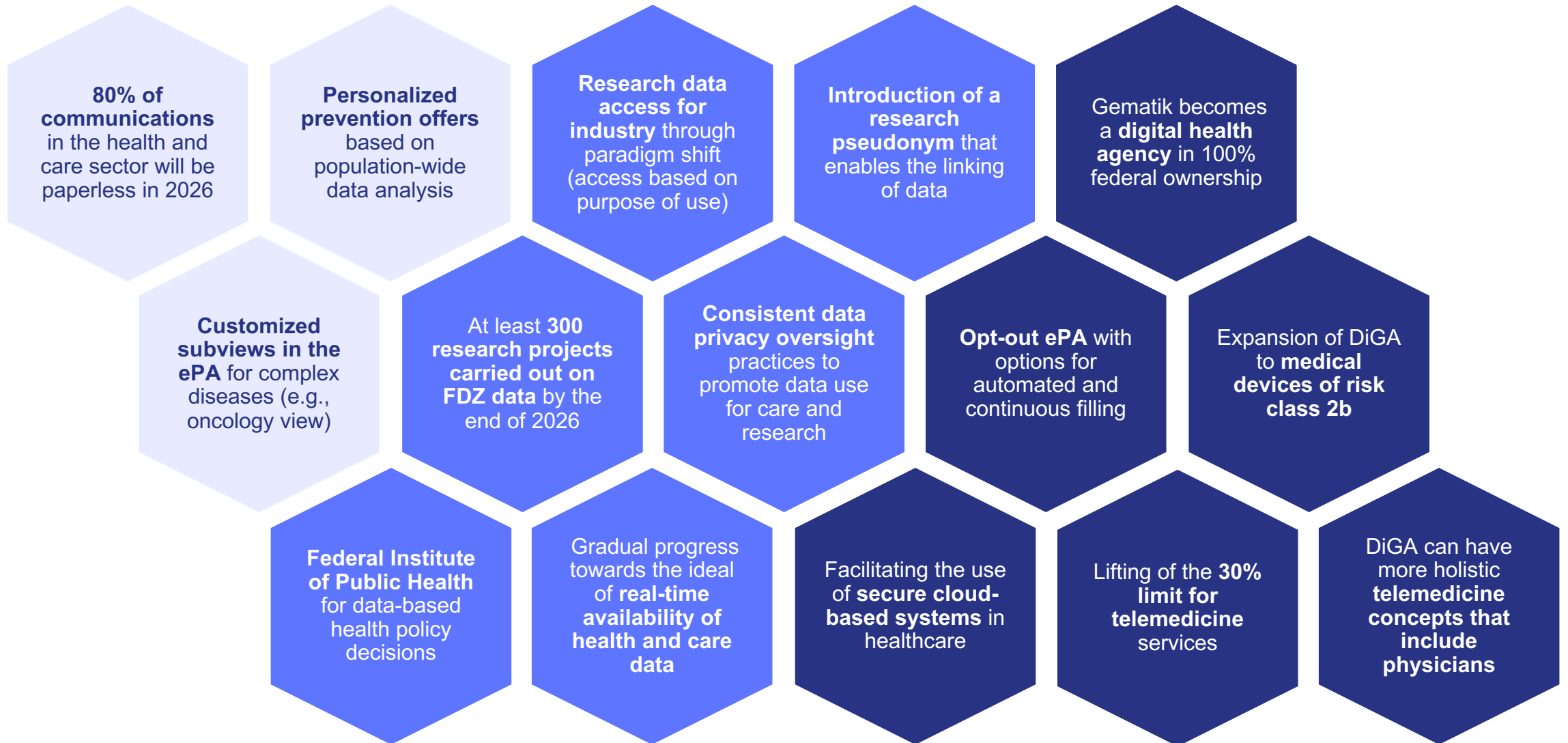# "Sharing data means better healing!" – Germany and the EHDS – The important role of patients

