

# Innovative Future for Medicines and Health Technologies: Regulatory Strategies, Digitalisation and Integration

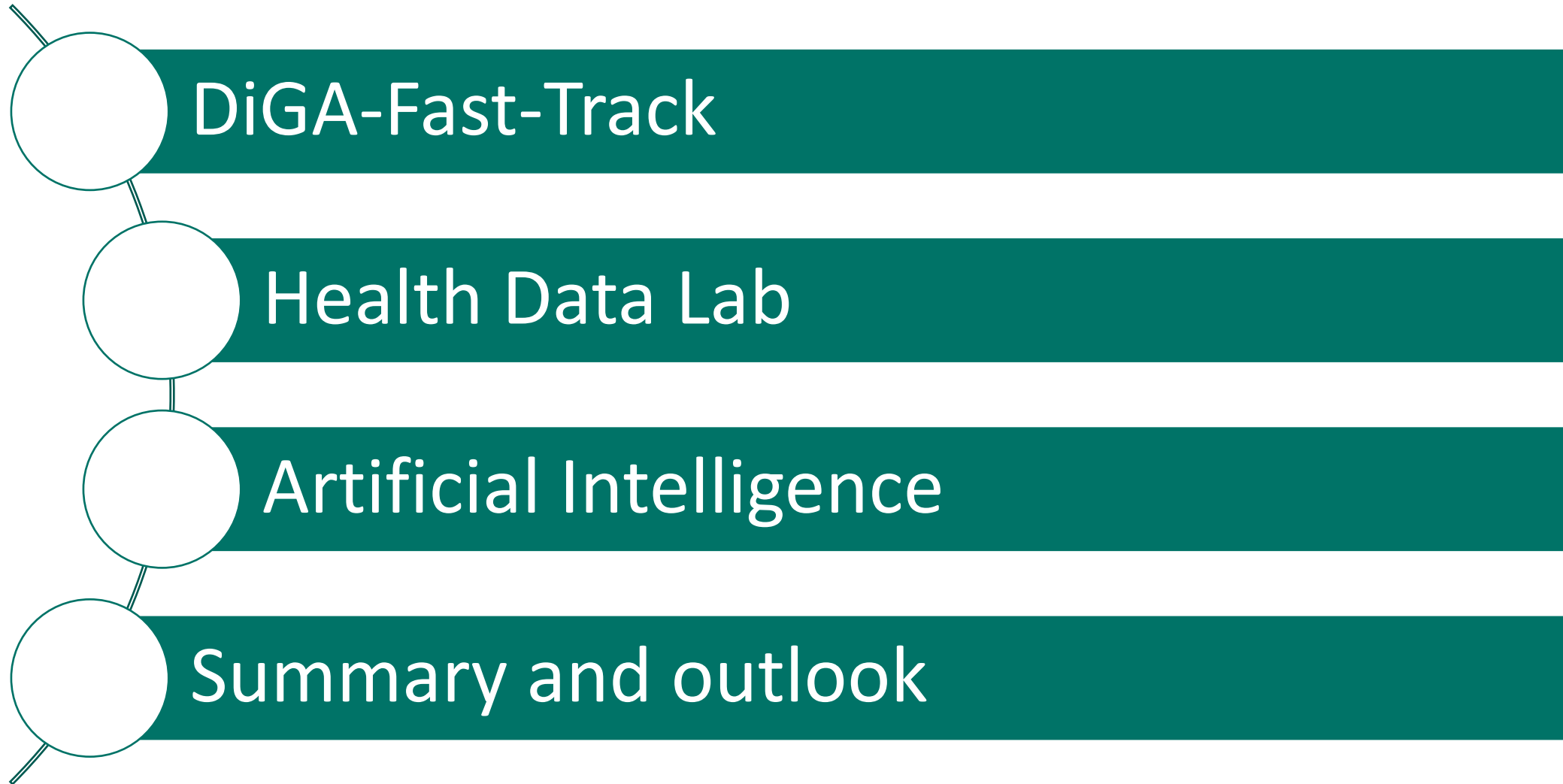
## Fostering digital health: The approach by BfArM

