



Federal Institute
for Drugs
and Medical Devices

Digital Health Applications Current Status and Challenges

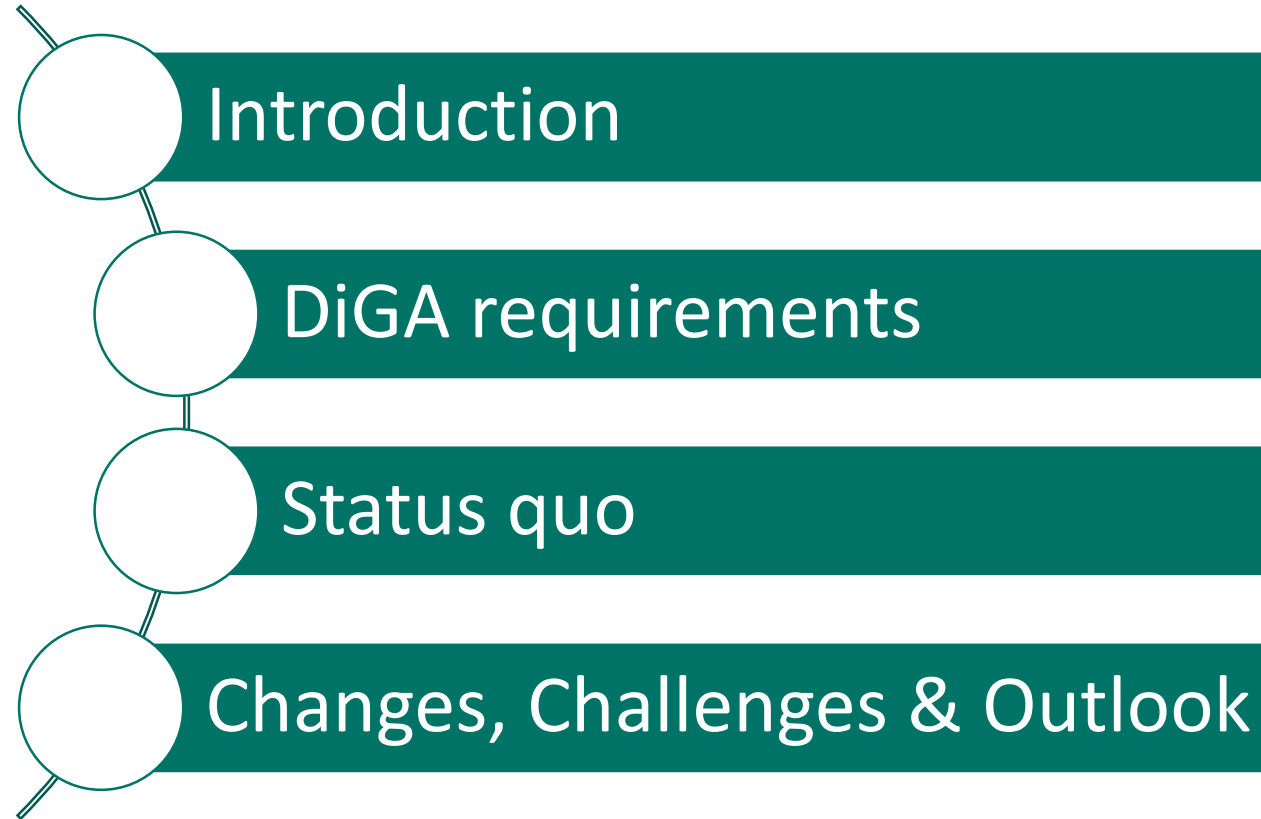
DGRA

Prof. Dr. Karl Broich, President BfArM

9.5.2025



Agenda








Introduction – DiGA requirements

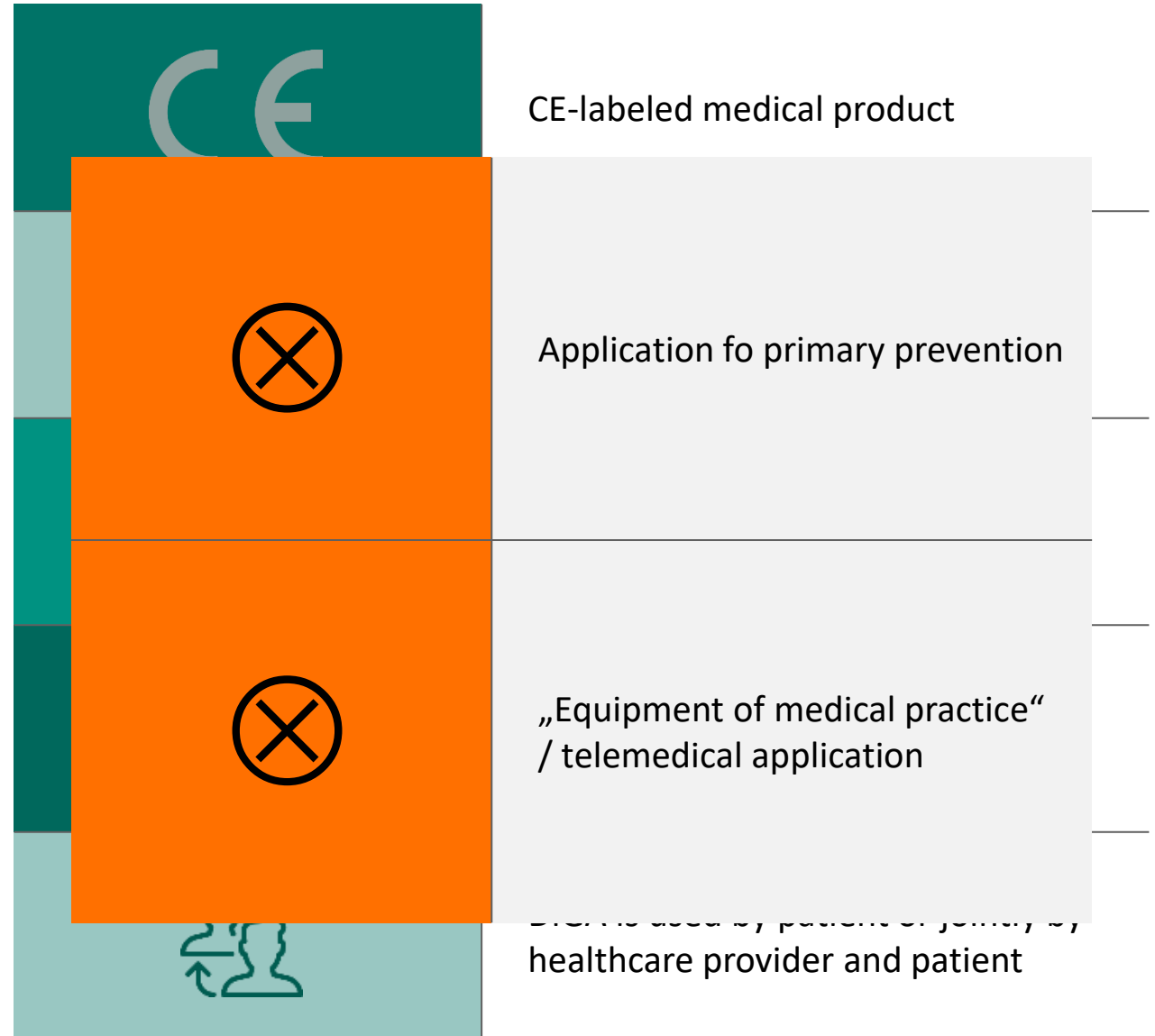


What is a DiGA?