5th Digital Health Society Summit

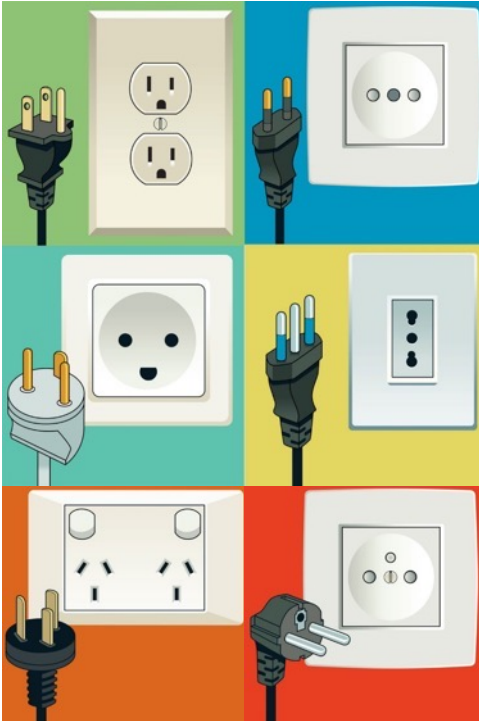**Prof. Dr. med. Dipl.-Ing. Sylvia Thun**

New German digitization strategy

80% of communications in the health and care sector will be paperless in 2026

Personalized prevention offers based on population-wide data analysis

Research data access for industry through paradigm shift (access based on purpose of use)

Introduction of a research pseudonym that enables the linking of data

Gematik becomes a **digital health agency** in 100% federal ownership

Customized subviews in the ePA for complex diseases (e.g., oncology view)

At least **300 research projects carried out on FDZ data** by the end of 2026

Consistent data privacy oversight practices to promote data use for care and research

Opt-out ePA with options for automated and continuous filling

Expansion of DiGA to **medical devices of risk class 2b**

Federal Institute of Public Health for data-based health policy decisions

Gradual progress towards the ideal of **real-time availability of health and care data**

Facilitating the use of **secure cloud-based systems** in healthcare

Lifting of the **30% limit for telemedicine** services

DiGA can have more holistic **telemedicine concepts that include physicians**

Challenges

Source: Wikipedia
Tower of Babel

Semantic

Source: latimes

Syntactic

Lexical ambiguity

The presence of two or more possible meanings within a single word.

"I saw her **duck**"

Syntactic ambiguity

The presence of two or more possible meanings within a single sentence or sequence of words.

"The chicken is **ready to eat**"

