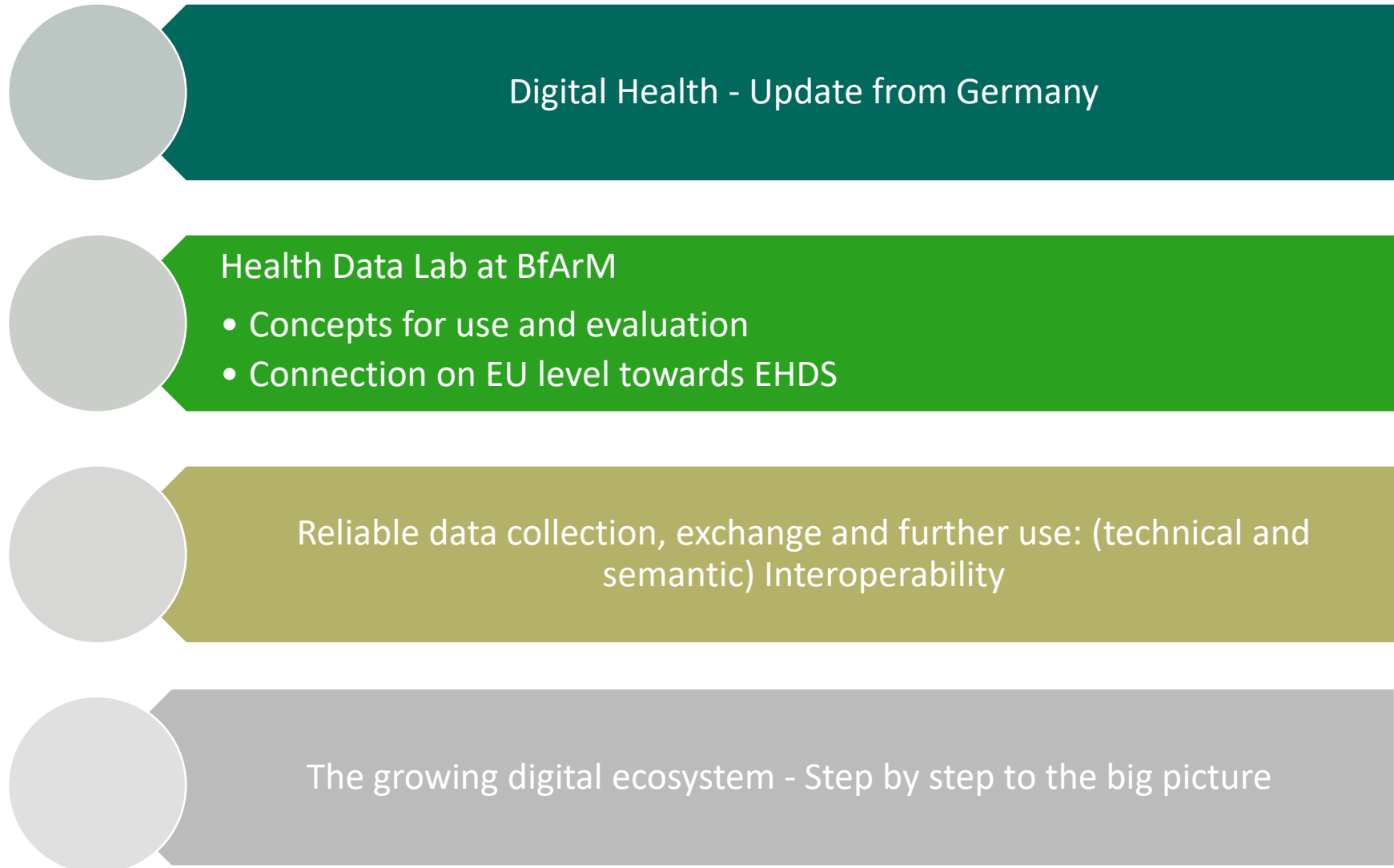


“Health Data Lab at BfArM – Concepts for Use and Evaluation / Interaction with European Activities (EHDS)”