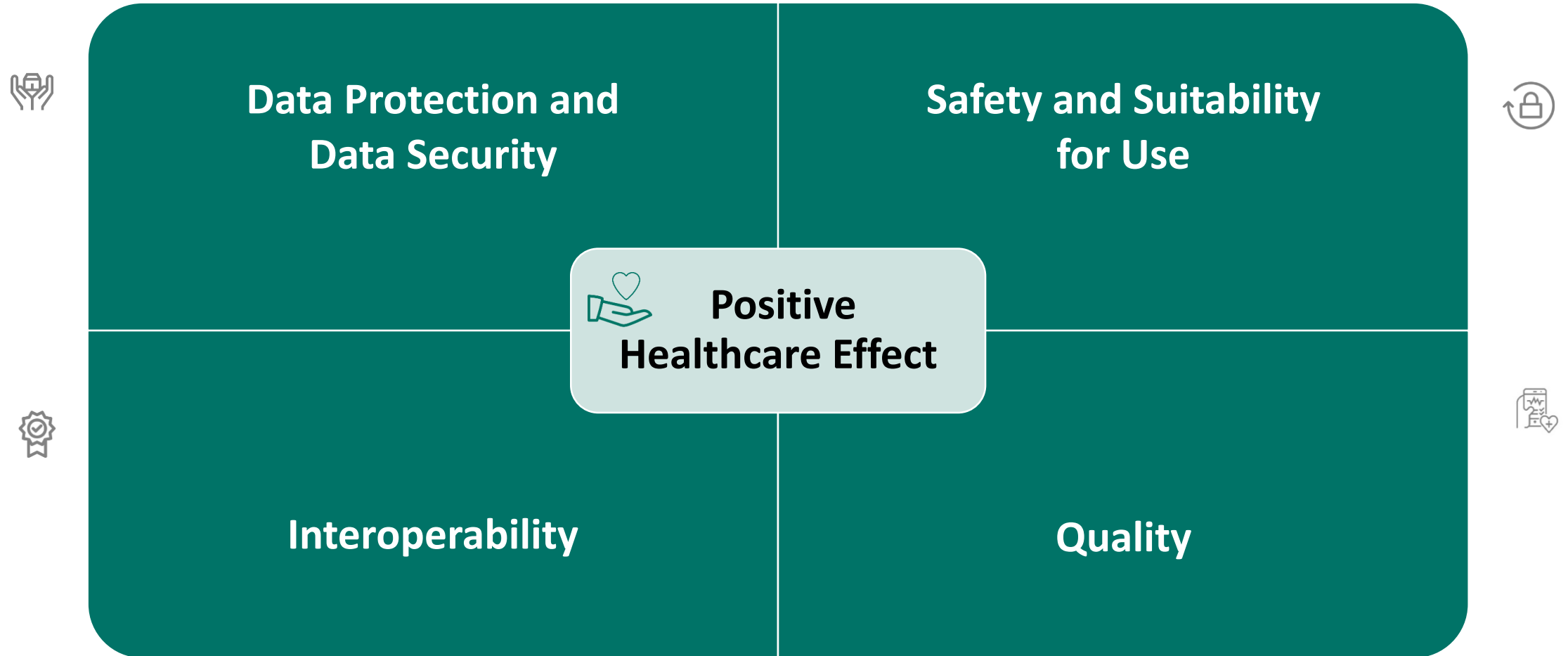


	CE-labeled medical product
	Risk class (I, IIa, IIb)
	Digital main function
	Positive health care effect
	DiGA is used by patient or jointly by healthcare provider and patient

What is a DiGA?



Requirements for DiGA (according to SGB V* und DiGAV**)



Requirements for study to demonstrate positive healthcare effect(s)

**Quantitative
comparative study**

**Use of the DiGA
better than non-use**

**Implementation in
Germany** [exception:
transferability to
health care context in
Germany]

**Comparison group
must be geared to the
reality of health care**

**Registration in a
public study registry**

**Complete publication
latest 12 months after
completion of the
study**

Positive healthcare effect

Medical benefit*



Patient-relevant effects, particularly regarding:

- improvement of the state of health
- reduction of the duration of disease
- prolongation of survival
- 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**