Source: ThoughtCo

Current situation: Medical documentation in Germany

International Cooperation

International Patient Summary
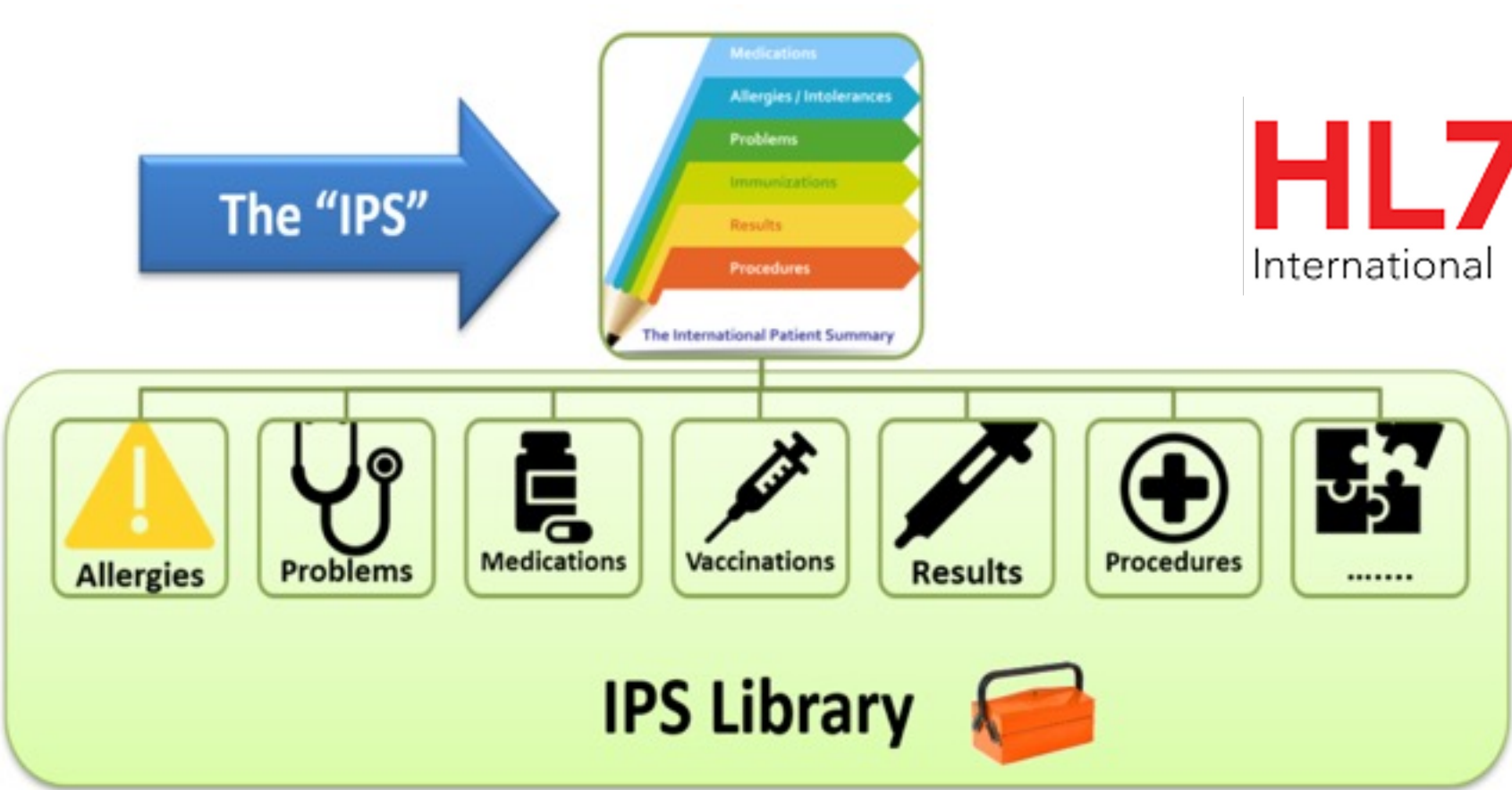
European Health Data Space (EHDS)

OBJECTIVES

✓ Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;

✓ Unleash the data economy by fostering a genuine single market for digital health services and products;

✓ Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.

Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Empower **individuals** to have control over their health data

Enable **health professionals** to have access to relevant health data

Electronic health records

Health data from apps and medical devices

Health data in registries

Assist **policy makers and regulators** in accessing relevant non-identifiable health data

