



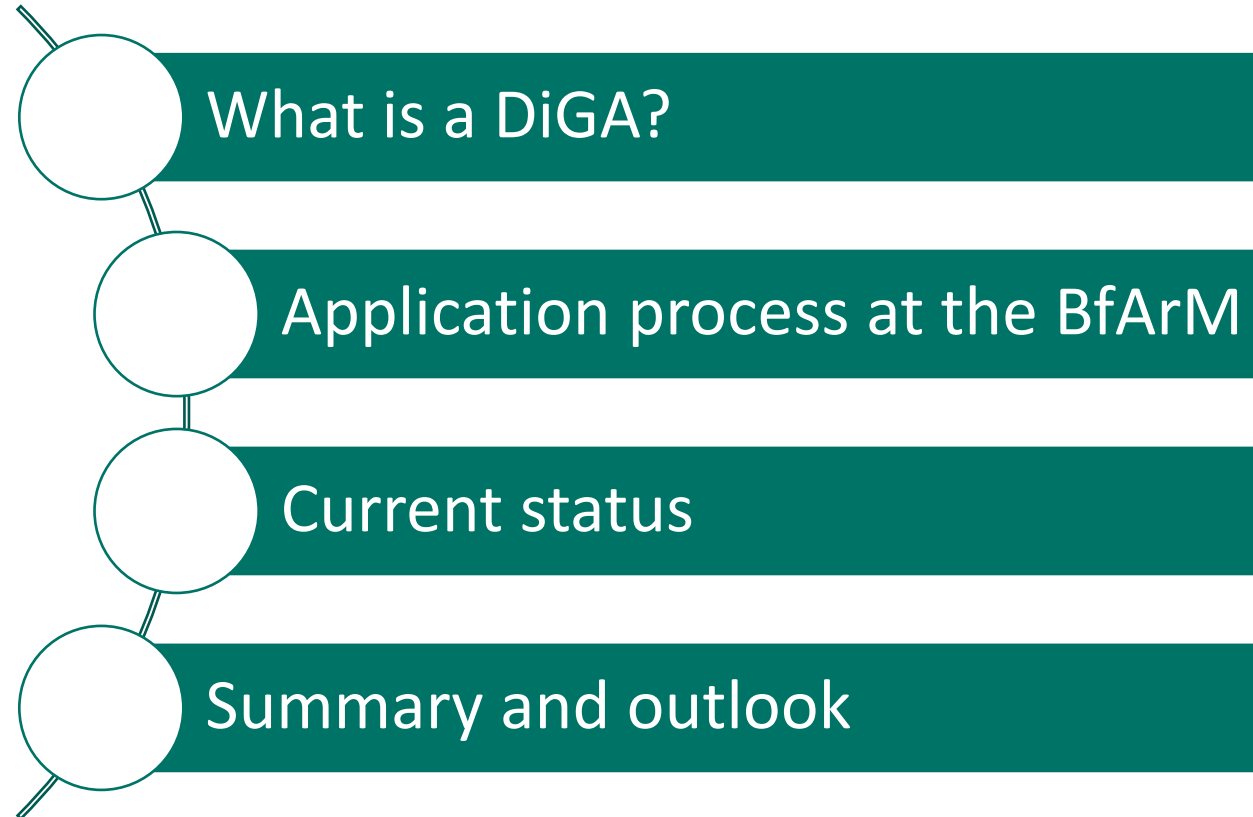
Federal Institute
for Drugs
and Medical Devices

The DiGA-Fast-Track process in Germany

Dr. Tobias Möllers, BfArM
26.09.2023



Agenda









What is a DiGA? (Digitale Gesundheitsanwendung, Digital Health Application)

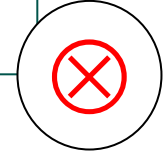


What is a DiGA?



-  Medical device
-  Intended medical purpose
-  Main function based on digital technologies
-  Low risk class (I or IIa)
-  Positive healthcare effect
-  Used by the patient alone or by the patient together with the healthcare professional

And what not?