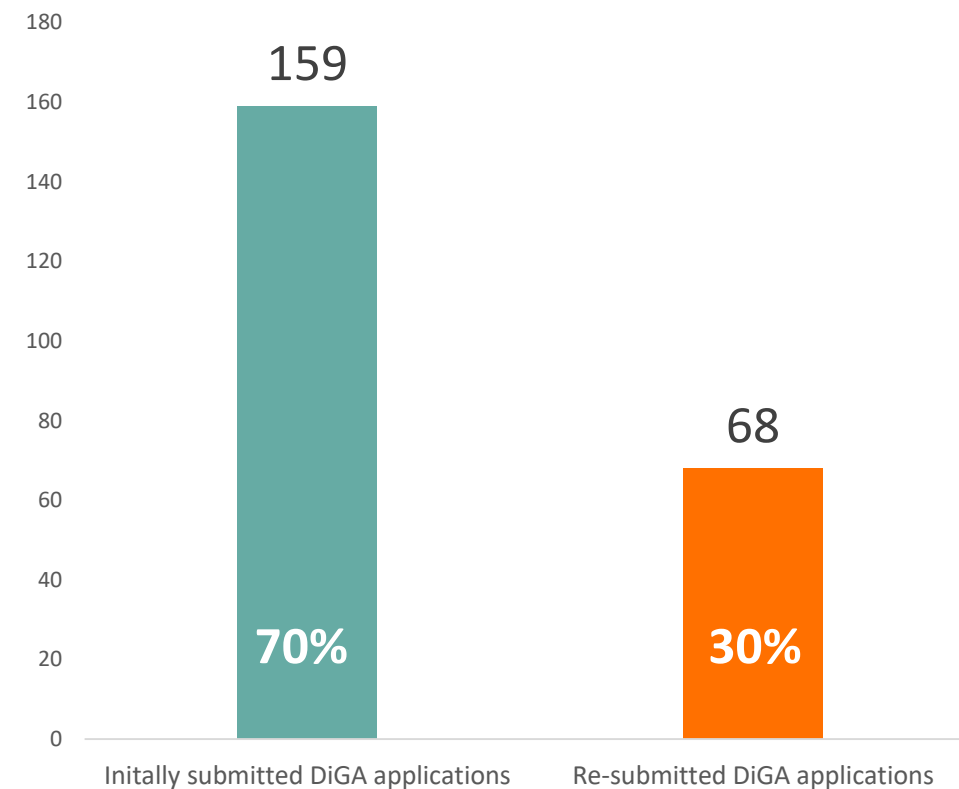
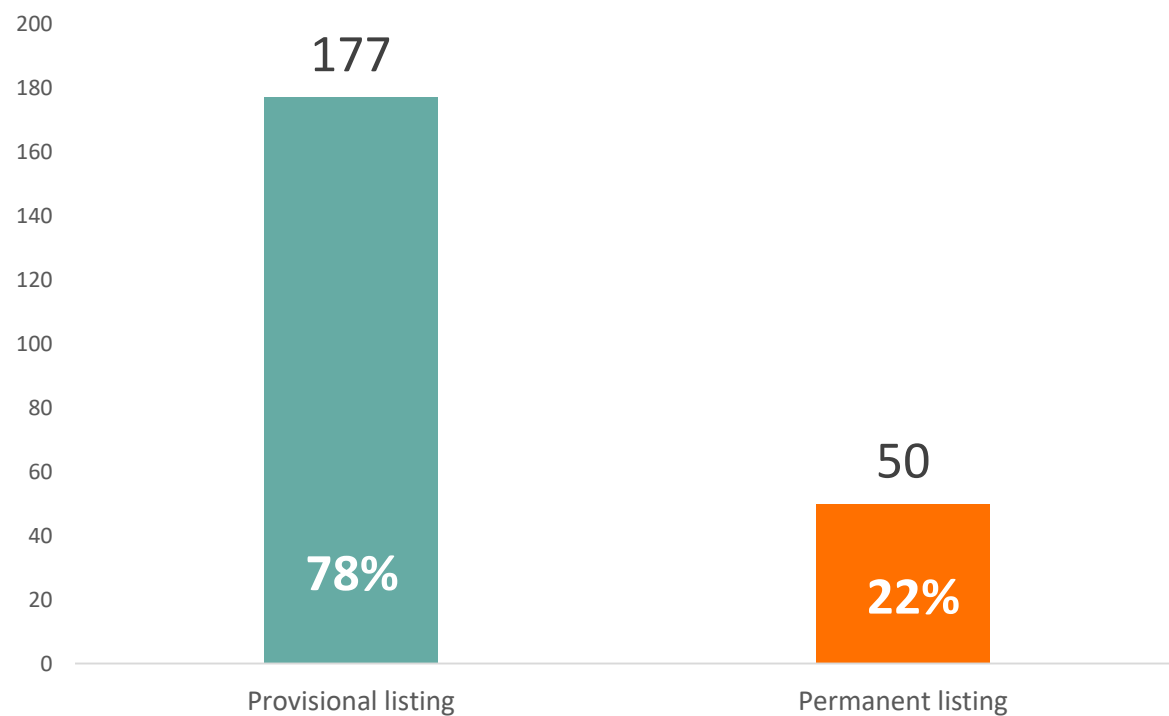
- Study has to be completed
- Pre-specified study protocol and analysis plan
- Detailed study report