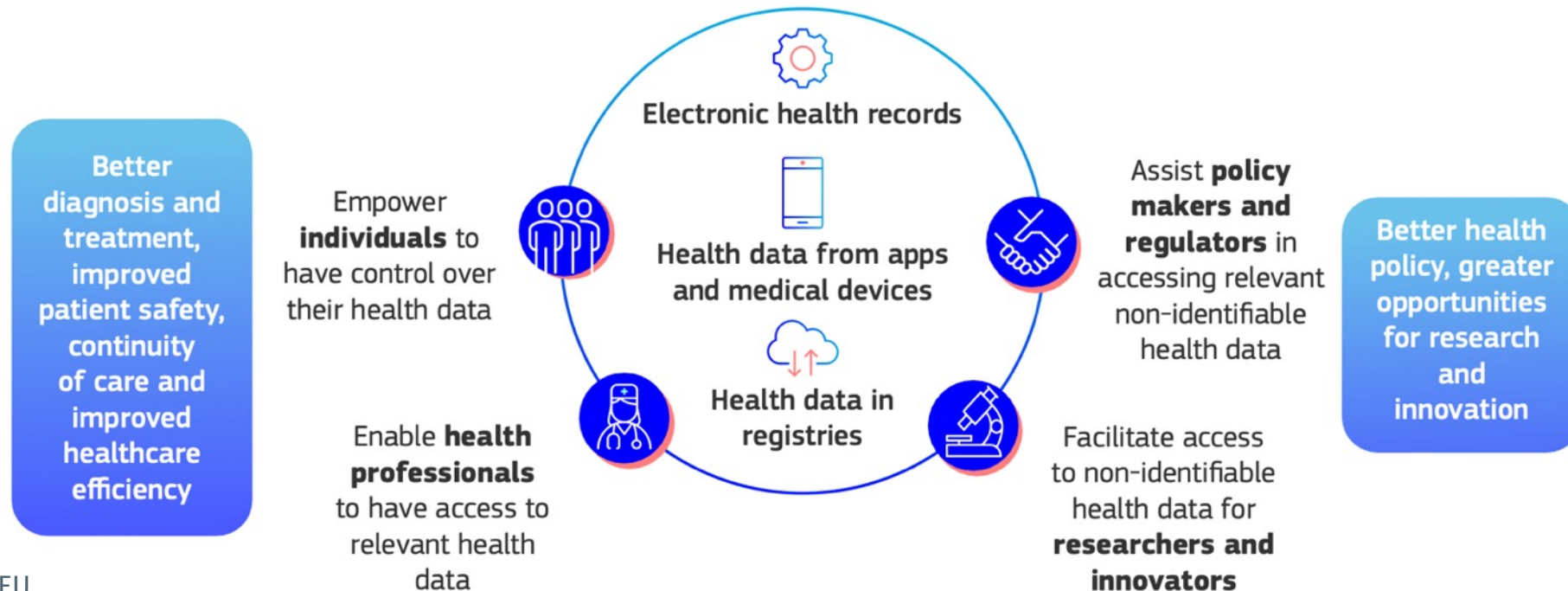Facilitate access to non-identifiable health data for **researchers and innovators**

Better health policy, greater opportunities for research and innovation

BIH Berlin Institute of Health @Charité

FHIR

- **F**ast
- **H**ealthcare
- **I**nteroperability
- **R**esources

- FHIR is a set of XML/JSON health data resources, plus a REST API for accessing them.

Source: HL7

LOINC – Regenstrief Institute

Source: Regenstrief Institute

LOINC CODE
81154-7

LONG COMMON NAME
Dengue and Chikungunya and Zika virus panel by NAA with probe detection

Term Description

This LOINC panel is used to report the qualitative detection and differentiation of Dengue, Chikungunya, a or CSF specimens, as well as for detecting Zika virus in human urine or amniotic fluid specimens. The panel use to, the Centers for Disease Control and Prevention's Trioplex real time reverse transcriptase PCR assa during the acute phase of infection when viral RNA is detectable for a limited period of time following onse five days for Dengue, eight days for Chikungunya and seven days for Zika). Negative results do not rule out Chikungunya and/or Zika virus.

Source: Regenstrief LOINC

Panel Hierarchy

Details for each LOINC in Panel | LHC-Forms

LOINC	Name
81154-7	Dengue and Chikungunya and Zika virus panel by NAA with probe detection
81150-5	Dengue virus 1+2+3+4 5' UTR RNA [Presence] in Serum by NAA with probe detection
81151-3	Dengue virus 1+2+3+4 5' UTR RNA [Presence] in Cerebral spinal fluid by NAA with probe detection
81152-1	Chikungunya virus non-structural protein 1 (nsP1) RNA [Presence] in Serum by NAA with probe detection
81153-9	Chikungunya virus non-structural protein 1 (nsP1) RNA [Presence] in Cerebral spinal fluid by NAA with probe detection
80825-3	Zika virus envelope E gene [Presence] in Serum by NAA with probe detection
80826-1	Zika virus envelope E gene [Presence] in Cerebral spinal fluid by NAA with probe detection
81148-9	Zika virus envelope E gene [Presence] in Urine by NAA with probe detection
81149-7	Zika virus envelope E gene [Presence] in Amniotic fluid by NAA with probe detection