- Primary prevention
- “Practice equipment“/telemedicine application/
video consultation

Requirements for DiGA



Medical device of the risk class I or IIa
(according to MDR or MDD as part of the transition regulations)



Safety and Suitability for Use
§ 3 DiGAV*



Data Protection and Data Security
§ 4 DiGAV

Requirements of SGB V** and DiGAV



Quality and Interoperability
§§ 5 and 6 DiGAV



Positive Healthcare Effects
§§ 8 to 15 DiGAV

medical benefit or patient-relevant improvement of structure and processes

Positive Healthcare Effect

Medical Benefit



Patient-relevant effects, particularly regarding:

- the improvement of the state of health
- the reduction of the duration of disease
- the prolongation of survival
- an improvement in quality of life

AND/OR

Patient-relevant improvement of structure and processes (pSVV)



New possibilities for improving care, especially with regard to processes in the patient:

- coordination of treatment procedures
- alignment of treatment with guidelines and recognized standards
- adherence
- facilitating access to care
- patient safety
- health literacy
- patient autonomy
- coping with illness-related difficulties in everyday life
- reduction of therapy-related efforts and strains for patients and their relatives

Different paths for listing

Provisional Listing

- Systematic literature review
 - Evidence synthesis of similar therapeutics
- Systematic data analysis
 - Data on the use of the DiGA
 - Justification of the improvement of healthcare
- Evaluation concept
 - Study concept for the trial phase