Status quo

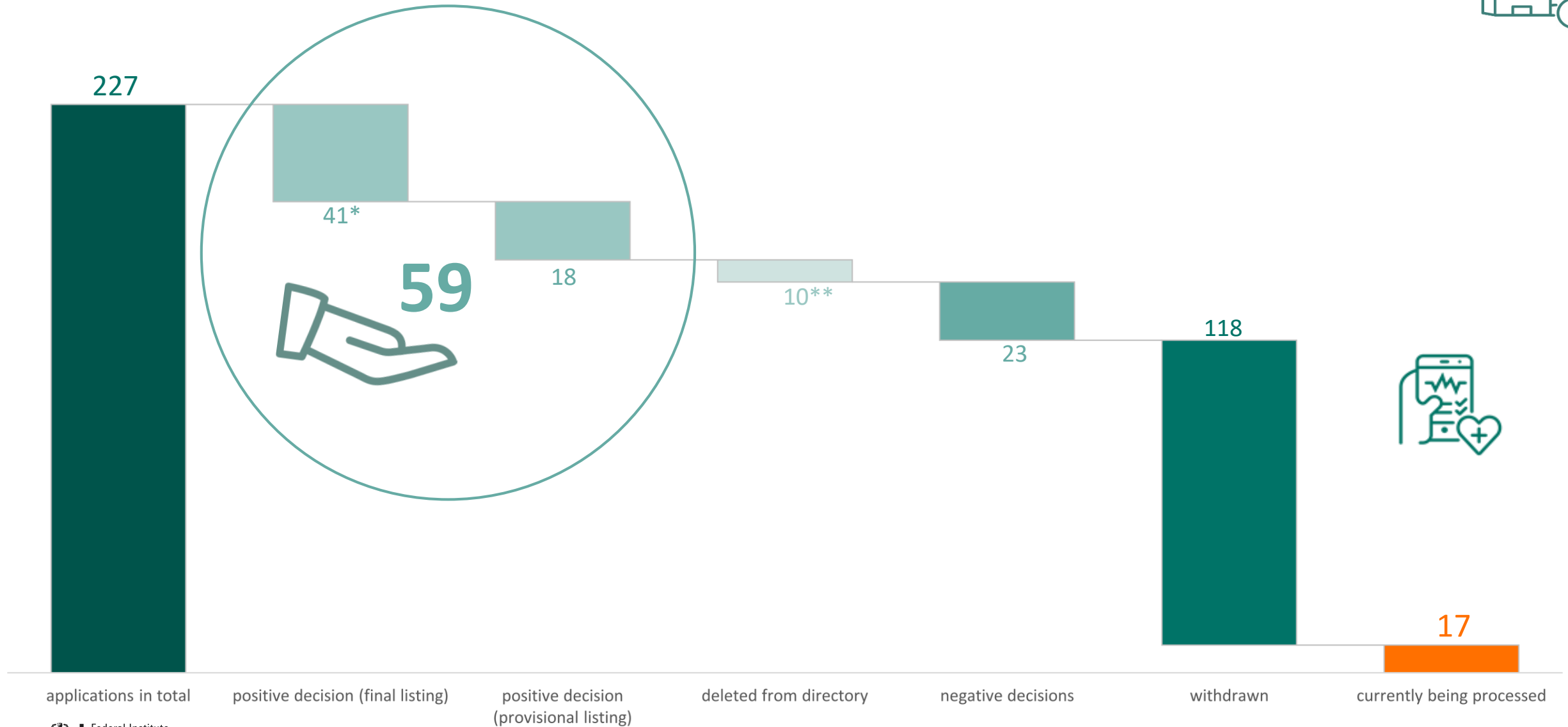


Number DiGA applications since start

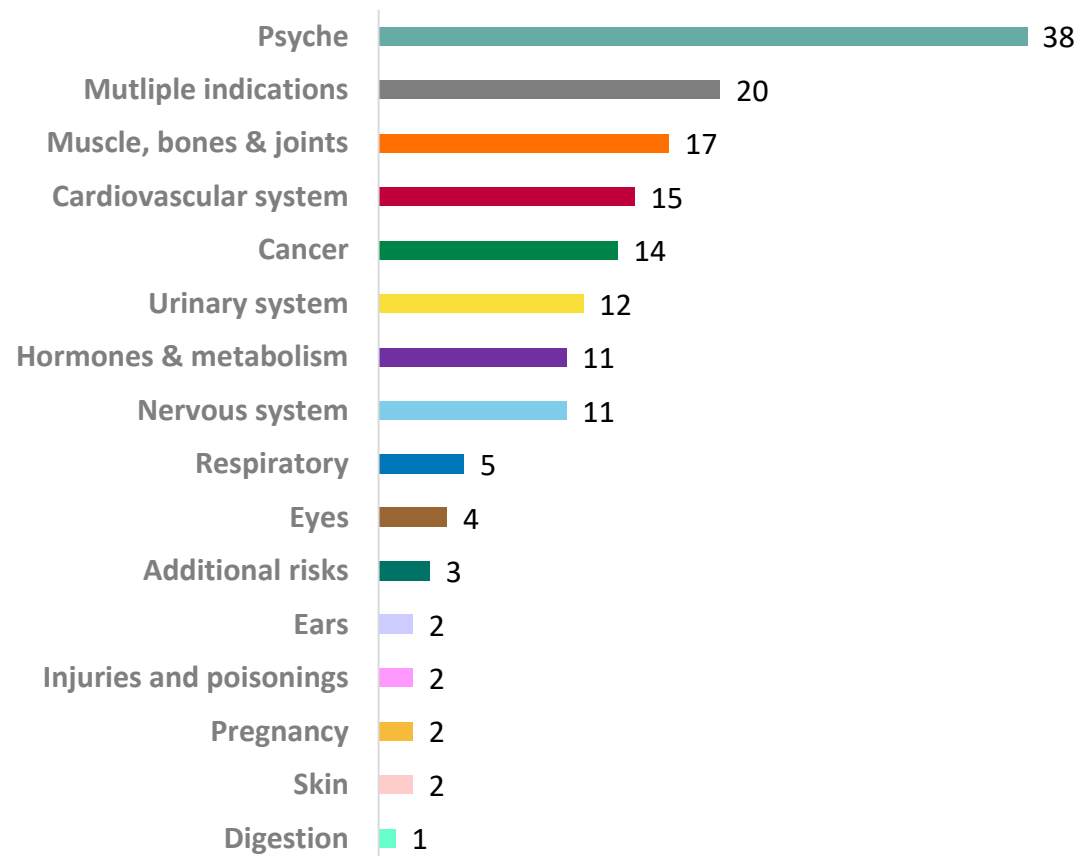
n=227



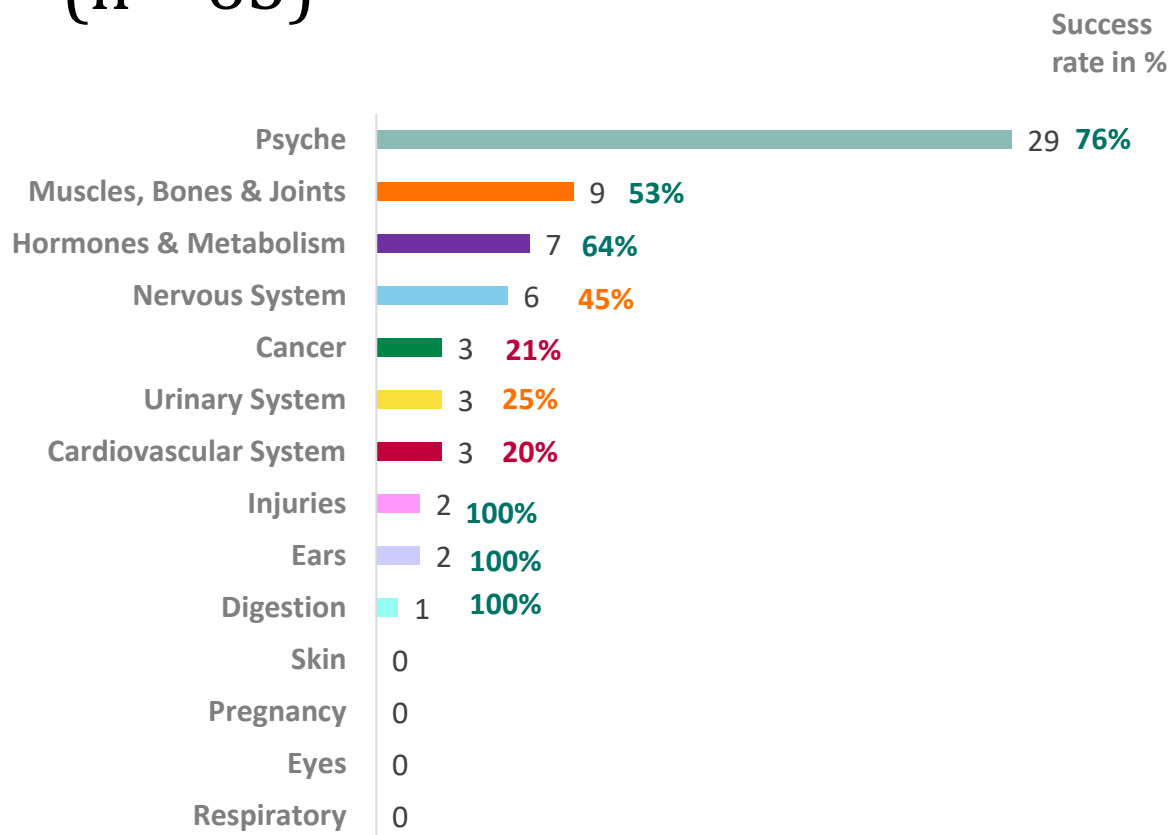
Assessment outcomes



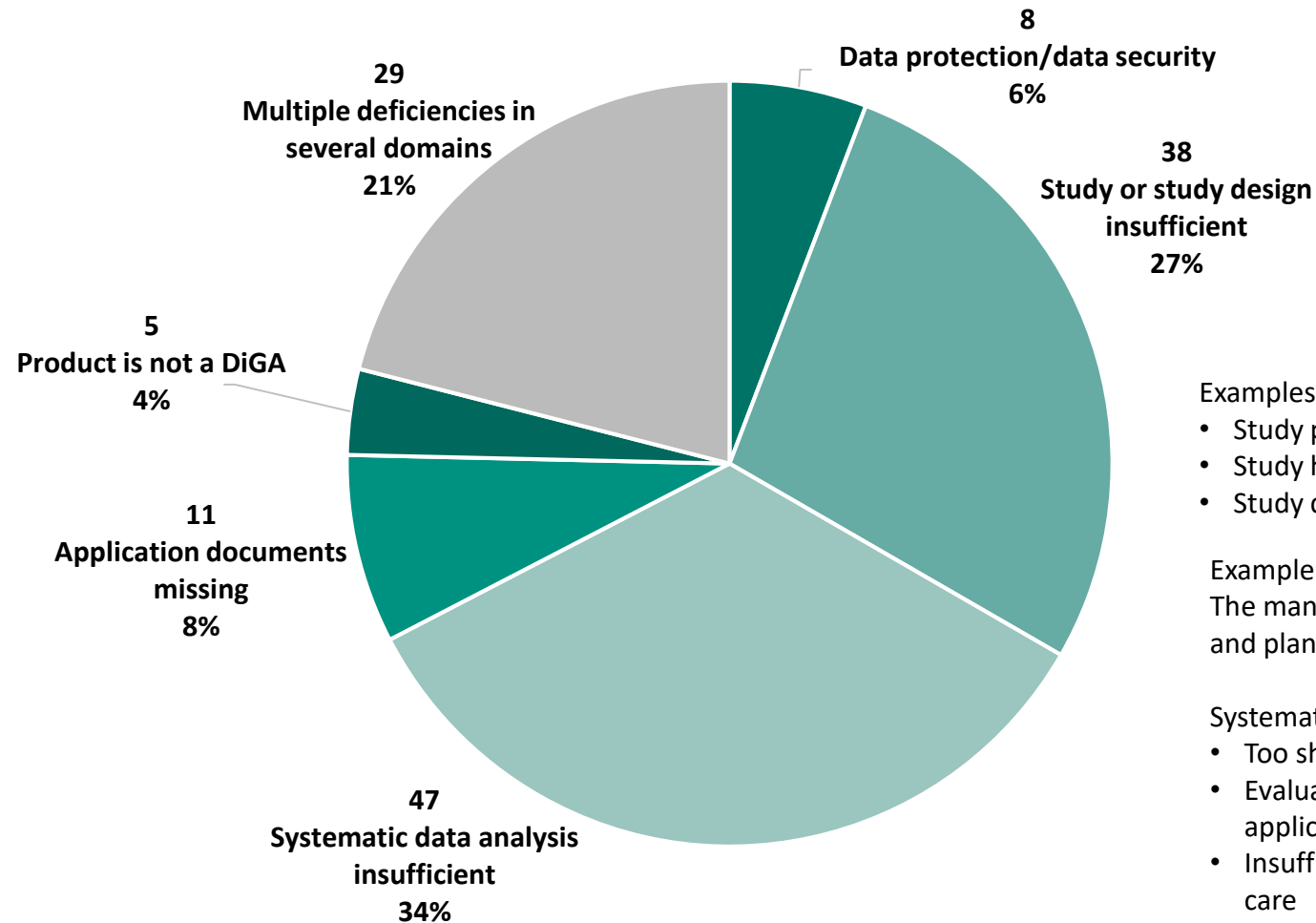
Indication areas of initial DiGA applications (n = 159)



Indication areas of **listed** DiGA (n = 65)



Reasons for withdrawal or rejection of applications



Examples in the case of **applications for final listing**:

- Study protocol, or prespecification is missing
- Study has significant limitations
- Study does not show confirmatory evidence