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20.11.2024



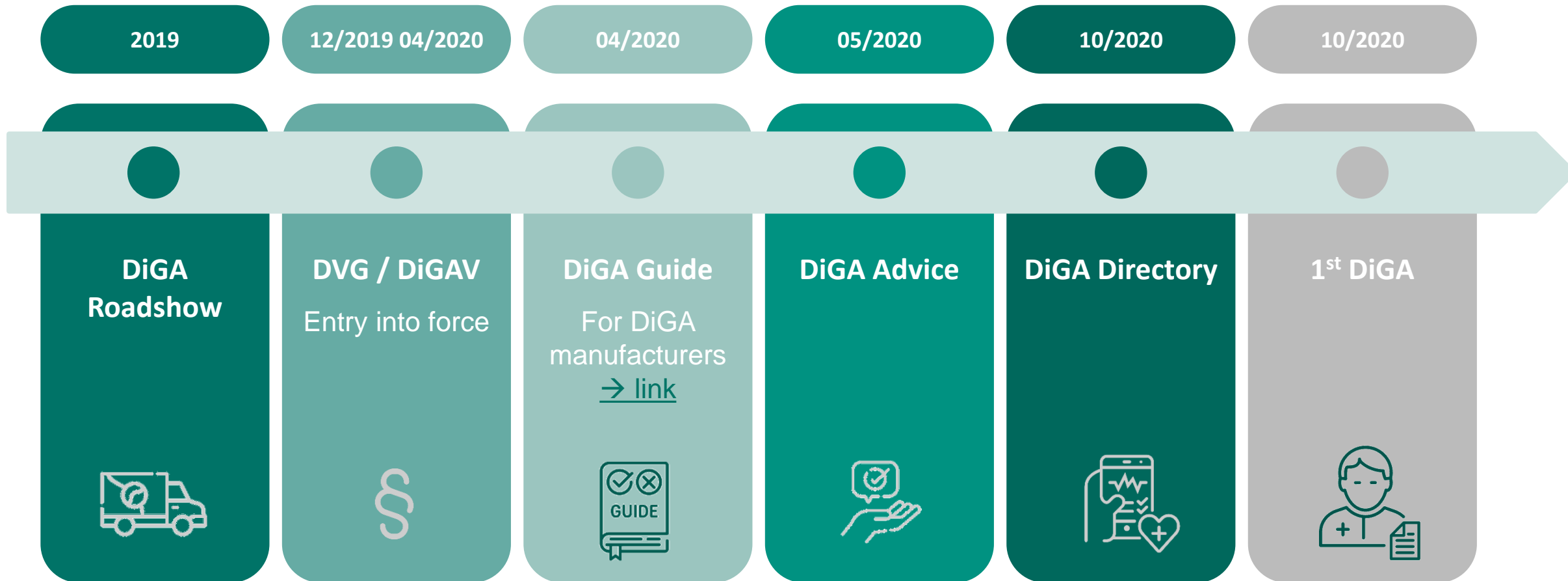
# Agenda



# DiGA-Fast-Track








# Roadmap to DiGA

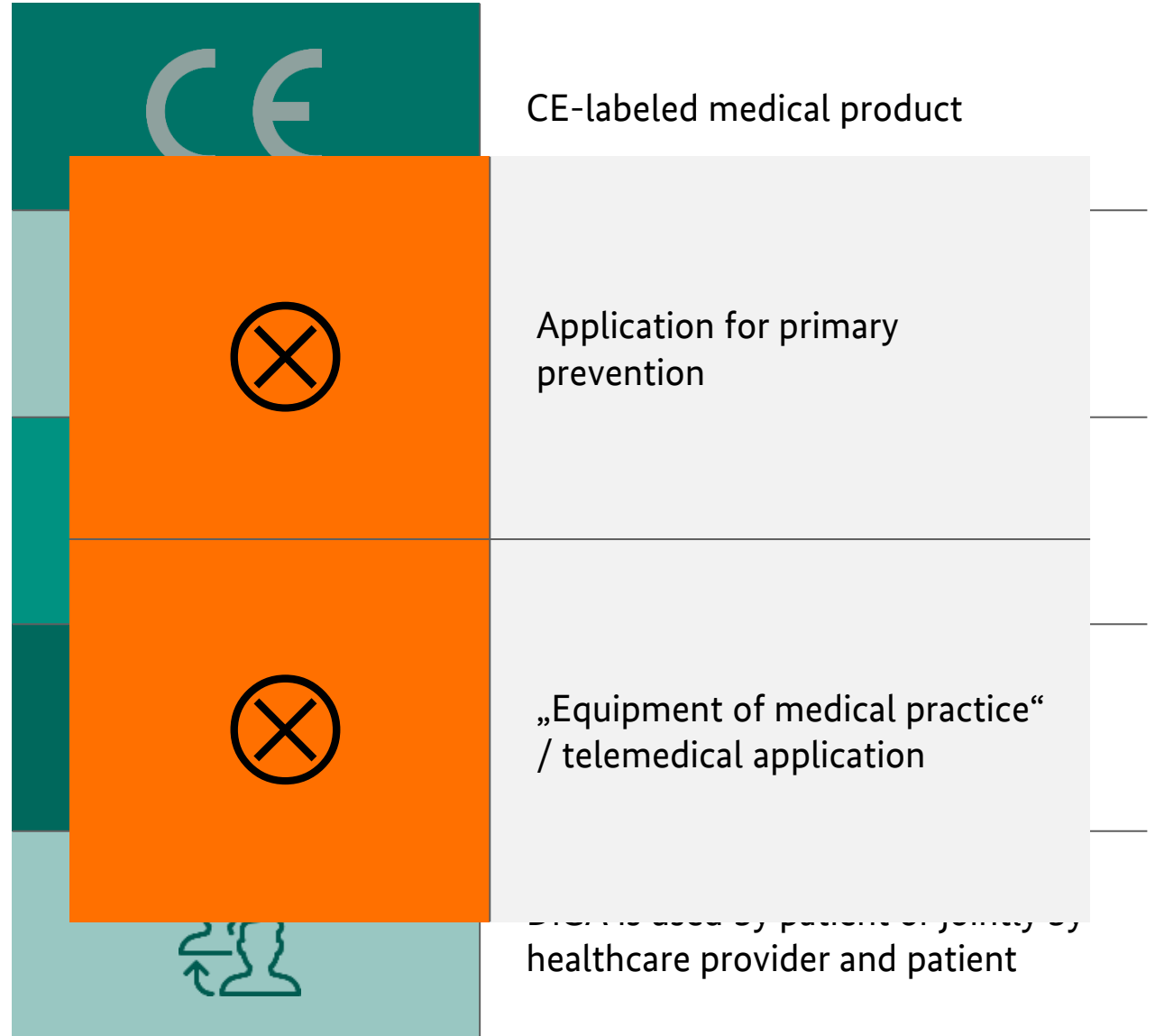


# What is a DiGA?

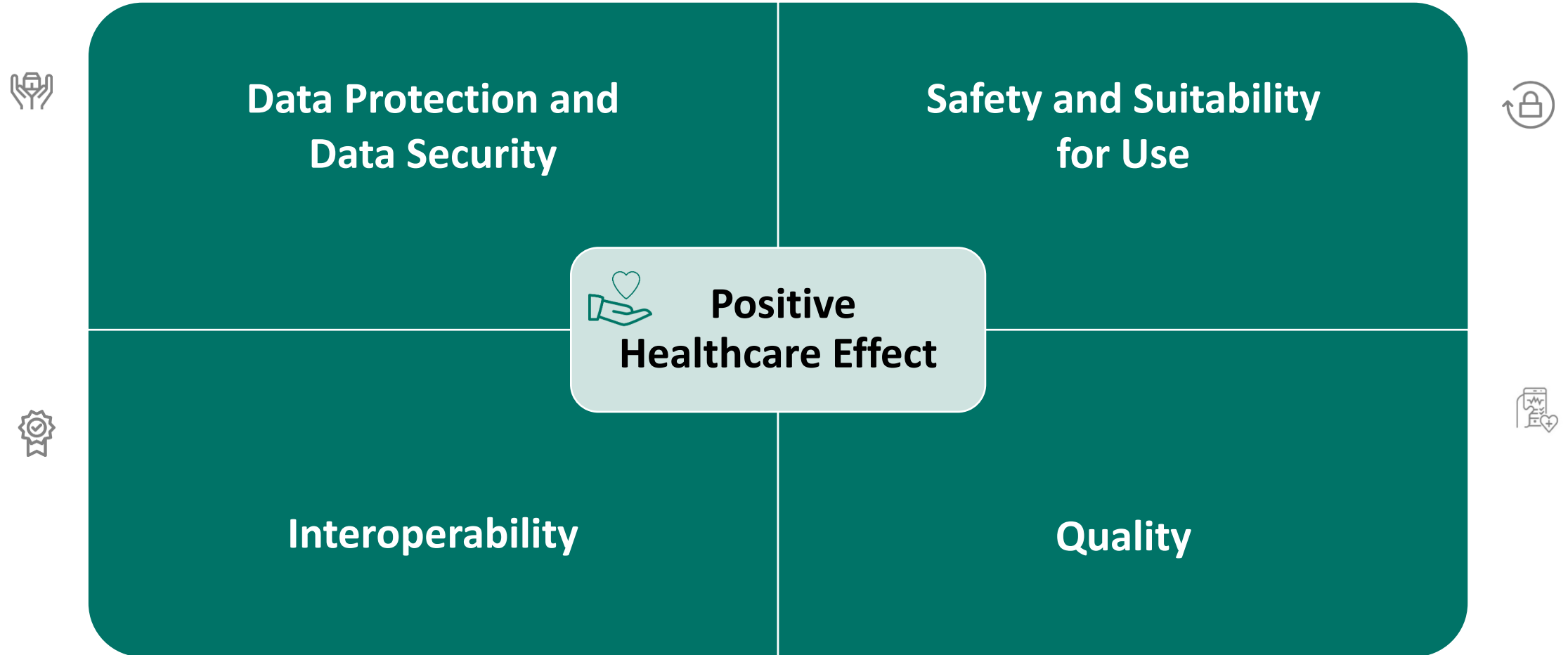


	CE-labeled medical product
	Low risk class (I or IIa)
	Digital main function
	Positive Care Effect
	DiGA is used by patient or jointly by healthcare provider and patient