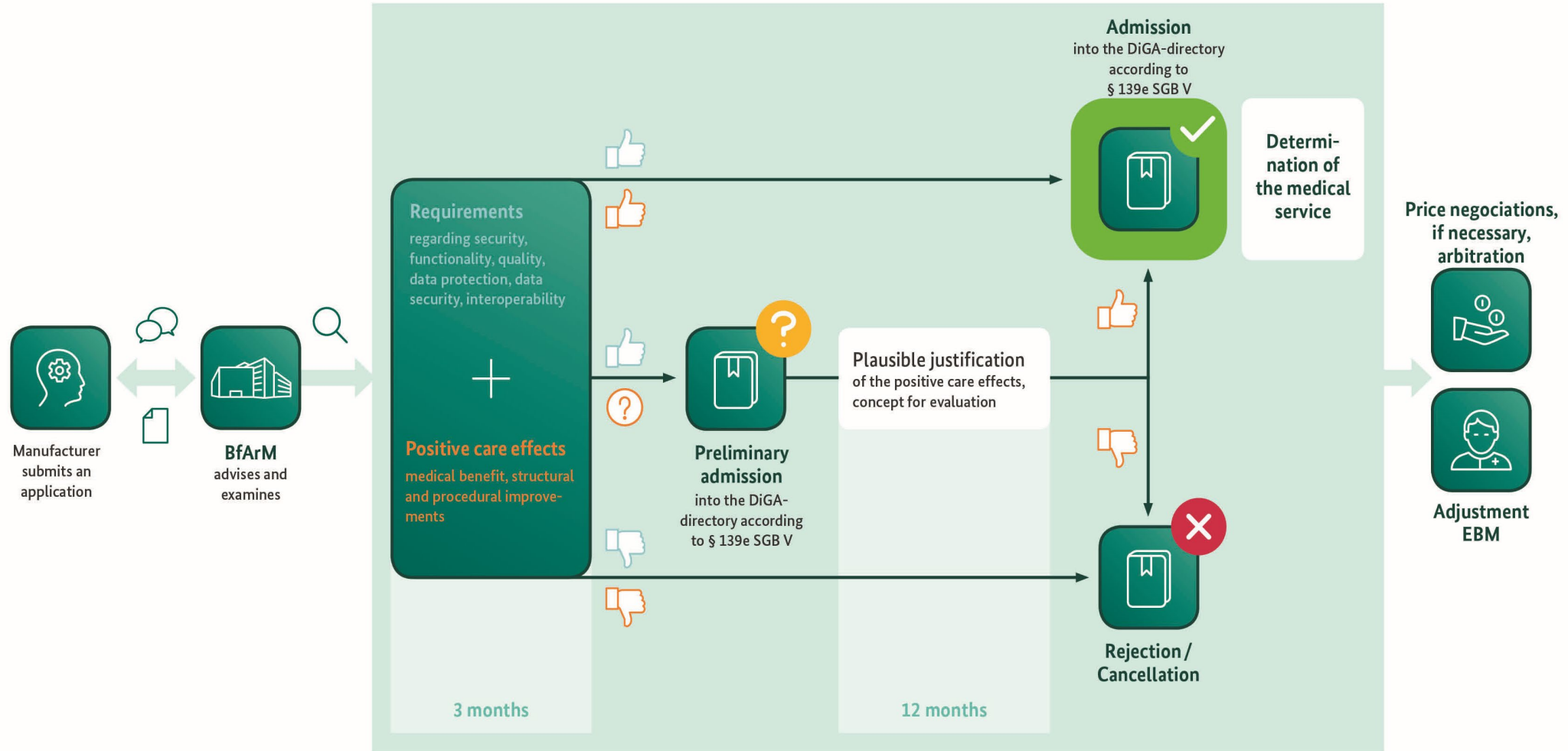
Permanent Listing

- Study has to be completed
- Pre-specified study protocol and analysis plan
- Detailed study report

Application process at the BfArM



The DiGA-Fast-Track process



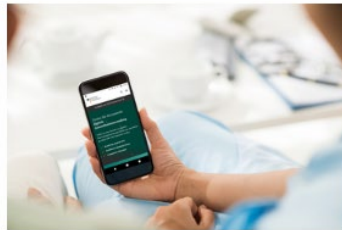
The DiGA directory: Transparency and Guidance for Users, Health Care Professionals, Statutory Health Insurances...



- DiGA directory
- DiGA Guide
- Innovation office
- Interesting facts
- Contact
- Further information

Tasks of the BfArM > Digital Health Applications (DiGA)

Here you will find all relevant information – advice regarding the connection with the procedure for listing in the directory of rein listing of a DiGA in that directory, information regarding prescrip documents and other webpages



Finden Sie die passende digitale Gesundheitsanwendung

Treffen Sie eine Auswahl aus digitalen Gesundheitsanwendungen (DiGA), die vom BfArM gemäß § 139e SGB V bewertet wurden.

- ✓ Erstattung durch die GKV
- ✓ Zertifizierte Medizinprodukte
- ✓ Transparent aufbereitet

DiGA-Verzeichnis