Prof. Dr. Karl Broich, President BfArM |
DGRA Annual Congress May 2023

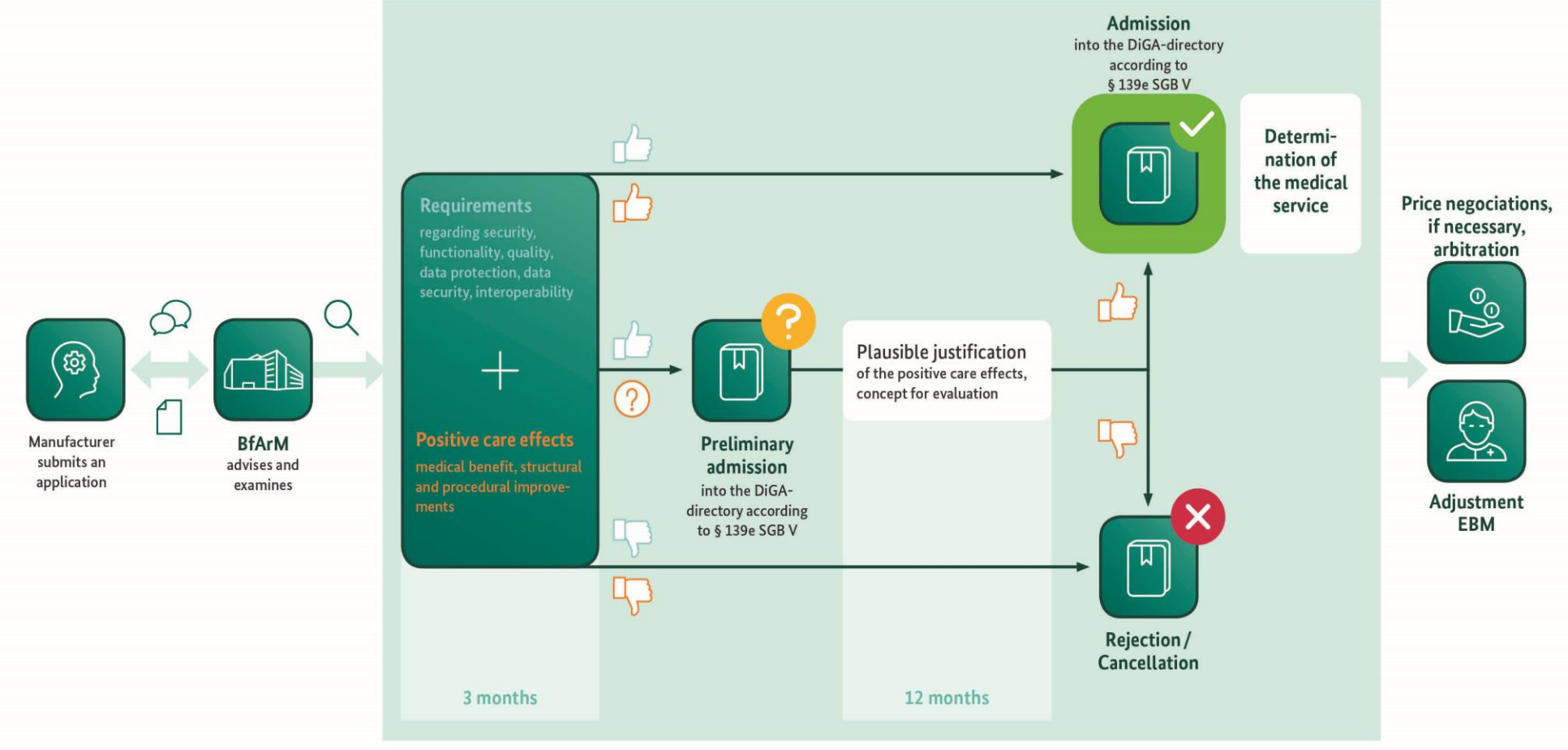


Overview

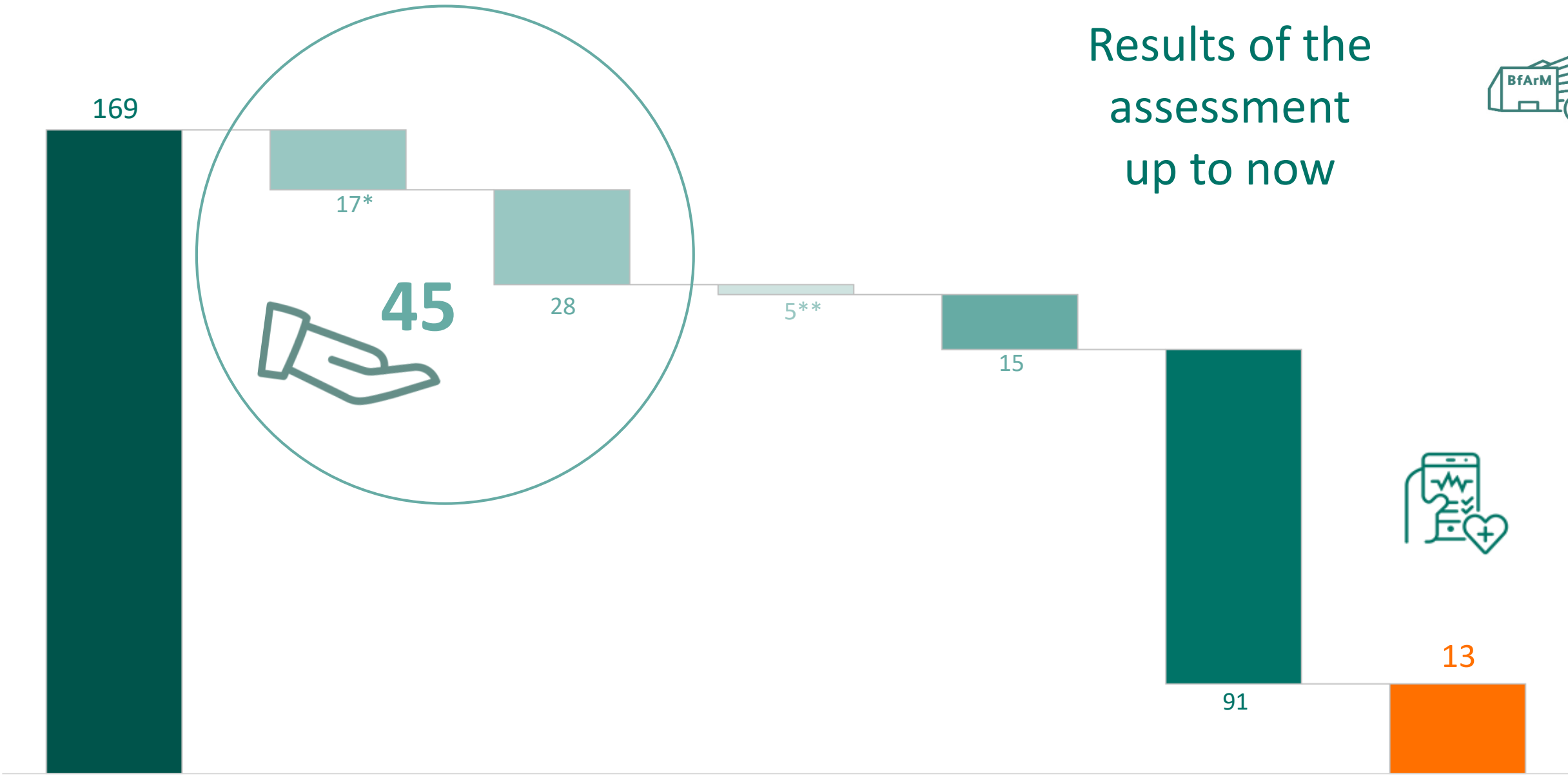




Update - Digital Devices: App on Prescription – the DiGA-Fast Track



Results of the assessment up to now



* 7 out of the 17 finally admitted DiGA provided proof during the trial phase
 ** 2 out of the 5 deleted DiGA were deleted on application of the manufacturer

European/international activities



European Taskforce for Harmonised Evaluation of Digital Medical Devices in the EU

- Taskforce member, Co-Chair Working Packages 2 - linical evidence of DMDs

EU HORIZON - Development and harmonisation of methodologies for assessing DHTs in Europe

- member

Internationaler Austausch zum Thema DiGA mit...

- DK (DKMA), NL, BE (KCE), AUT (AGES), Korea (MFDS), USA (FDA)...
- planned: FR (HAS), FIN (FinCCHTA), UK (NICE)

Together Digital – Next steps for DiGA & DiPA: Extension and combination with other therapy services

Digitization strategy of the Ministry of Health for the healthcare and nursing sectors – planned implementations:

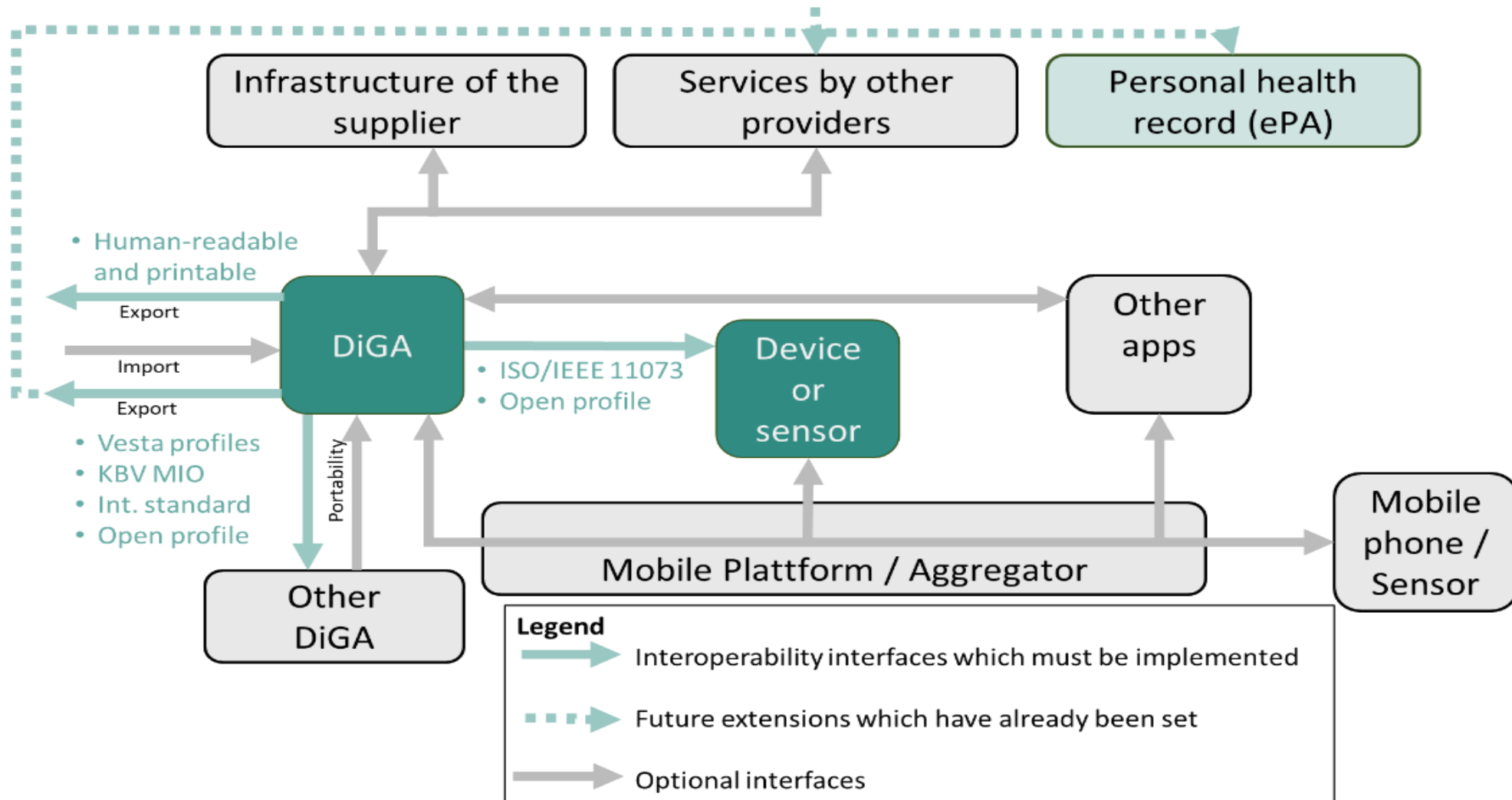
...short-term:

Telemedicine	Mapping of more comprehensive telemedical care concepts involving physicians in DiGA
Risk classes	DiGA extension to medical devices - risk class IIb
Interoperability	Possibility for DiGA and DiPA to read data from the ePA, if necessary and useful

...mid- to long-term:

Care processes	DiGA as an integral component of digitally supported care processes (e.g. in DMP)
Data export to ePA	Automated transfer of data from DiGA use to ePA → possibility of data use for research purposes
Interoperability	Stronger interconnectivity of DiGA, DiPA and other digital applications in the sense of an interoperable, digitally supported health- and care system

DiGA as Part of German e-Health Structure: Interoperability



National Competence Centre for Medical Terminologies / Semantics Centre at the BfArM

SNOMED CT global clinical terminology is introduced in Germany

Licenses issued through Germany's MII



Standardisation & Semantics (inter-)national:

- Publication of official classifications such as
- **ICD-10-GM** (§§ 295 und 301 SGB V)
- Implementation **ICD-11** in Germany
- Maintenance of classifications, medical terminologies, thesauri, nomenclatures and other conceptual systems as a service for the health care system

SNOMED-CT

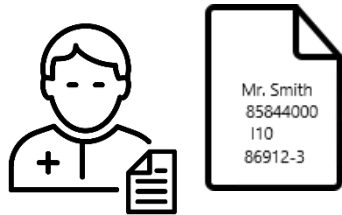
- Routine licence for health care

DVG / DiGA Ordinance:

- Commitment to interoperable design of DiGA taking into account recognised standards (HL7/SNOMED CT, ...)

Interoperability - terminology / technically

Provision of structured data through the use of coding systems



SNOMED CT

ICD-10-GM

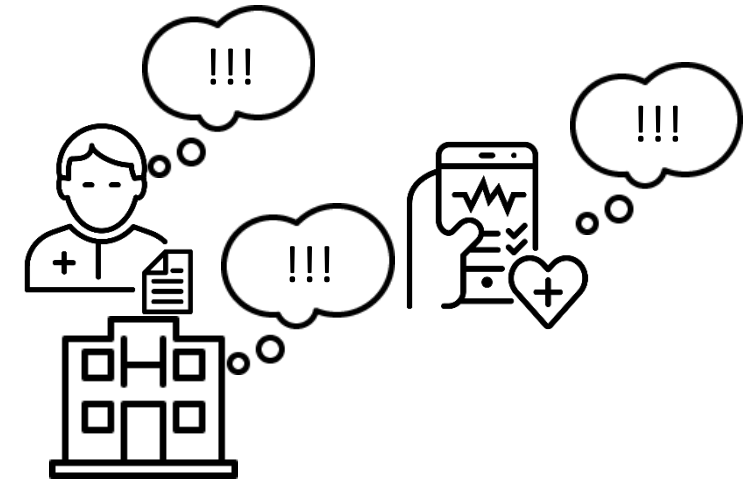
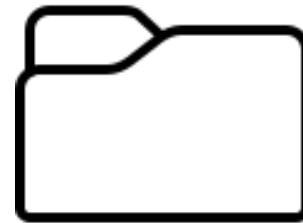
OPS

ICF

LOINC

ATC

...

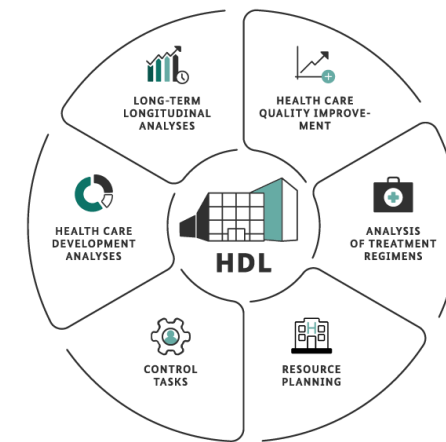


MIO Patient (short) Health record
MIO Vaccine pass
MIO Maternity pass
MIO Children`s U Booklet



Aims of the HDL

Developing the new environment and processes in an agile way in close collaboration with researchers towards the **aims** of the HDL:



Research

- **Iterative** and interactive research processes
- **Transparency and predictability** of the application process
- Direct data processing with **new possibilities for data access**