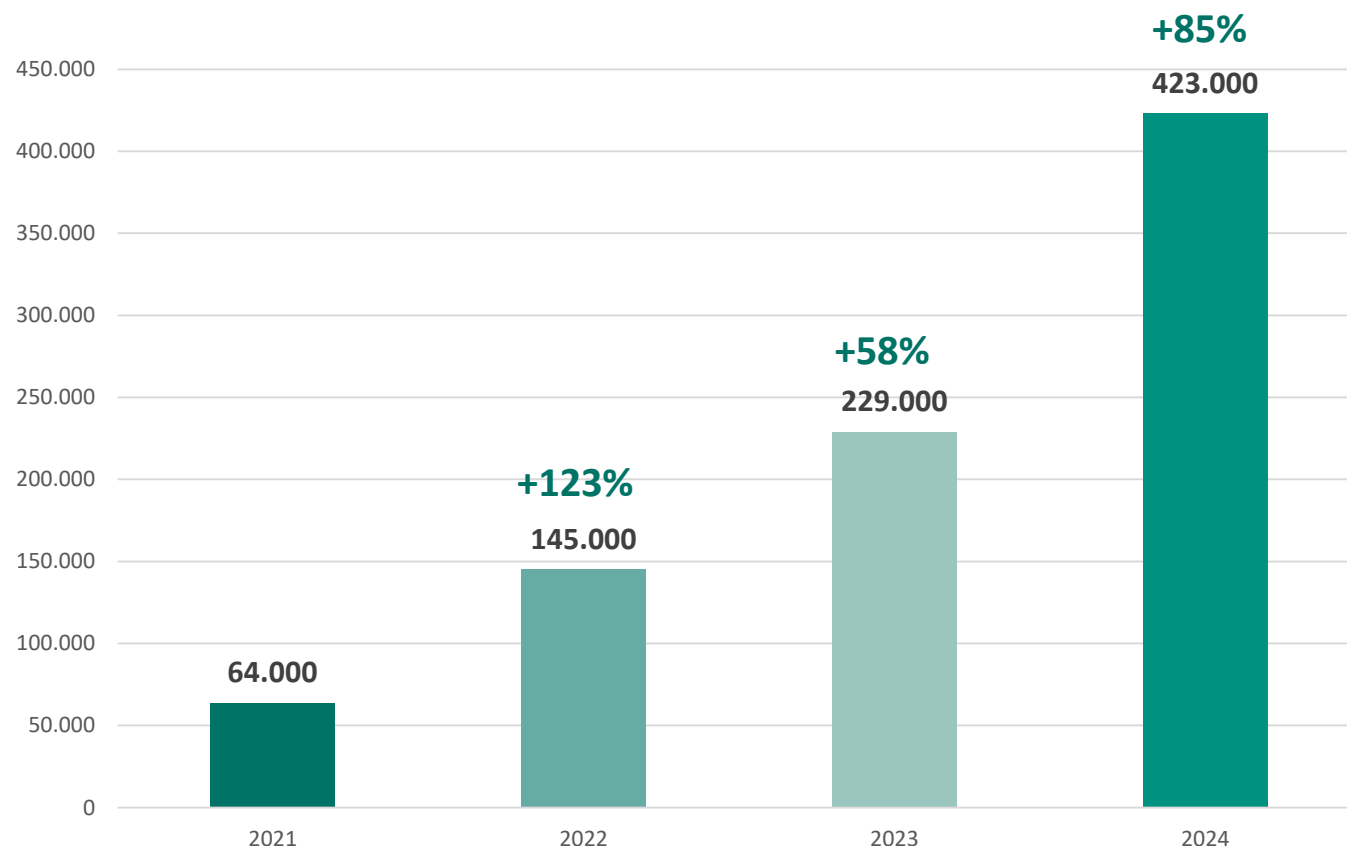
Example in case of **applications for provisional listing**:

The manufacturer lacks time to complete the data and adjust the documents and planning.

Systematic data evaluation:

- Too short observation period
- Evaluation was not performed with DiGA that is the subject of the application
- Insufficient number of subjects (e.g., $n=5$, $n=9$) to justify improvement in care
- Postulated positive effects on care were not addressed in the submitted evaluation