Geben Sie Ihren Suchbegriff ein... oder [DiGA-Verzeichnis öffnen](#)

Das DiGA-Verzeichnis

Antworten zur Nutzung von DiGA

Willkommen beim Verzeichnis für digitale Gesundheitsanwendungen (DiGA)!

Filter

Kategorie

- Alle
- Atemwege
- Geschlechtsorgane, Nieren und Harnwege
- Herz und Kreislauf
- Hormone und Stoffwechsel
- Krebs
- Muskeln, Knochen und Gelenke
- Nervensystem
- Ohren
- Psyche
- Sonstige
- Verdauung

Plattform

- Alle
- Apple App Store
- Google Play Store
- Webanwendung

Anzuwenden bei

Diagnose nach ICD-10 eingeben...

Geben Sie Ihren Suchbegriff ein...

43 von 51 DiGA werden angezeigt | Filter zurücksetzen

Cara Care für Reizdarm

Verkäuflich aufgenommen | HDG-Technologie GmbH, Deutschland

Plattformen	Anzuwenden bei	Eigenschaften
Apple App Store	K58 Reizdarmyndrom	Herstellpreis: 374,98 €
Google Play Store	K58.1 Bläuhäufigkeit, Diäther-prädominant (RDS-D)	Keine Mehrkosten
	K58.2 Reizdarmyndrom, Obstipationsprädominant (RDS-D) und 2 weitere	Keine Zusatzgebühren
		Keine vertragsspezifischen Leistungen erforderlich
		Verfügbare Sprachen: Deutsch