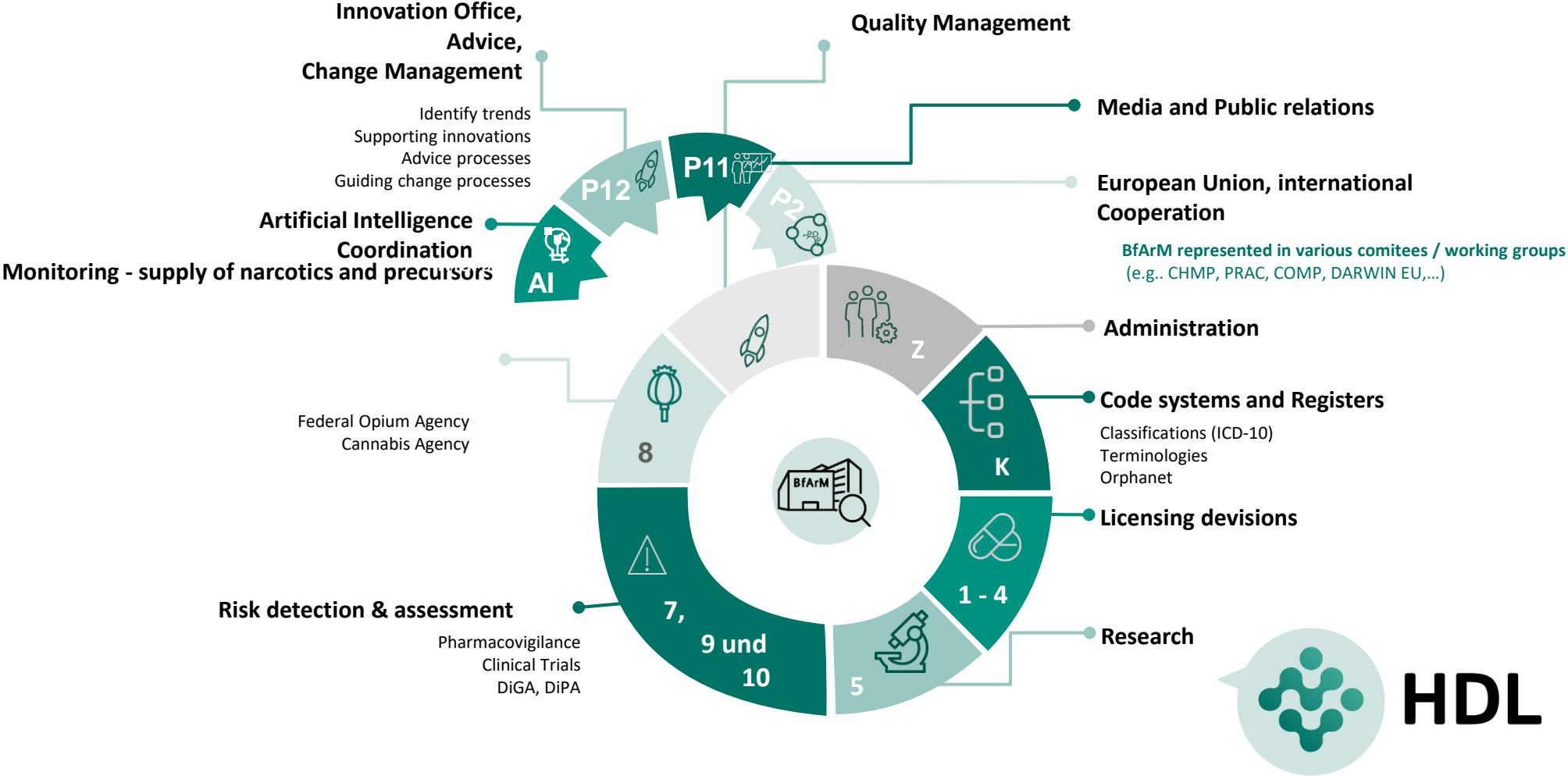
Scalability

- **Efficient processing** of applications even in case of increasing demand
- Continuous **improvement** of data usability

Security

- **Modern IT-security** methods
- **Minimisation of re-identifikation risk**

BfArM - Overview



RWD and RWE at BfArM



The main focus of the Health Data Lab (HDL) is:

- providing claims and EHR data for secondary use
- R & D focuses on optimizing the research process & data driven decision making
- Enabling RWE research



The Research Division

- Conducts research based on several data sources, e.g.:
 - Secondary data (pharmacoepidemiology)
 - Primary data
 - Genetic data (pharmacogenomics)

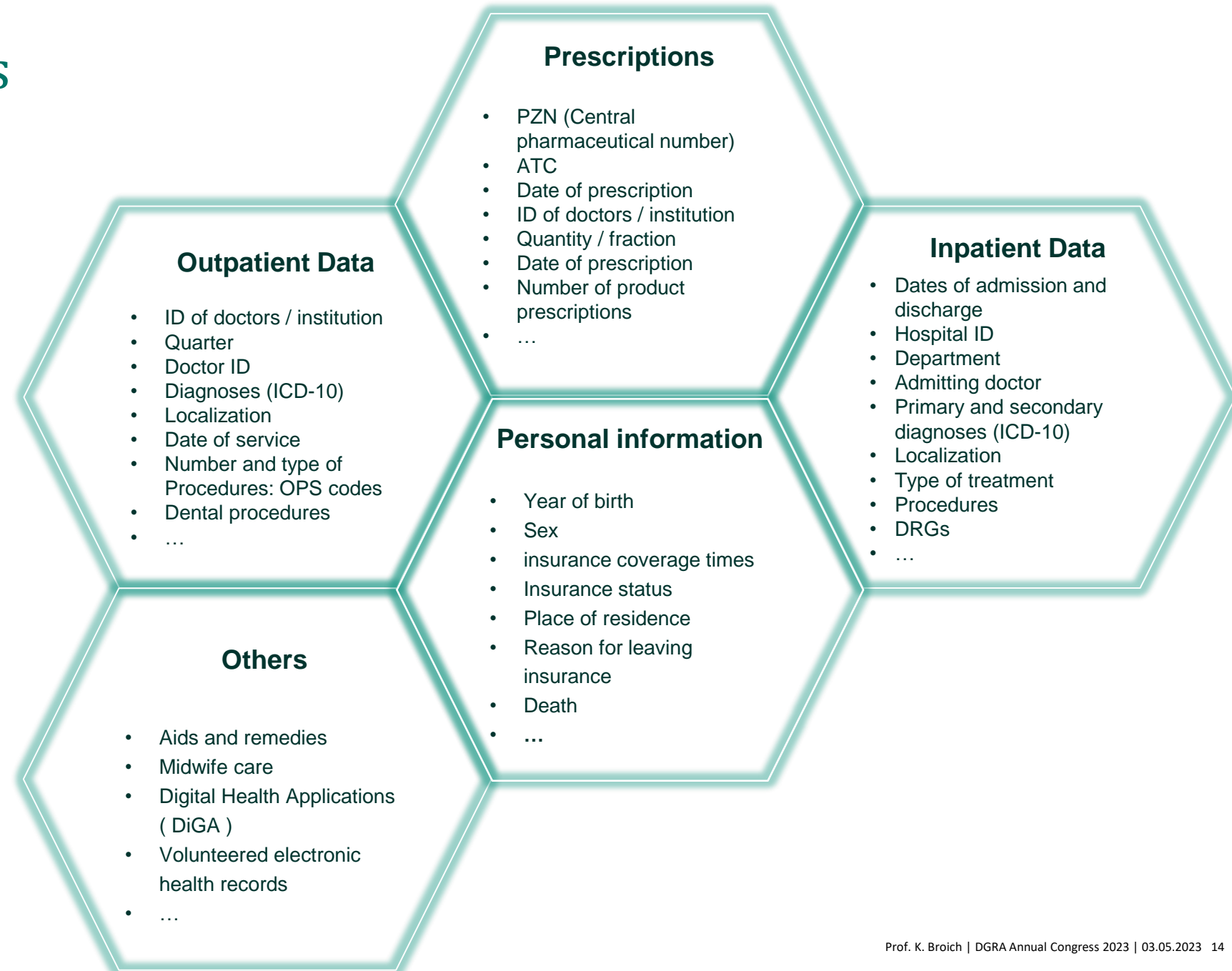


To enable synergies it is paramount that:

- Researchers (e.g. research division) have deep knowledge about the data generating processes
- Data providers have deep knowledge of the requirements of researchers to optimise the research process

Data Characteristics

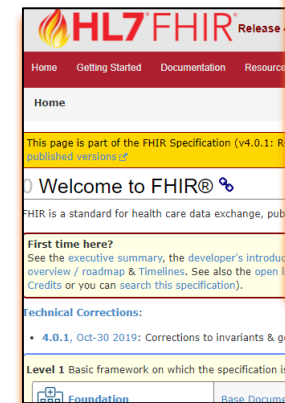
- 73 million people with statutory health insurance in Germany
- Information from all health care sectors linked on the individual level
- Longitudinal data starting from 2009
- Interoperability with established code systems (e.g. ICD10, ATC)