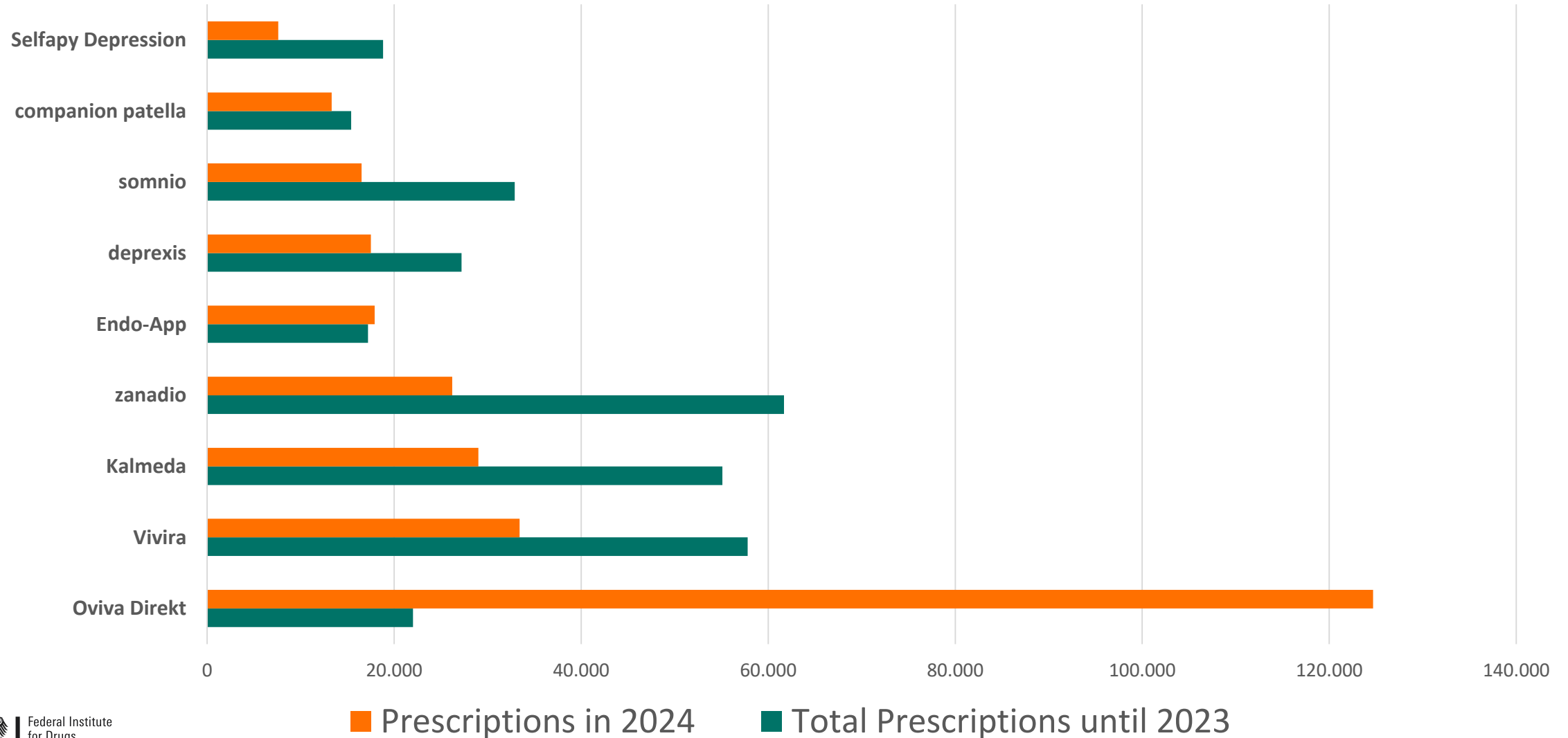
Number of prescribed DiGA



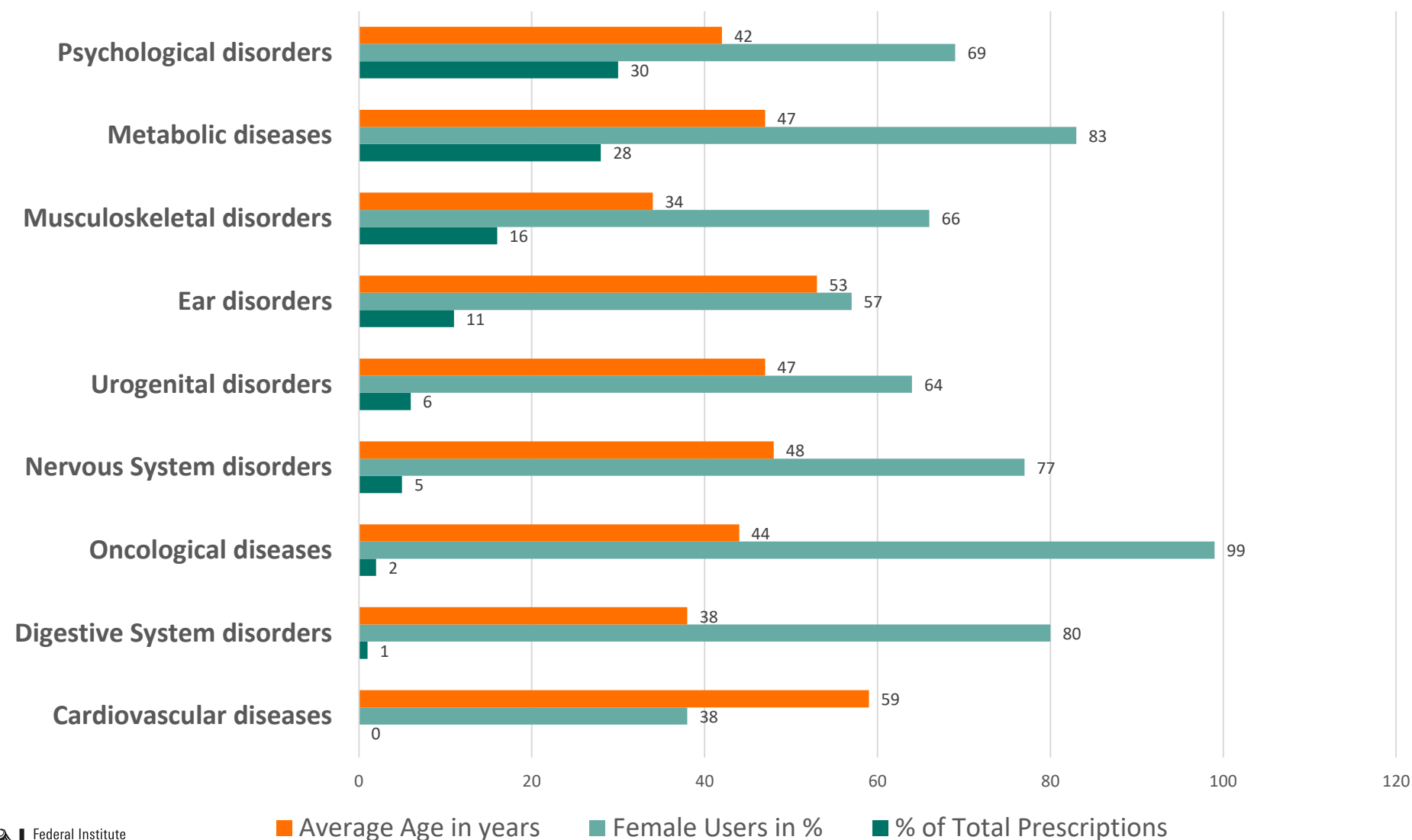
From very start in September 2020 until December 31, 2024

- a total of **861.000** DiGA prescriptions were redeemed
- The number per quarter increased steadily
- But not necessarily due to the increase of DiGA entered in the directory
- But rather due to few DiGA that caused sharp increase

Most frequently prescribed DiGA

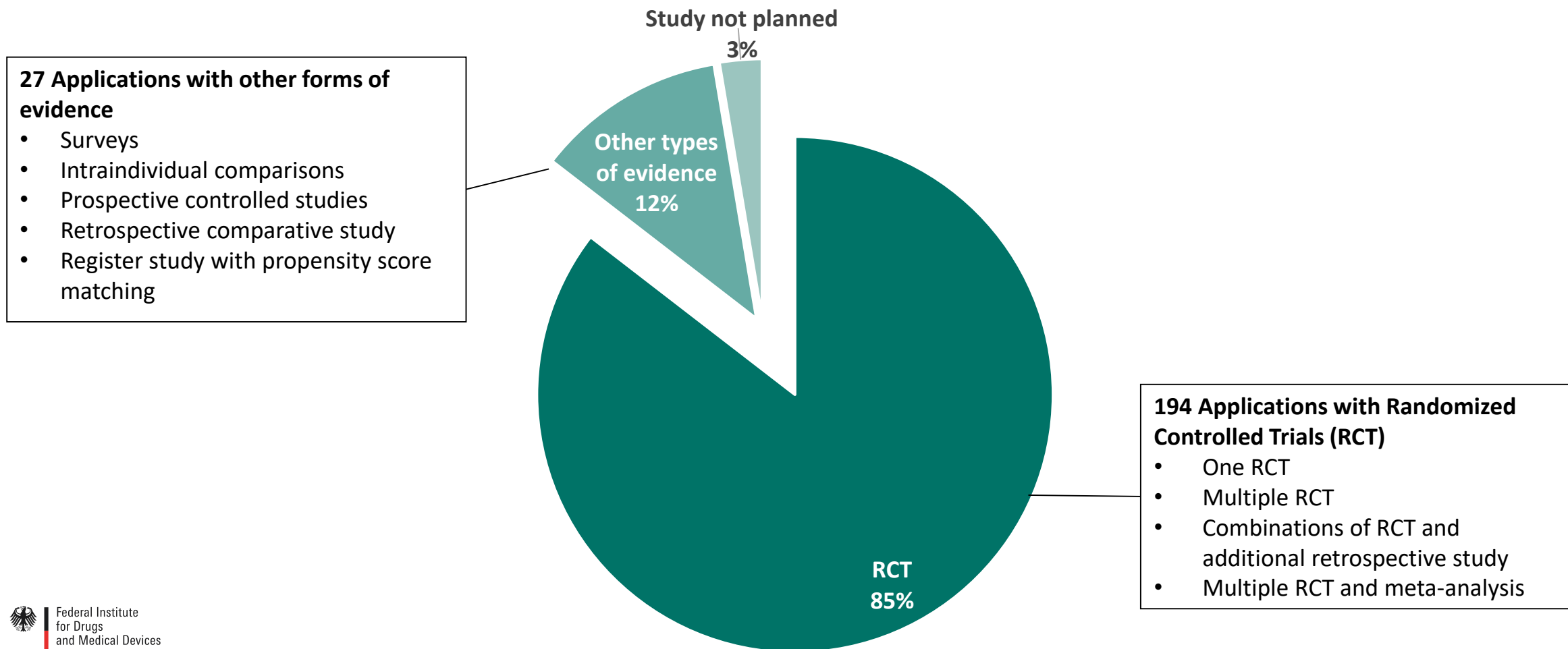


Specifics of prescribed DiGA



Overview evidence ("study types")

The type of the evidence of the 227 applications is as follows:



Criticism on these approaches:

- Recruiement Bias
- Not blinded as clinical trials with medicinal products, request of sham treatments
- Prescription complicated, no sufficient information
- No regular use, no efficiency control over time

The DiGA directory: Transparency and guidance for users, health care professionals, statutory health insurances...