Core Data Set @ International Patient Summary

Source: TMFEV
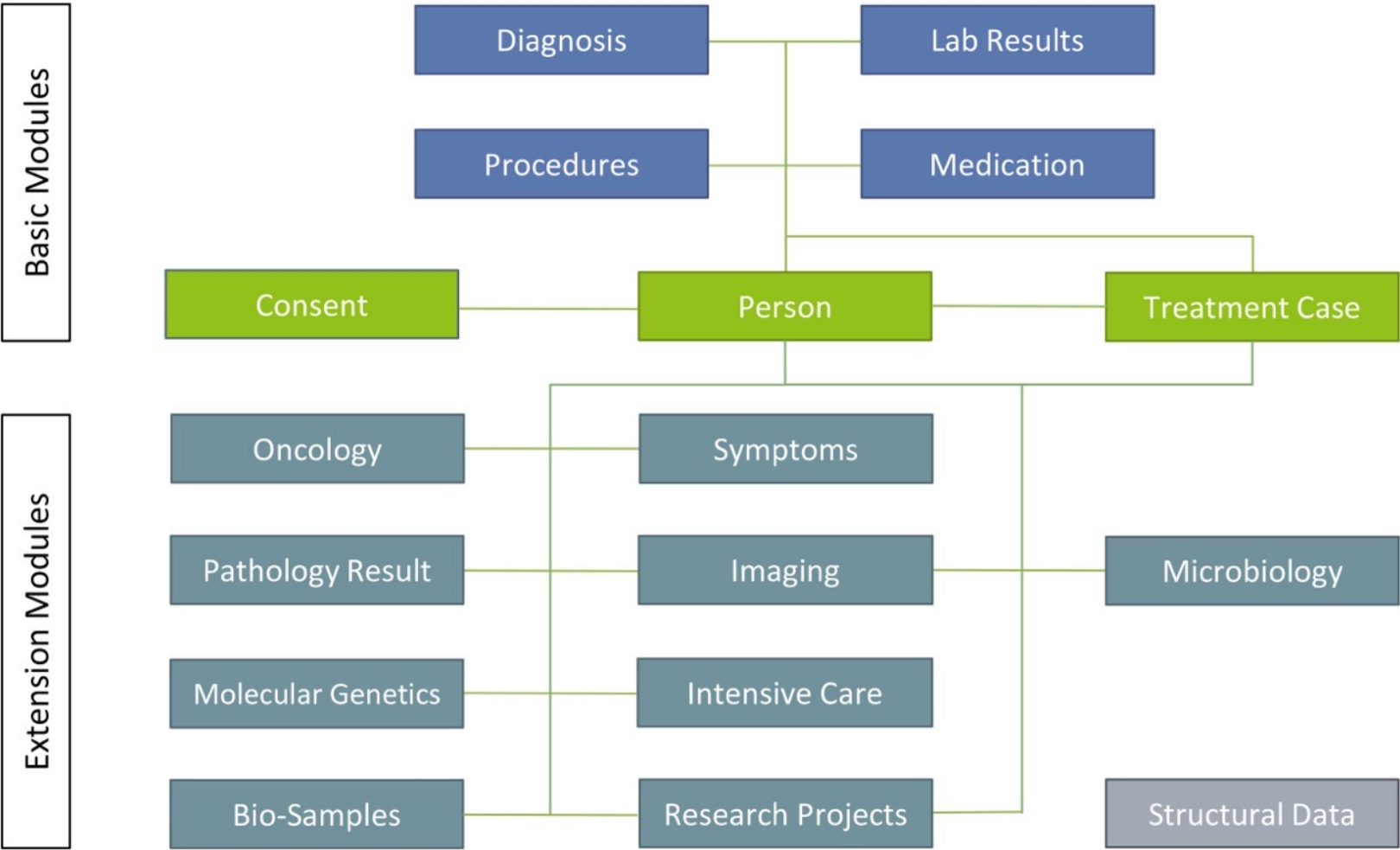
German Portal for Medical Research Data (FDPG)

Datenübersicht

Hier finden Sie eine Übersicht über alle voll automatisch abfragbaren Daten. Stand Mai 2023. Die für Datennutzungsprojekte beantragbare Datenmenge kann größer sein.