# What is a DiGA? – and what is not?



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



# 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

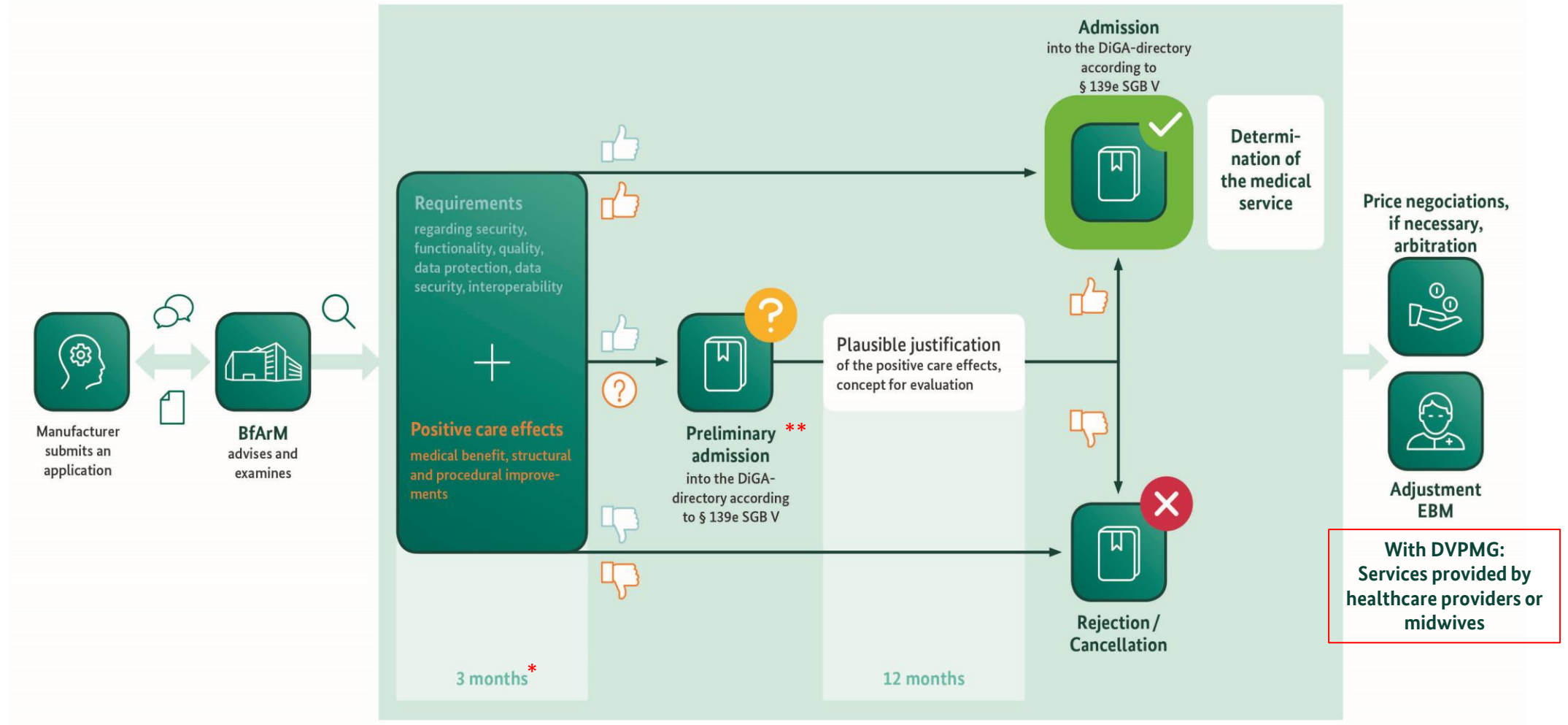
## Provisional listing\*

- 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

# The DiGA-Fast-Track Process



\*In justified individual cases, the deadline can be extended by up to a further 3 months