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

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

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

Changes, Challenges & Outlook



Changes by Digital Act (DigiG)

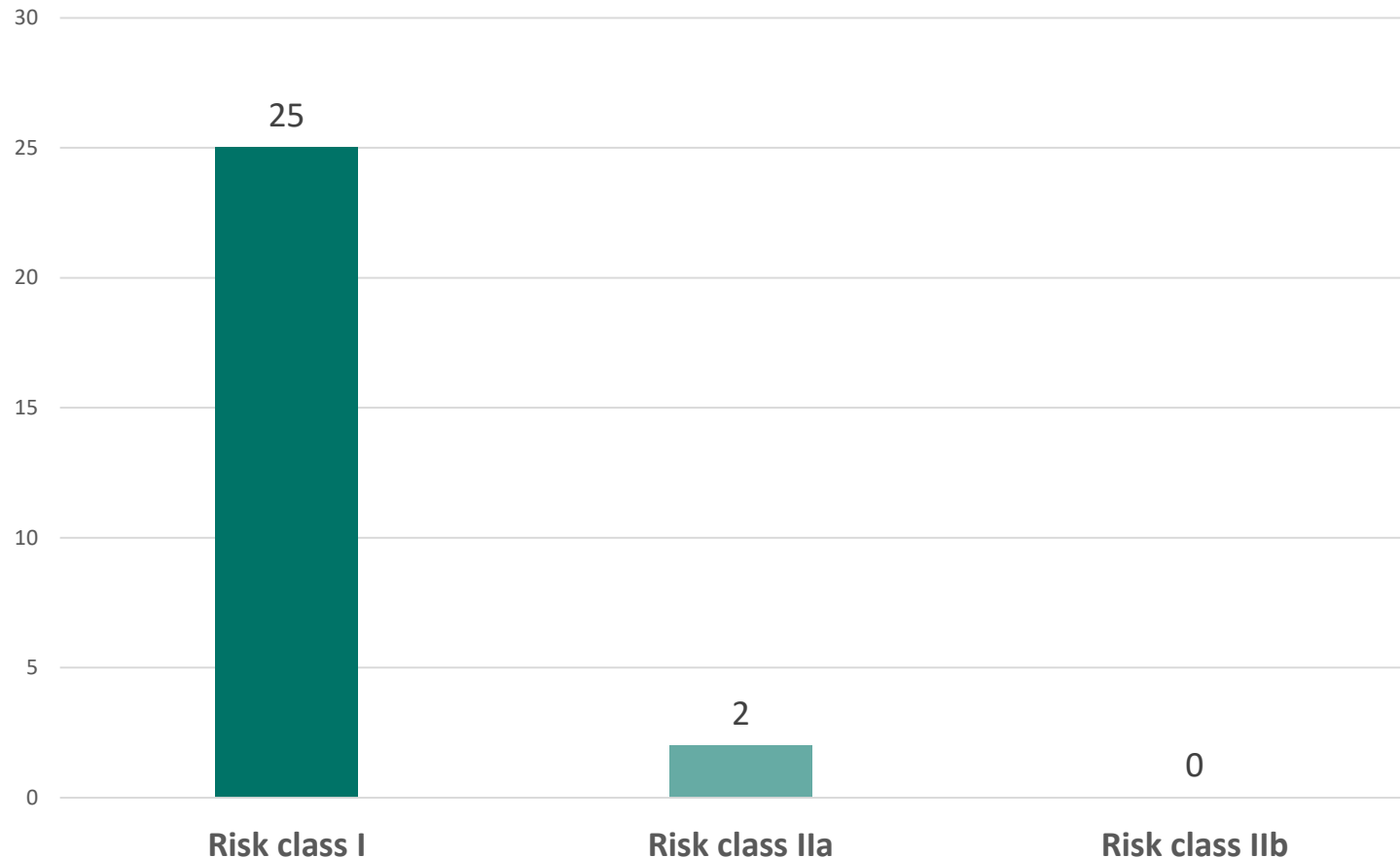


- March 2024: **Change** of DiGA framework
- Introduction of **ePA** (achieved on 29th April 2025)
- DiGA scope widened, **Class IIb products** included
- **Telemedicine/ hybrid care models** (map more comprehensive telemedicine care concepts involving physicians)
- **Faster** activation codes for prescribed DiGA



- § 139e (13) SGB V introduces **performance measurement (AbEM)** for all DiGA manufacturers
- Manufacturers must submit anonymized and aggregated data, including the **duration and frequency of use, patient satisfaction, and patient health status during use**
- Starting January 1, 2026, the BfArM will **publish the AbEM results** of digital health applications in the DiGA directory

Risk classes of DiGA-applications since scope extension



From March 2024 until today a total of **27** DiGA applications has been received

- 25 risk class I, 2 risk class IIa
- No risk class IIb applications, presumably
 - Because of mandatory permanent listing (full data analysis completed)
 - Regulatory hurdles - early detection diagnostics might fail due to exclusion of primary prevention

Challenges

- The DiGA-Fast-Track process can be a **challenge** for manufacturers and **evidence is the most critical aspect** with regard to withdrawals and rejections
- **Line between too high and too low standards for evidence is hard to draw**
- **Certificates for data protection (date: tbd) and data security (01.01.2025)**
- **Connection to ePA**
- **Acceptance of DiGA (patients, carers, physicians)**
- **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

- Ongoing evaluation of and improvement of system
- Further exchange on European level to reach a mutual understanding in order to harmonise the assessment criteria in the European Union
- Franco-German cooperation
- Certificates for data protection and data security
- Further exchange nationally with ethics committees about Good Clinical Practice (GCP)
- Performance measurement of DiGA in real-world use
- **DiGA as part of national Digital Disease Management Programs/Recommendations in Treatment Guidelines**

Thank you very much for your attention!



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