[Weitere Informationen zur DiGA](#)

companion patella powered by medi - proved by Dt. Kniegesellschaft

Verkäuflich aufgenommen | PatApp GmbH, Deutschland

Plattformen	Anzuwenden bei	Eigenschaften
Webanwendung	M22.2 Krankheiten im Patellafemoralebereich	Herstellpreis: 345,10 €
		Keine Mehrkosten

<https://diga.bfarm.de/de/verzeichnis>

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

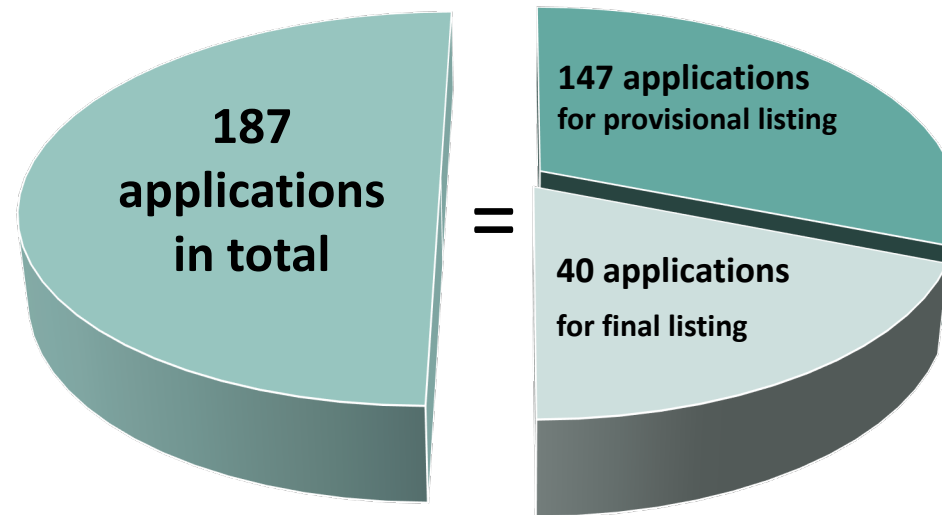
<https://diga.bfarm.de/de>

Current status



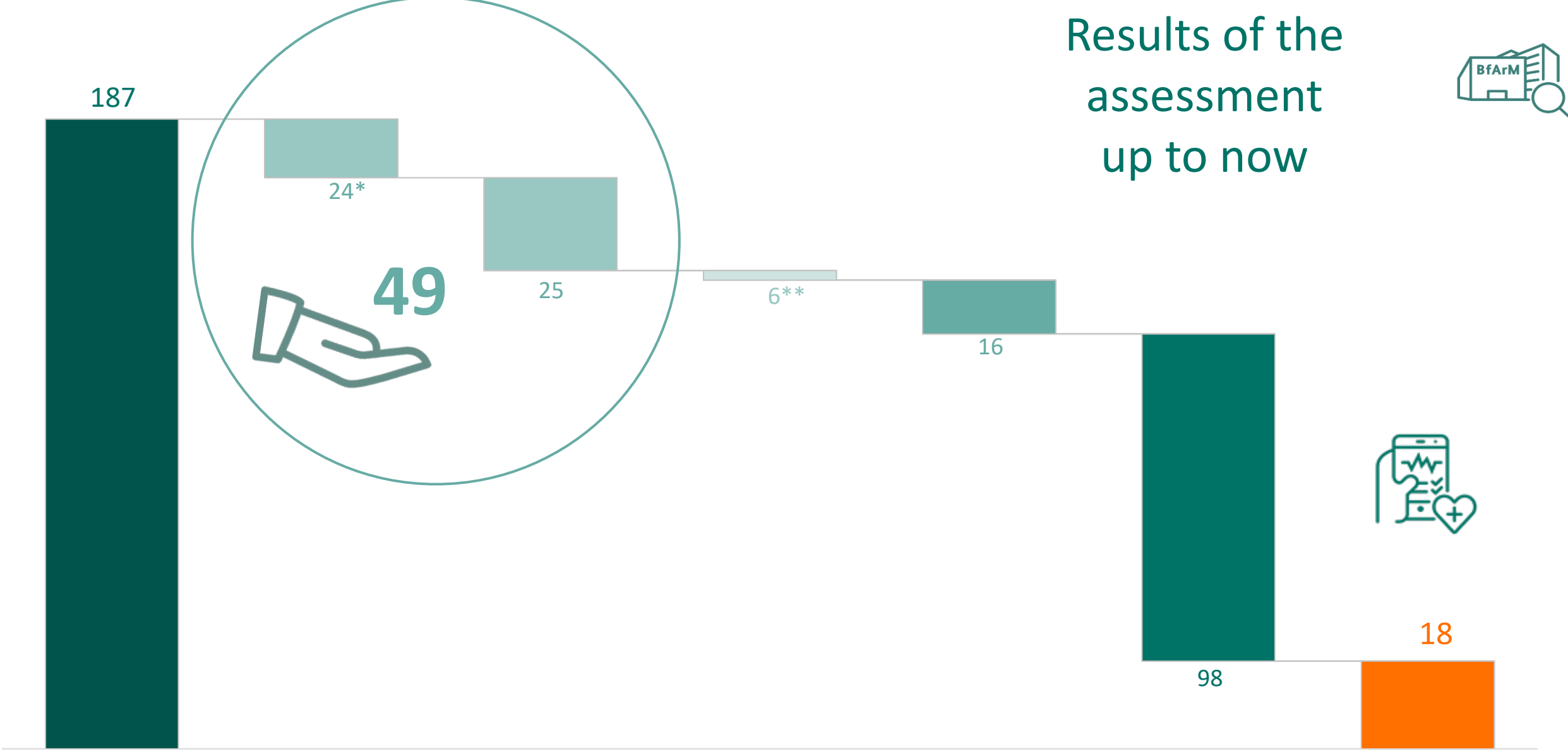
DiGA applications

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