\*\*Only for risk classes I und IIa

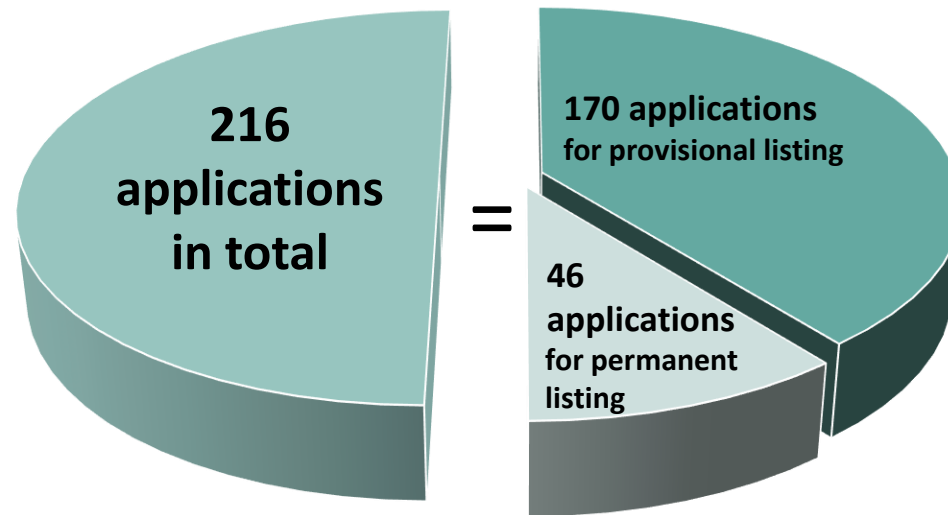


# Statistics



# DiGA applications

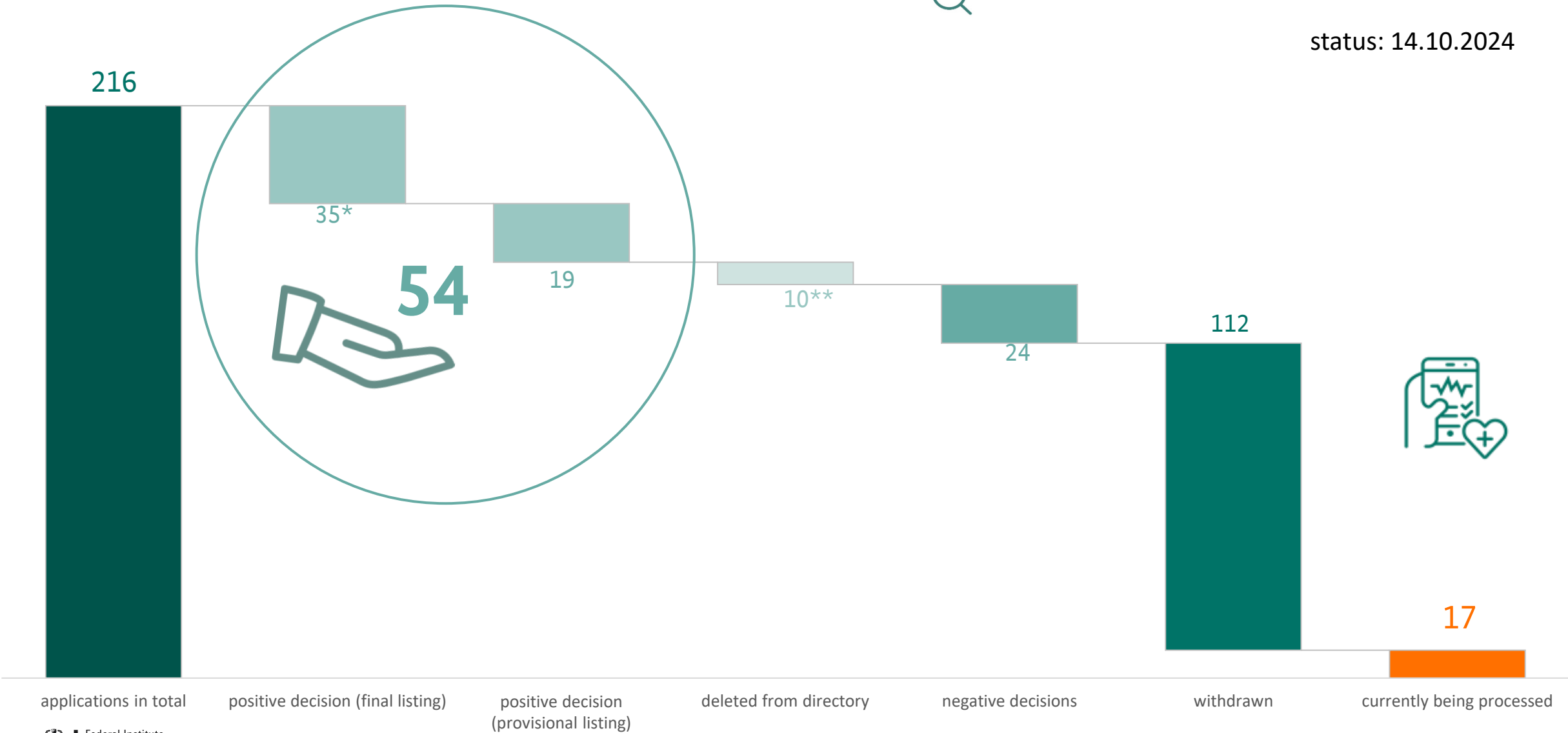
How many applications have been submitted to the BfArM for assessment since the start of the DiGA application portal?