Electronic Health Record (eHR)

Voluntarily shared electronic Health Records:

- 2023: Structured medical information objects (MIO) in HL7/FHIR®
- E.g.:
 - Digital certificate of vaccination
 - Digital maternity record
 - Digital child examination booklet



Immunization	0..*	Immunization
meta	Σ	1..1 Meta
text		0..1 Narrative
extension		0..* Extension
status	Σ ?!	1..1 code Binding Fixed Value
vaccineCode	Σ	1..1 CodeableConcept
patient	Σ	1..1 Reference(KBV_PR_MIO_Vaccination_Patient)
occurrence[x]	Σ	1..1
primarySource	Σ	1..1 boolean Fixed Value
manufacturer	Σ	0..1 Reference(Organization)
lotNumber	Σ	1..1 string
note	Σ	1..2 Annotation
protocolApplied	Σ	1..1 BackboneElement

Typical Data Provisioning Process

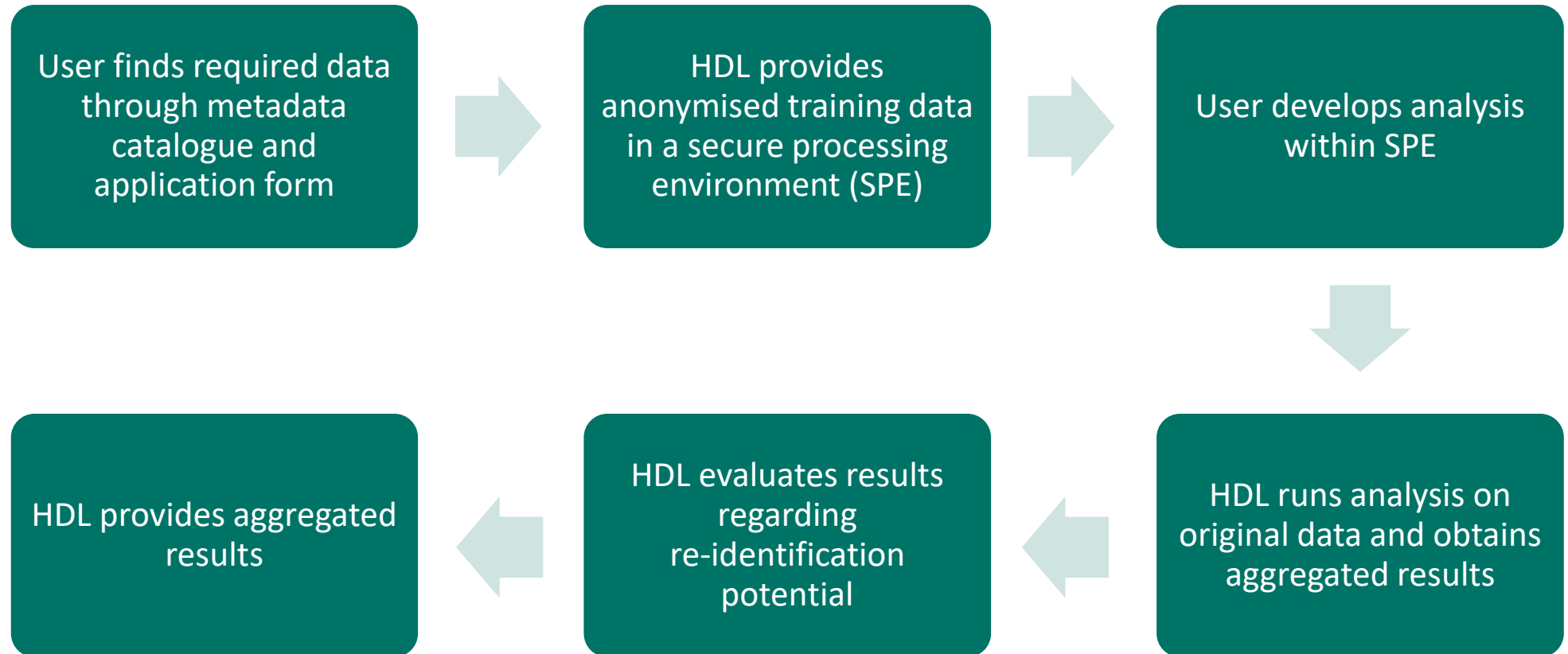
- Process to **find** data is unclear
- Process to **access** data is unclear, especially when several data sources need to be linked
- Usability and safety of **processing** the data is unclear, especially concerning processing environment

User envisions analysis



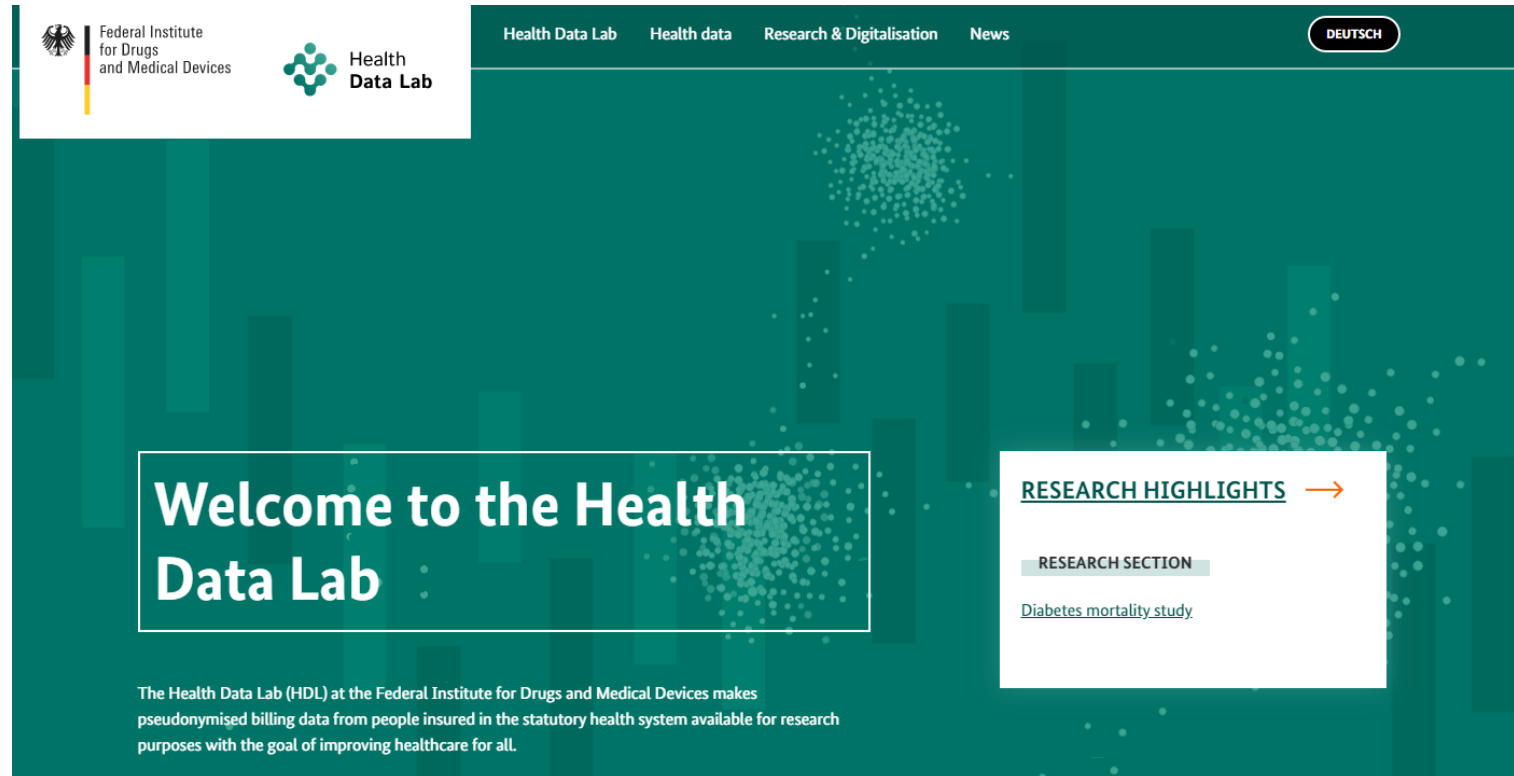
runs analysis on
some original data
somewhere

