project (6-12 months, only in one step projects)
- Open topic
- Specific topics
- Most options can be combined

Exemplary funding information for 2024:

NVF, two step, long, specific topics:

1. oral health models for people in need of care and people with disabilities
2. ambulantisation in healthcare provision
3. further development of cross-sectoral care facilities and care networks
4. digital support concepts to strengthen accessibility in the healthcare system
5. domestic and sexualised violence - care and prevention
6. data- and algorithm-based decisions in GP practices - new care concepts for strengthening guideline-based care
7. improvement of care processes in emergency services and emergency and acute care
8. improvement of care processes through data-based identification of needs and design of care pathways
9. care models to strengthen nicotine and tobacco cessation

Take-Home Messages (1/2)



DiGA reimbursement

- Germany is the first country in Europe to reimburse **digital medical devices: DiGAs and DiPAs**, decided on by **BfArM**
- **Fast track** available for DiGAs, but not for DiPAs

Selective Contracts

- Market Access based on a care concept and with selected health insurances
- Relatively fast, but limited to patients of participating health insurances
- Attractive reimbursement option for digital device manufacturers not fitting the DiGA/ DiPA niche

Innovation Funds

- Instrument for the promotion of projects for the introduction, implementation or evaluation of innovative approaches in the German health care system and thus to further develop health insurance benefits.

Take-Home Messages (2/2)

Alternative Revenue Streams

- If collective / selective reimbursement does not fit the purpose of medical software alternative sales concepts need to be assessed.
- Negotiating partners vary depending on the type of software (practitioners, consumers, hospitals etc.).



Thank You for Your Attention



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