# Results of the assessment up to now

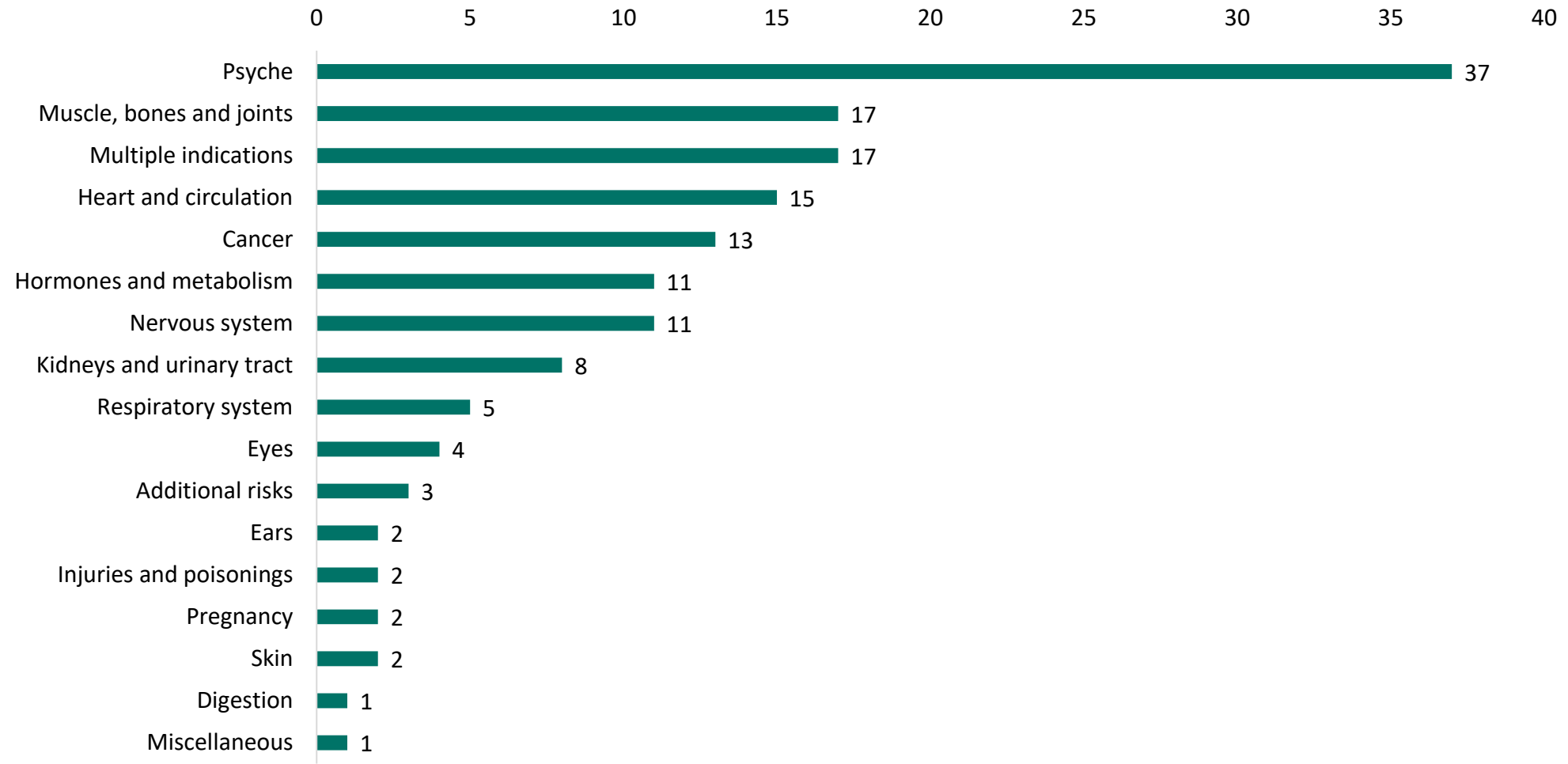


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\* 24 out of the 35 permanently listed DiGA provided proof during the trial phase  
\*\* 3 out of the 10 deleted DiGA were deleted on application of the manufacturer

# Categories of the initially submitted DiGA applications (n = 151)



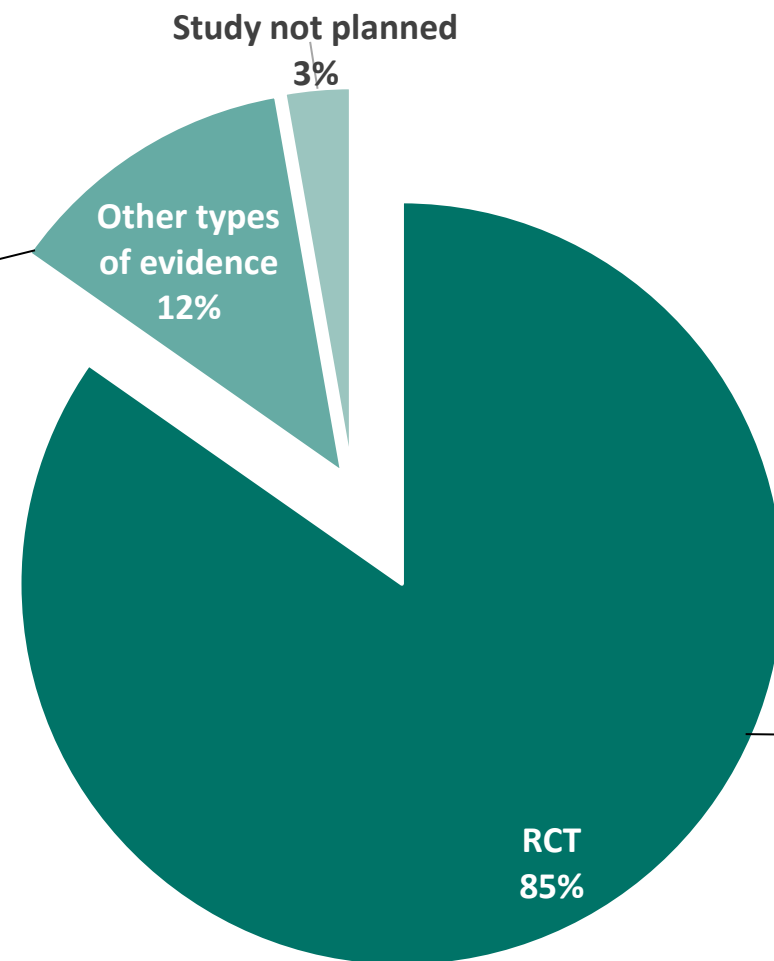
# Overview evidence ("study types")

The type of the evidence of the 216 applications is as follows:

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## 27 Applications with other forms of evidence

- Surveys
- Intraindividual comparisons
- Prospective controlled studies
- Retrospective comparative study
- Register study with propensity score matching