status: 25.09.2023

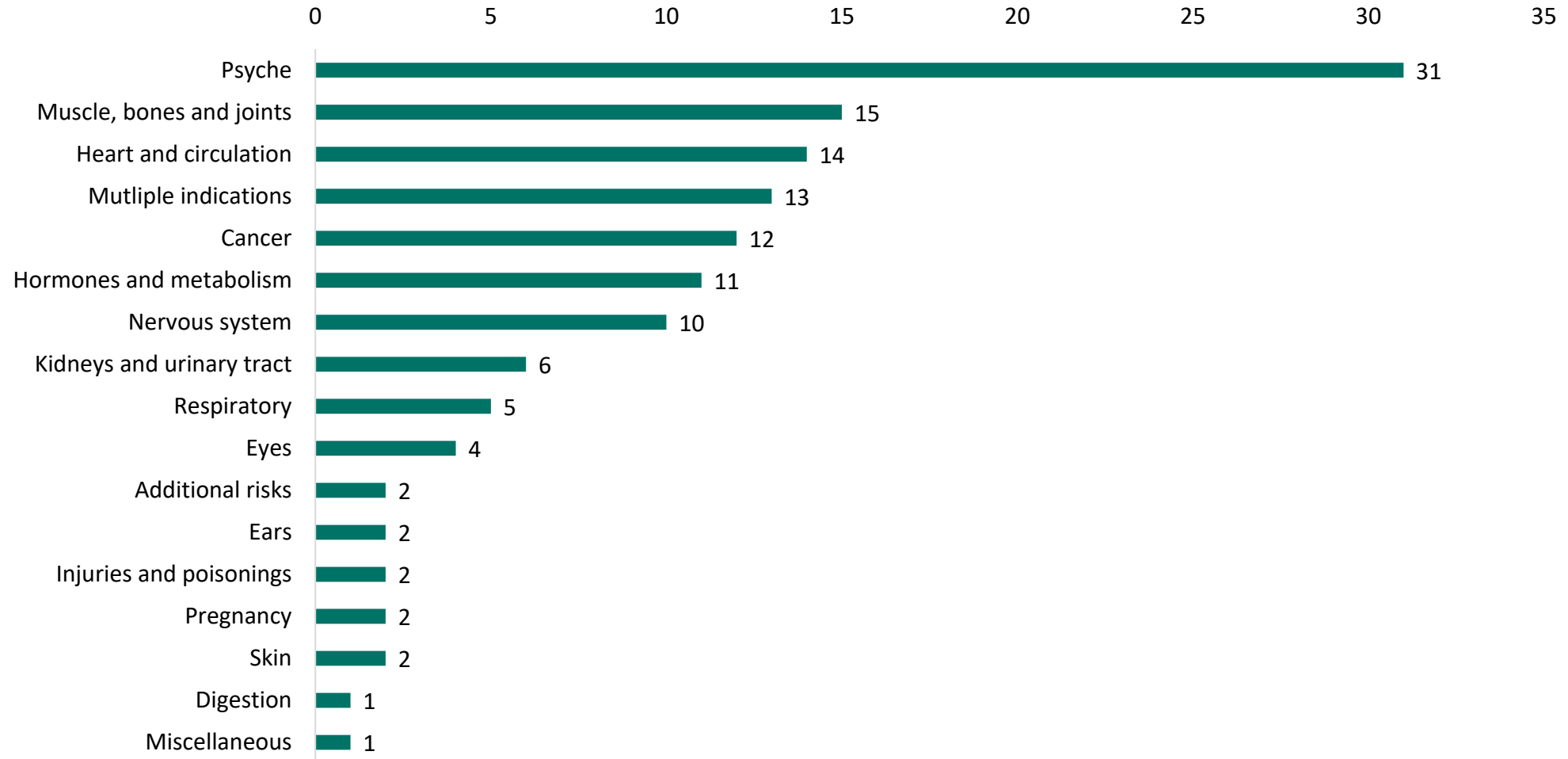
Results of the assessment up to now



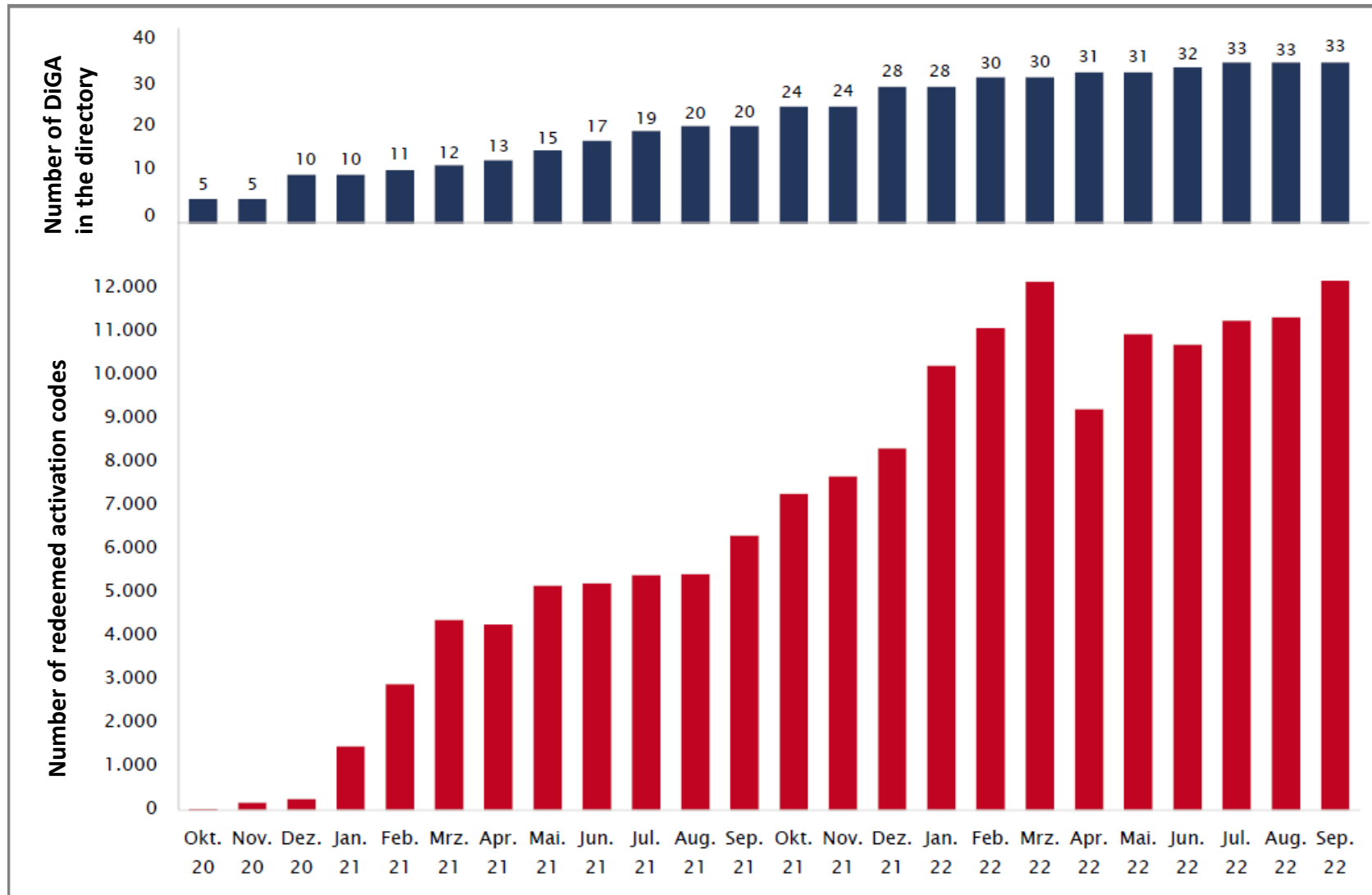
* 14 out of the 24 finally admitted DiGA provided proof during the trial phase
 ** 2 out of the 6 deleted DiGA were deleted on application of the manufacturer