Data Provisioning Process @HDL



Homepage

<https://www.healthdatalab.de/>



The screenshot shows the homepage of the Health Data Lab. The header includes the logo of the Federal Institute for Drugs and Medical Devices and the Health Data Lab logo. The navigation menu contains links for Health Data Lab, Health data, Research & Digitalisation, and News. A language selector button labeled 'DEUTSCH' is also present. The main content area features a large white box with the text 'Welcome to the Health Data Lab'. Below this, a paragraph describes the lab's mission: 'The Health Data Lab (HDL) at the Federal Institute for Drugs and Medical Devices makes pseudonymised billing data from people insured in the statutory health system available for research purposes with the goal of improving healthcare for all.' To the right, there is a 'RESEARCH HIGHLIGHTS' section with an arrow pointing right, and a 'RESEARCH SECTION' with a link to 'Diabetes mortality study'.

Federal Institute for Drugs and Medical Devices

Health Data Lab

Health Data Lab Health data Research & Digitalisation News DEUTSCH

Welcome to the Health Data Lab

The Health Data Lab (HDL) at the Federal Institute for Drugs and Medical Devices makes pseudonymised billing data from people insured in the statutory health system available for research purposes with the goal of improving healthcare for all.

[RESEARCH HIGHLIGHTS](#) →

RESEARCH SECTION

[Diabetes mortality study](#)

Fully Digital Data Application Process

Bundesinstitut für Arzneimittel und Medizinprodukte

Neuer Antrag DE EN **FDZ**

1 Start

2 Projektbeschreibung

3 Datenbeschreibung

4 Beteiligte Personen

5 Sonstiges

6 Rechtliches

Projektbeschreibung

Bitte vergeben Sie einen Projekttitel und ein Projektkürzel.

Projekttitel Antragsregister

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Verbleibende Zeichen: 0

Projektkürzel

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Verbleibende Zeichen: 0

Zurück **Weiter**

Institution

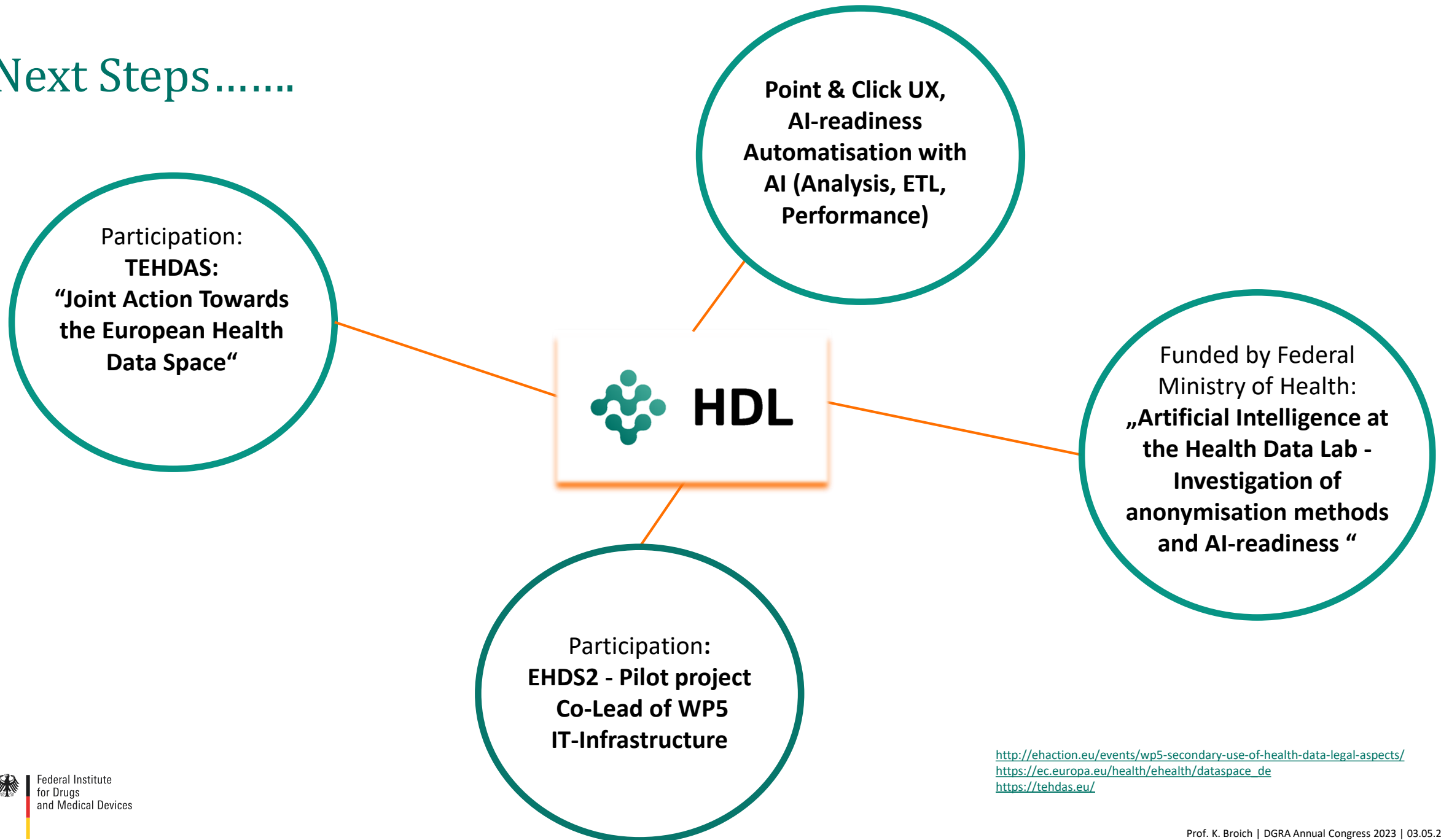
Anträge

Profil

Datenschutz

Abmelden

Next Steps.....