## 183 Applications with Randomized Controlled Trials (RCT)

- One RCT
- Multiple RCT
- Combinations of RCT and additional retrospective study
- Multiple RCT and meta-analysis

# Summary

- **Continuously high interest** of manufacturers but also other stakeholders in DiGA-Fast-Track and growing interest of other countries
- The DiGA-Fast-Track 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



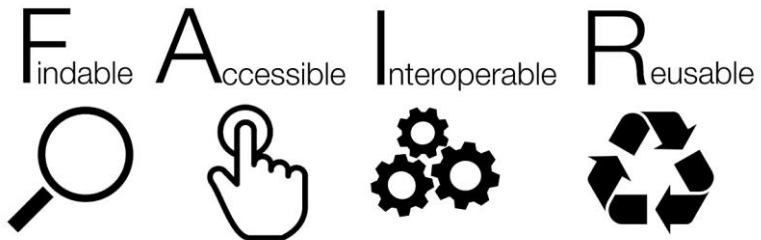


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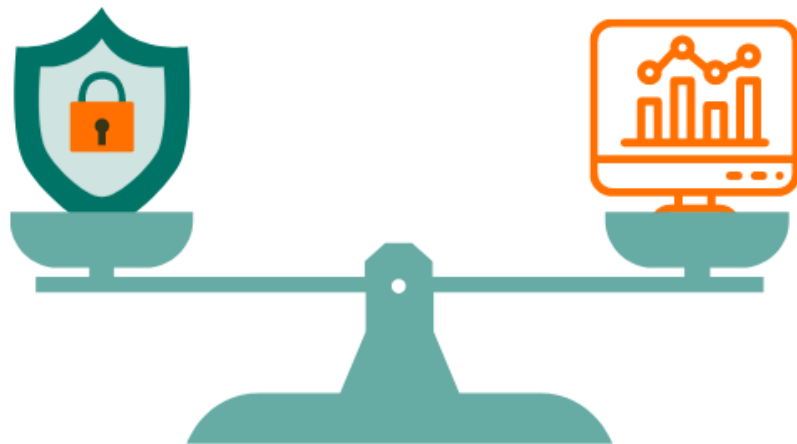
# The Health Data Lab



# Systematic challenge for secondary data research



Wilkinson et al. (2016). "The FAIR Guiding Principles for scientific data management and stewardship". Scientific Data