status: 25.09.2023

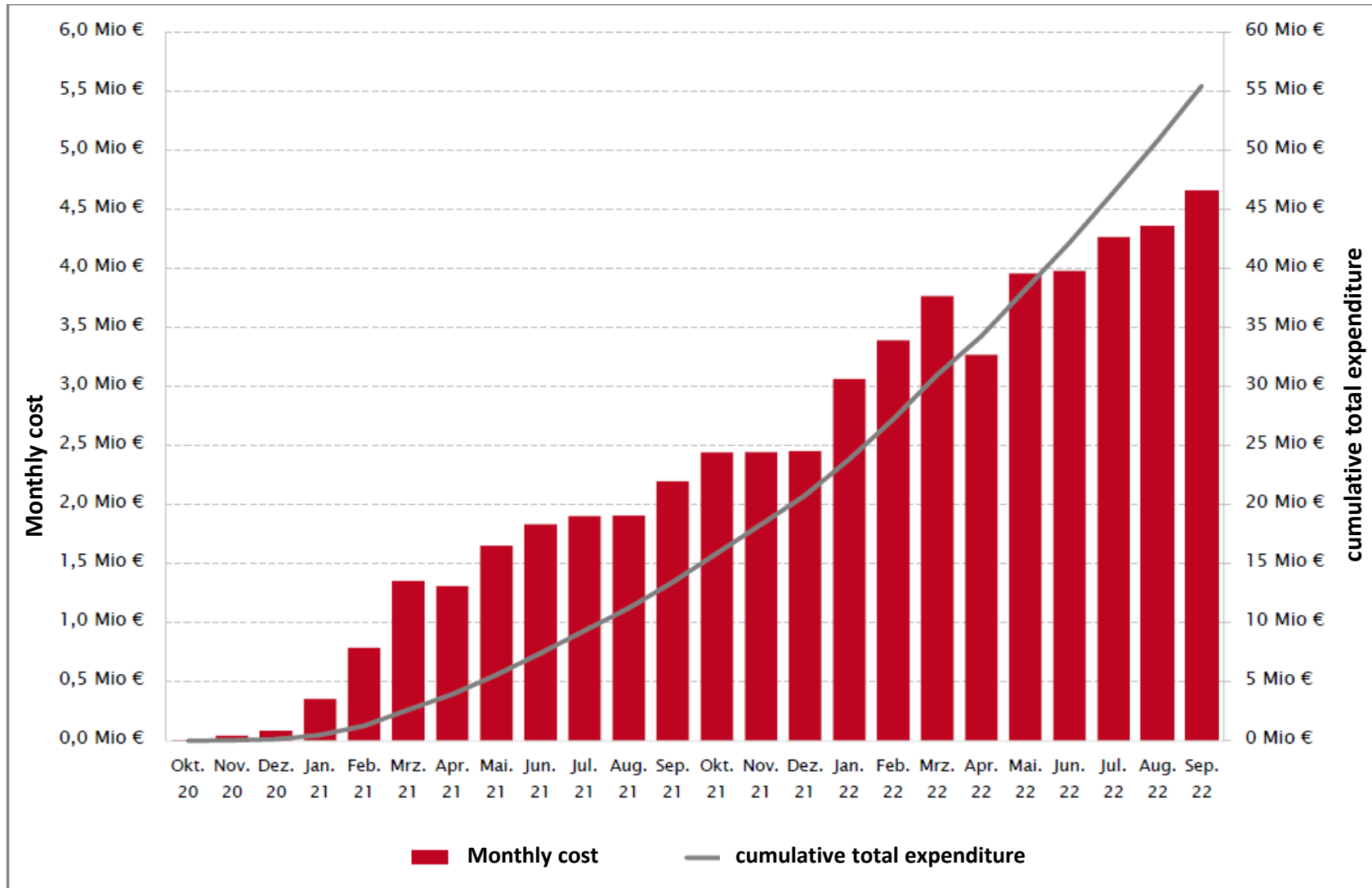
DiGA categories of the initially submitted DiGA applications



Prescriptions and cost in the first two years DiGA-Fast-Track (01.09.2020–30.09.2022)



Prescriptions and cost in the first two years DiGA-Fast-Track (01.09.2020–30.09.2022)

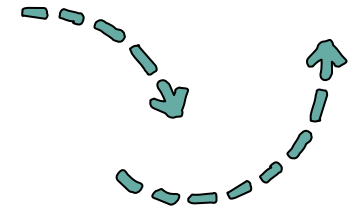


Source:
GKV-
Spitzenverband
according to § 33a
section 6 SGB V

Summary and outlook

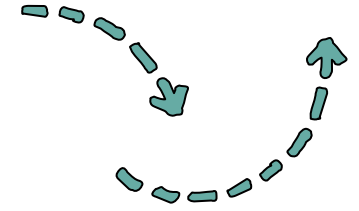


Summary



- **Continuously high interest** of manufacturers but also other stakeholders in DiGA-Fast-Track process and growing interest of other countries
- The DiGA-Fast-Track process can be a **challenge** for manufacturers and **evidence is the most critical aspect** with regard to withdrawals and rejection
- **Learning system** with continuous exchange with all relevant stakeholders
- **Comprehensive support** for manufacturers with BfArM Guidance documents, webinars and additional advice is offered by the BfArM

Outlook



- **Further Exchange on European level** to reach a mutual understanding in order to **harmonise the assessment criteria** in the European Union
- **Digital nursing applications (DiPA)**: Process started in December 2022.
- **Certificates for data protection (01.08.2024)** and **data security (01.01.2025)**
- **Digitalisation strategy** of the Federal Ministry of Health:
 - Hybrid care models (map more comprehensive telemedicine care concepts involving physician)
 - Higher risk classes (IIb)
 - Interoperability (read from the electronic health record if and to the extent that this is necessary and useful for personalising the DiGA/DiPA)

Thank you very much for your attention!



Contact

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