> 8 Mio
Personen

Basisdaten eines Krankenhausaufenthaltes von Patientinnen und Patienten

25
angeschlossene Standorte

Datenintegrationzentren, die Daten voll-automatisch abfragbar halten

> 40 Mio
Diagnosen

Hier werden krankheitenbeschreibende und ergänzende Merkmale zu Personen abgebildet

> 300 Mio
Laborwerte

Daten zu Laboruntersuchungen von Patientinnen und Patienten

> 20 Mio
Prozeduren

Datenelemente zur Dokumentation von Operationen und medizinischen Eingriffen

> 50 Mio
Medikamentenverordnungen

Datenelemente zur Dokumentation von Arzneimittelverordnungen und -gaben

> 100 Tausend
Bioproben

Verfügbare Bioproben, die zur Diagnose oder Therapie entnommen wurden

> 100 Tausend
Einwilligungen

Verfügbare positive Einwilligungsinformationen von Patientinnen und Patienten
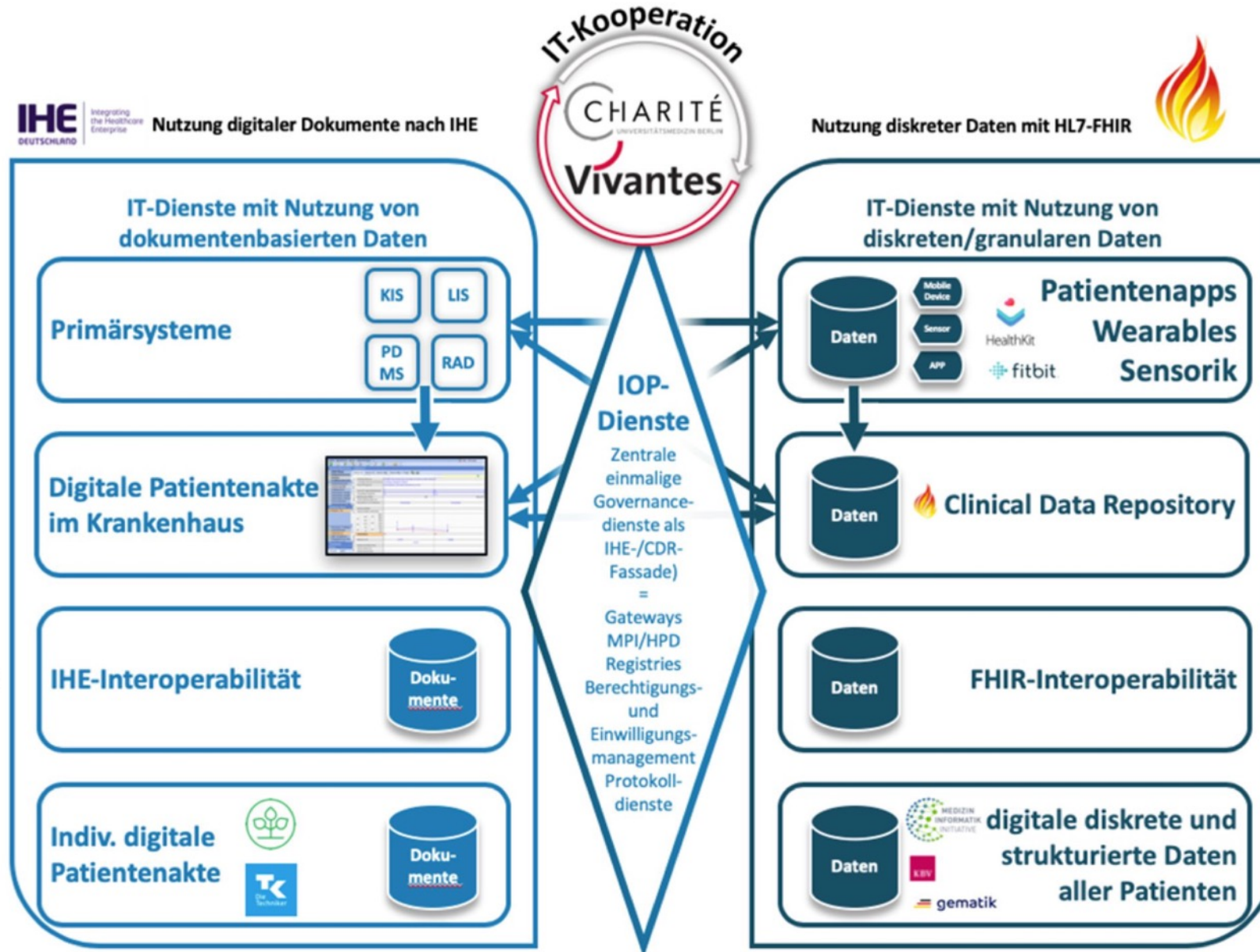
Projects