Data is scattered in silos

Application processes are non-transparent and analogue

Access is sometimes complicated, insecure and hardly reproducible

Data lack of representativeness

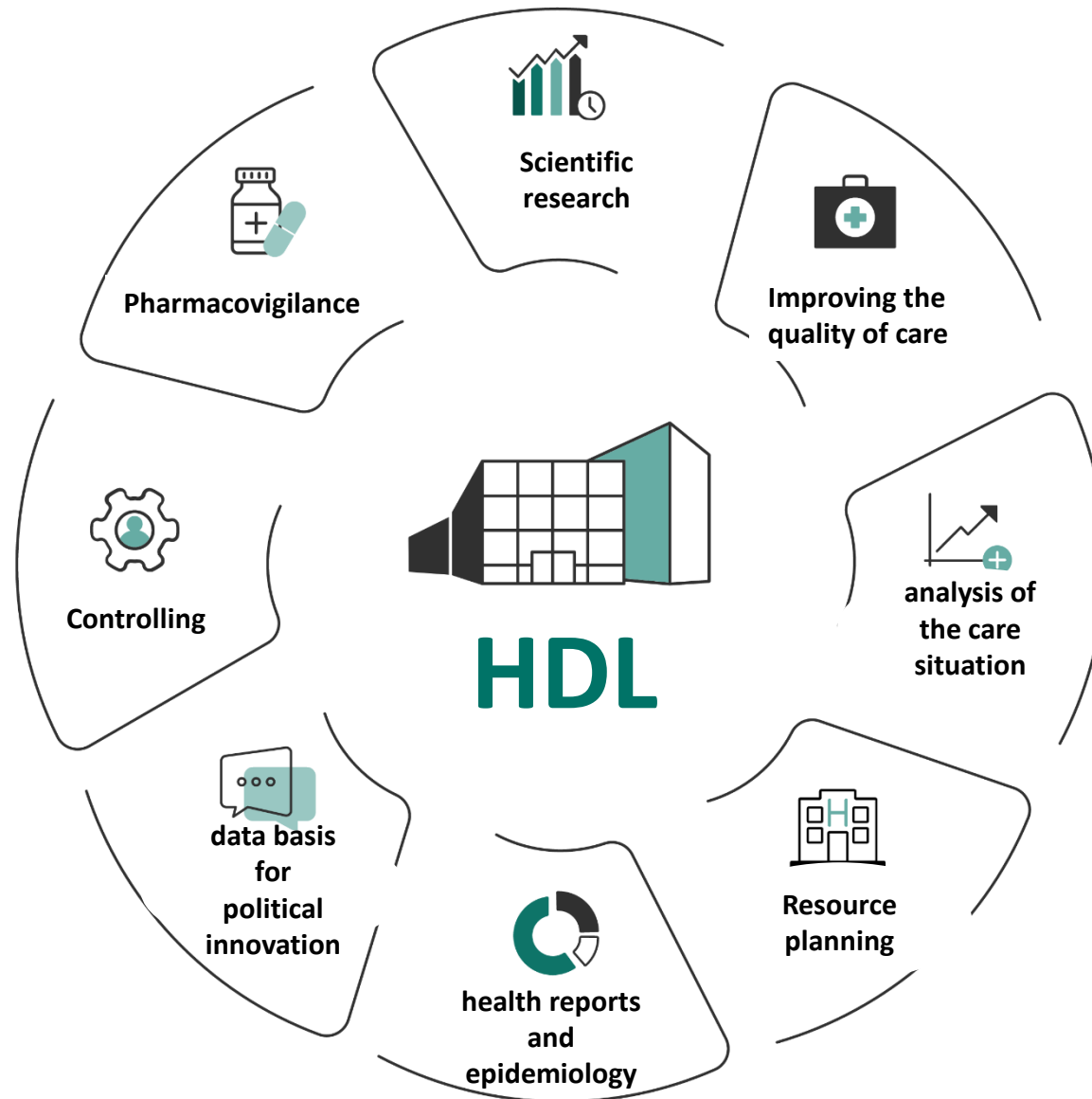
Data and access should be future-proof

# Our goal



**We want to significantly improve the medical care  
of patients in Germany and the EU.**

# The use of health data is regulated by law



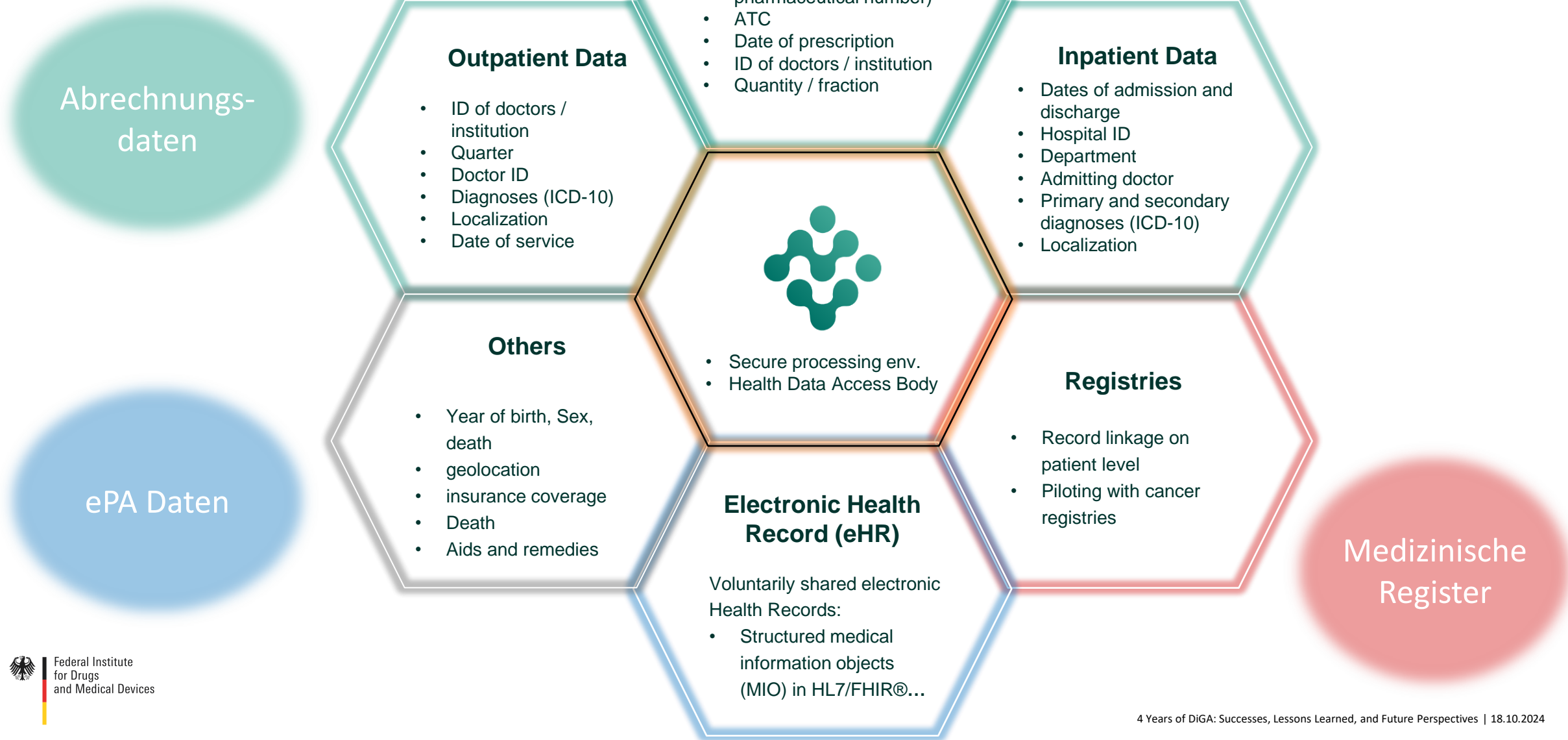
# Primary use of health data



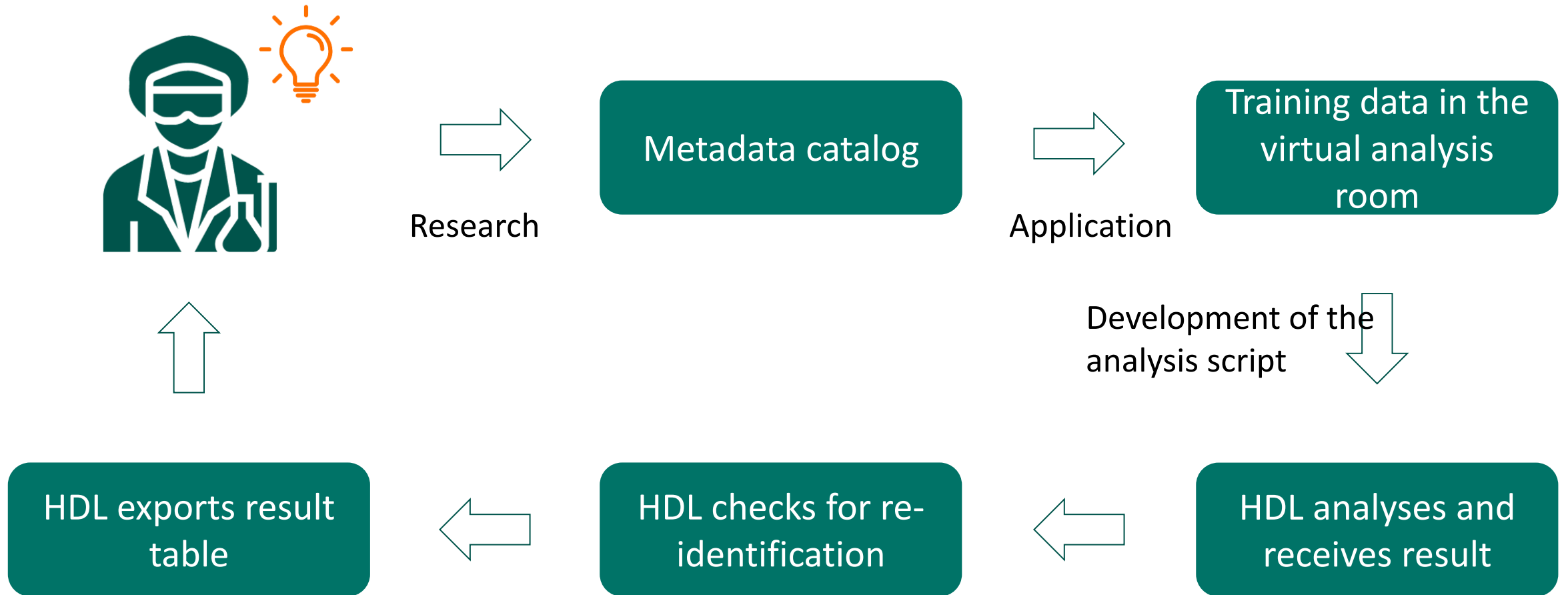
# Making secondary data usable



# Linkage am FDZ



# Research projects with secondary data at the Health Data Lab





# The balance between security and usability

**Organisational security measures**

**Technical security measures**



Only one application needed

Access to data is digital and transparent

# Artificial Intelligence



# AI activities of BfArM today

- Forecasts with AI → trend analyses-Delivery bottlenecks
- Signal detection with AI → Incident reports for medical products; counterfeit drugs, ADR reports
- Causality assessment with AI → UAW reports
- Synthetic data with AI → Representative patient data in the FDZ
- Working with AI-Real4Reg → Development of AI methods-  
Use of large language models for text creation / text  
classificationExplaining AI

# AI activities of BfArM tomorrow

- Promotion of innovation and economic growth