<http://ehaction.eu/events/wp5-secondary-use-of-health-data-legal-aspects/>
https://ec.europa.eu/health/ehealth/dataspace_de
<https://tehdas.eu/>



Synthetic Data and AI-readiness

Gefördert durch:



aufgrund eines Beschlusses
des Deutschen Bundestages



Aims

- Creating synthetic data with AI-methods and comparing them with „classically“ anonymised data
- Evaluation of AI-readiness
- European connectivity



Duration

November 2021 - December 2024



Partners

- InGef – Institute for Applied Health Research Berlin GmbH
- Berlin Institute of Health at Charité (BIH)
- Fraunhofer Institute for Digital Medicine MEVIS

Blog article: https://www.bfarm.de/EN/News/Blog/_docs/2022-03-10-forschungsdatenzentrum.html

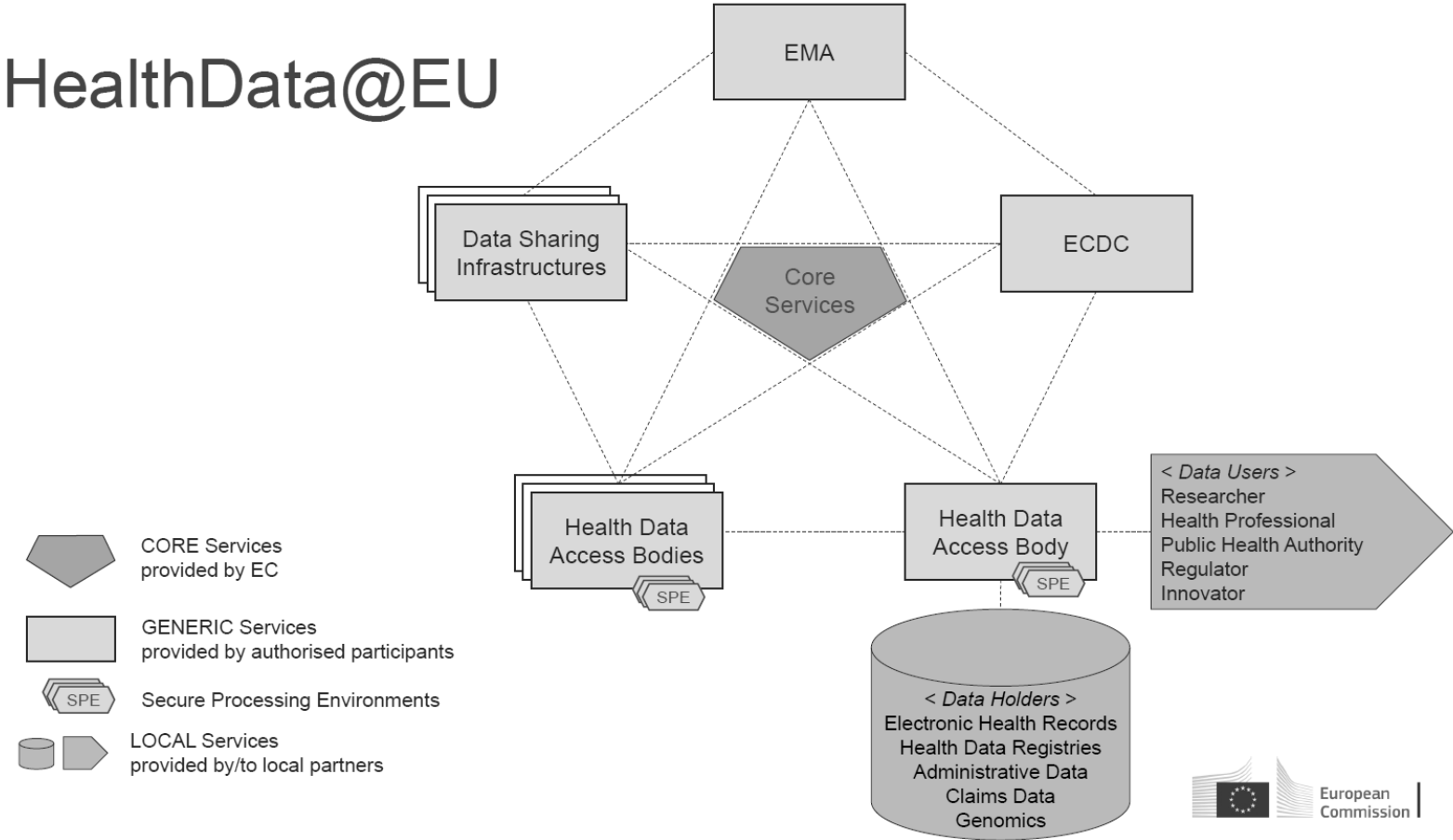
Proposal for a regulation - The European Health Data Space (EHDS)

Primary use	
Patients receive access to and control over electronic health data	Establishment of a cross-border data infrastructure (<i>MyHealth@EU</i>)

Secondary use	
Processors use data for research, innovation, regulatory purposes, policy-making and statistical purposes	Establishment of a European data platform (<i>HealthData@EU</i>), accessible via data access bodies

Publication date: 3 May 2022

Proposal for a Regulation - The European Health Data Space

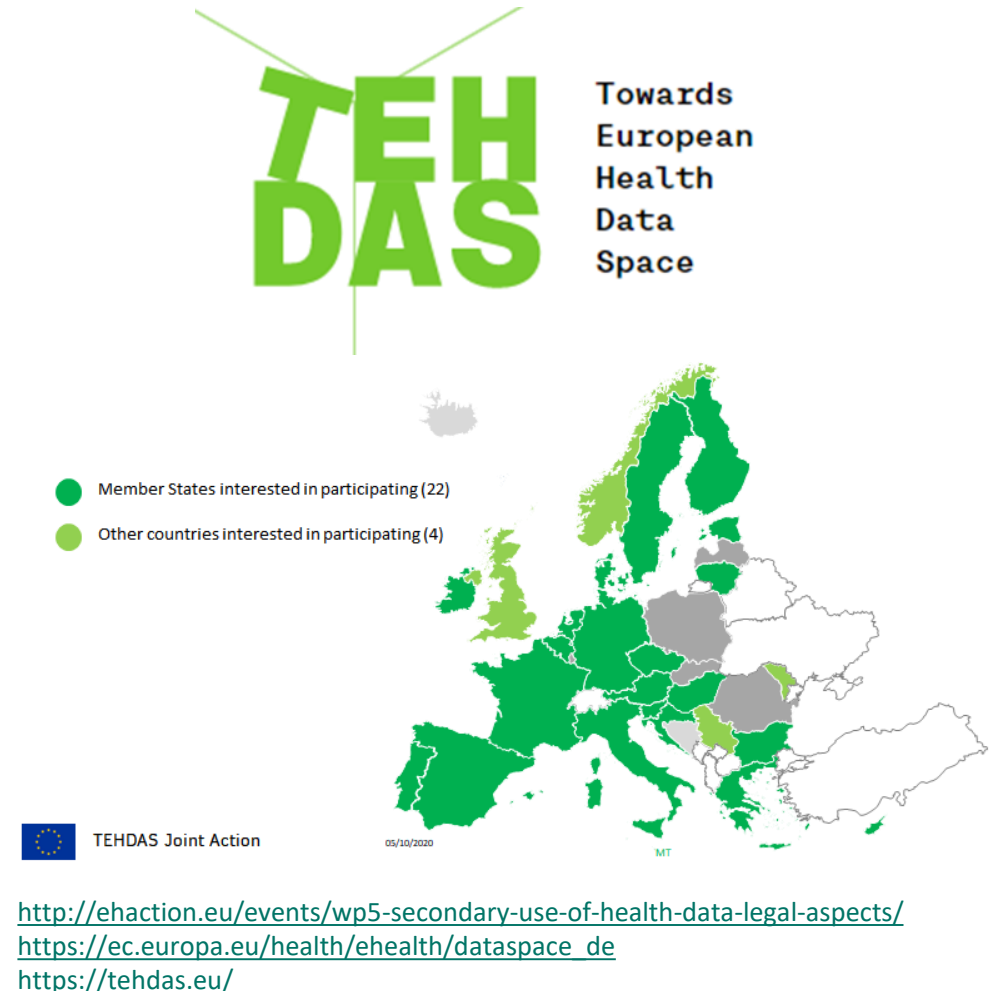


Source: European Commission


EHDS Initiative TEHDAS

Joint Action **T**owards the **E**uropean
Health **D**ata **S**pace with the following pillars:

- Reliable data governance system and principles for cross-border data use
- Data quality
- Secure infrastructure und interoperability
- HDL supports TEHDAS as part of a delegation coordinated by Federal Ministry of Health



Health Data@EU Pilot for a European Health Data Space on Secondary Use of Health Data

- Aim: Setup of a first version of the EHDS and testing of medical use cases
- Co-funded by EU Commission (EU4Health Programme)
- Project start: October 2022
- Planned duration: 24 months
- Coordination: Health Data Hub 
- Participants: 17 partners
(national nodes, ERICs, European agencies and research institutions)



Health Data@EU Pilot for a European Health Data Space on Secondary Use of Health Data



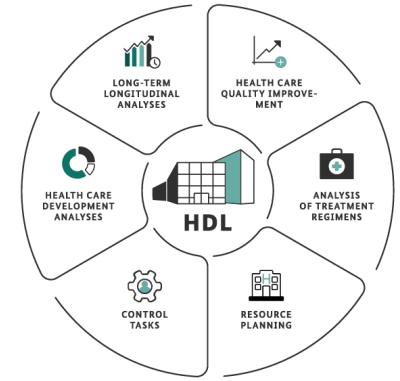
Selected use cases

- ✓ Mobilise and chain clinical and genomic data to enhance our understanding of colorectal cancer (led by ELIXIR)
- ✓ Compare COVID-19 testing, vaccination and hospitalisation between the general population and vulnerable subpopulations (led by Sciensano - Belgium)
- ✓ Demonstrate the feasibility of using the EHDS to carry out infectious disease surveillance, focusing on antimicrobial resistance (led by the European Centre for Disease Prevention and Control)
- ✓ Foster a better understanding of the risks of thrombosis in COVID-19 patients (led by the European Medicines Agency)
- ✓ Compare care pathways for cardiometabolic diseases in European countries and build prediction models, using artificial intelligence (led by the Health Data Hub - France)



Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

Advantages of the HDL



- The HDL enables RWD projects with **timely, representative and homogeneous data**
- Increased **data diversity** by linking data (eHR) and coming sources (inter-)nationally (EHDS)
- Strong **data protection** by organisational design and innovative methods (AI)
- **Research-friendly workflow** with more options for data provision is being continuously optimised with user feedback

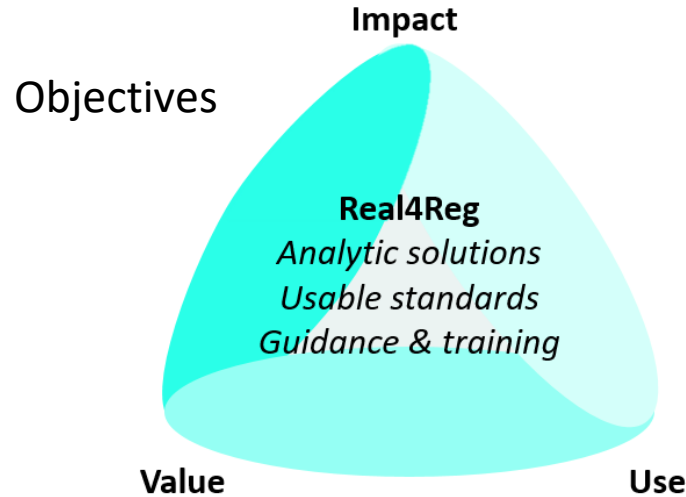
Real4Reg

Horizon Europe Project

Development, Optimisation & Implementation
of AI-Methods for RWD Analyses in Regulatory Decision-Making
& HTA along the Product Life-Cycle

Duration: 2023-2026, ~ 7 Mio €

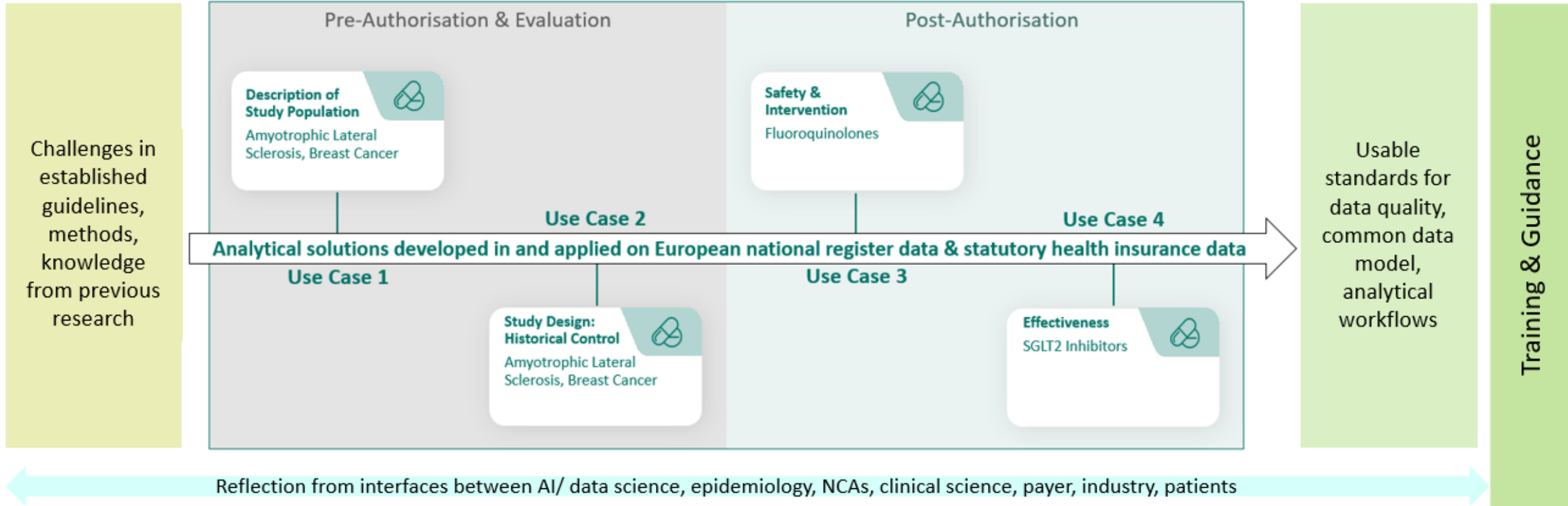
Consortium: 10 Partners, 6 EU countries, **Lead:** BfArM



Needs and Outcomes

- Unlocking potential of AI methods in the regulatory and HTA context
- Usable standards in RWD use
- Guidance and training in RWE use and RWD analyses for health regulatory and HTA bodies across all EU countries
- Acceptance and impact of RWD and synthetic data along the product lifecycle

Overall methodology



Conclusion and Outlook

BfArM#digital & change readiness:
with FDZ, DiGA/DiPA, coding systems, current AI approaches and (EU-)RWE projects for regulatory tasks
at a central location in the dynamically growing digital health ecosystem



Thank you very much for your attention!



Contact

Federal Institute for Drugs and Medical Devices
Prof. Dr. Karl Broich
President
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn

www.bfarm.de

Phone +49 (0)228 99 307-3219



www.bfarm.de

www.bfarm.de/innovation

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www.bfarm.de/digitalfuture

<https://www.forschungsdatenzentrum-gesundheit.de/>