- Development/expansion/reinforcement of expertise on AI and its applications in AM and MP
- Professional advice in committees
- Participation in DE/EU/Int. working groups
- Further development of innovative AI approaches in collaborative, regulatory research projects in the national, European and international environment
- European and international environment
- Data analysis and decision making
- BfArM-wide use of regulatory data
- Data enrichment / synthetic data
- Support for formal reviews
- Utilization of suggestion systems
- Application of trend analyses

# AI activities of BfArM tomorrow

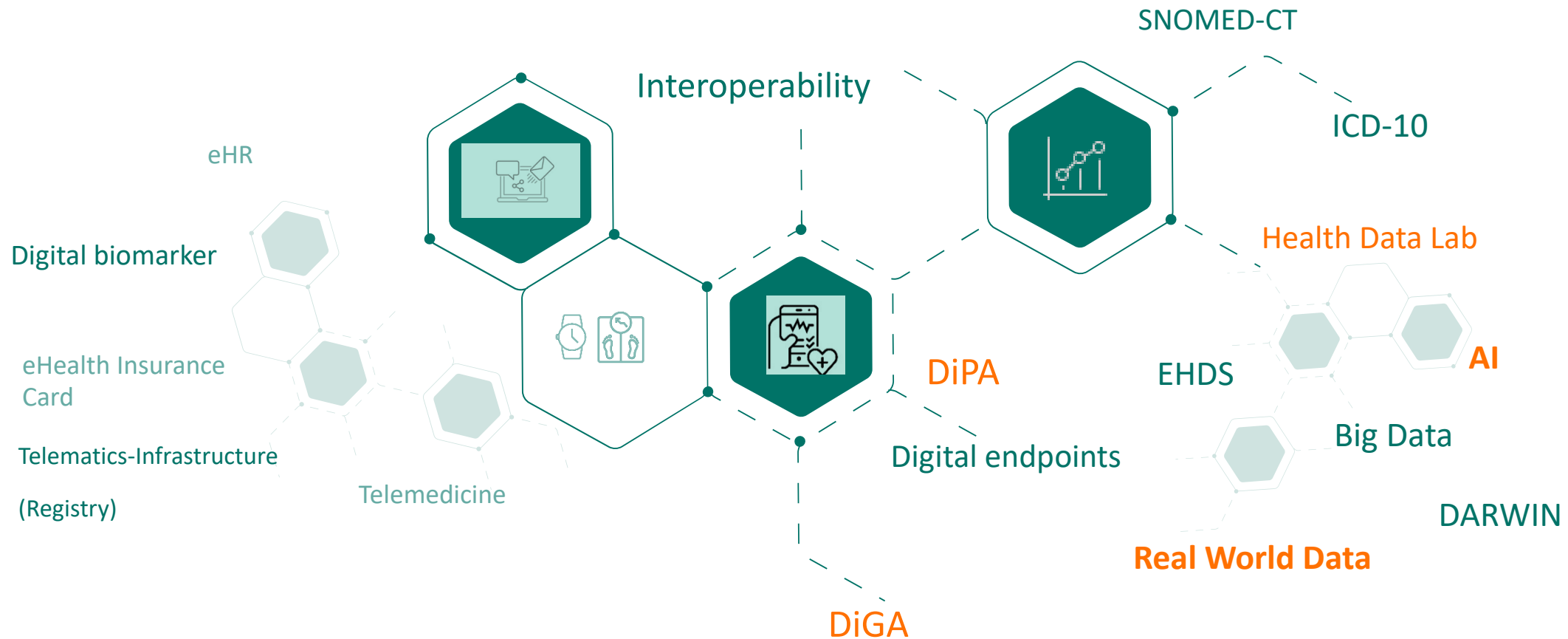
## Optimization of approval procedures:

- Verification of the completeness of documents
- Summary of essential statements
- Reduction of processing times
- Maintaining a consistent quality standard
- Interlinking of development and certification through continuous risk assessment (KIMEDS)

## Improvement of customer service

- Easy and low-threshold options for customers to conduct their own research
- Achieving an appropriate quality standard when using chatbots for customer inquiries at first-level level
- Increase the availability of first-level responses
- Supporting second-level employees in answering customer inquiries

# A growing digital ecosystem – BfArM with central tasks



# Vision 2030: Digital ecosystem





# Thank you very much for your attention!



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