- WEather-based STroke event and Outcome Risk Modeling (WE-STORM)

- CORD-MI-Study to Mukoviszidose (CF), PIMS, Phenylketonurie, Kawasaki

- NT-proBNP & Atrial Fibrillation

- Registry for Liver Cancer Center Heidelberg (LCCH-Register)

FHIR at Charité & Vivantes

Source: VIVANTES

EHR 2.0 and Medical Information Objects (MIO, ISIK)
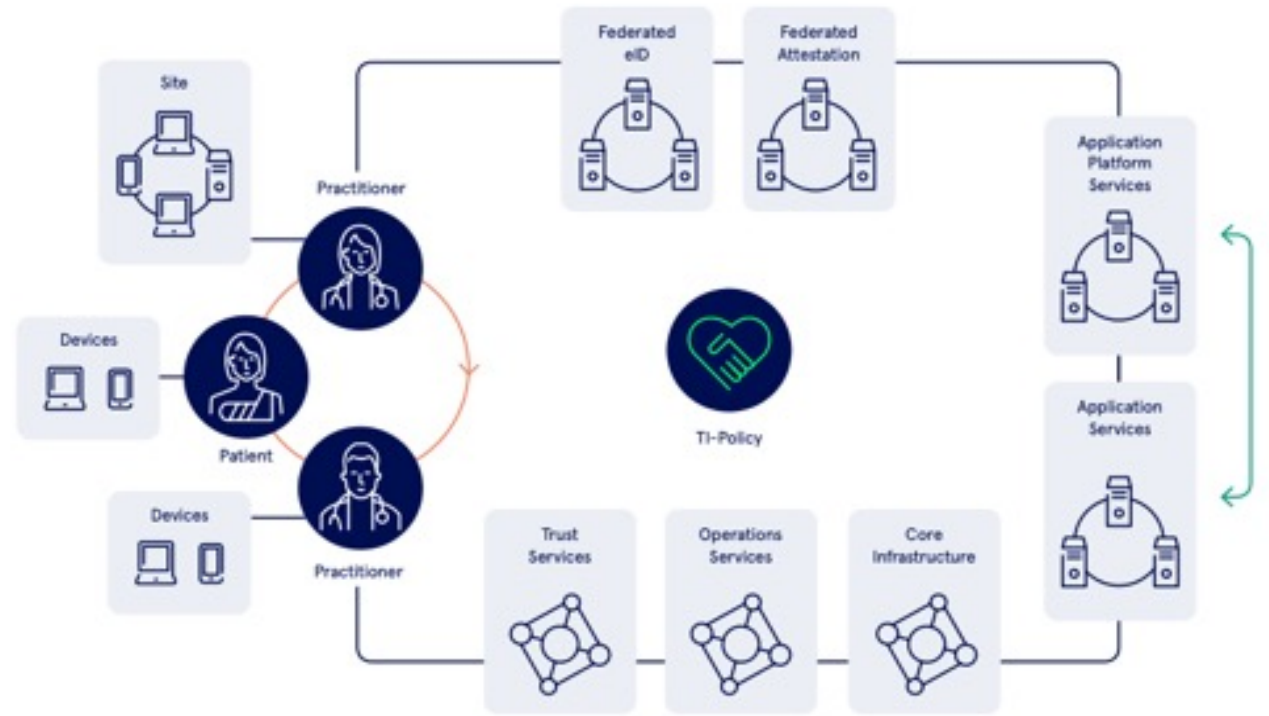
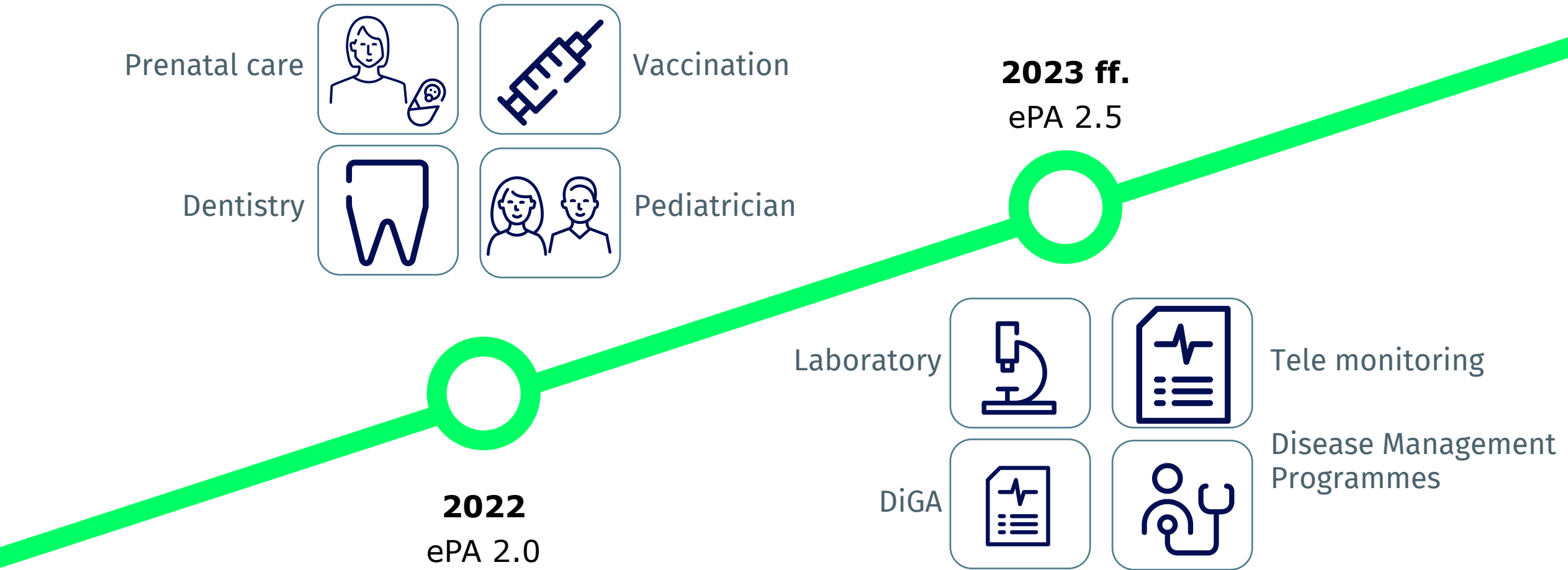Abbildung 3 – Gesamtbild der Architektur der TI 2.0
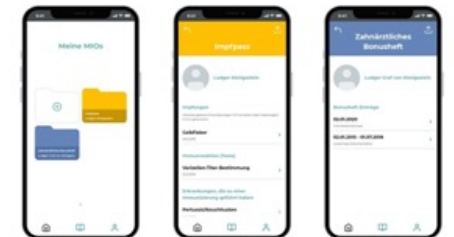
Document standardisation using SNOMED CT and FHIR (MIO)

Prenatal care

Vaccination

Dentistry

Pediatrician

2023 ff.
ePA 2.5

Laboratory

Tele monitoring

DiGA

Disease Management Programmes

2022
ePA 2.0

Digitale Gesundheitsanwendungen (DIGA)

HL7 FHIR

DIGA - TOOLKIT

Best Practice

- **Use FAIR principles:**
  - **F**indable
  - **A**ccessible
  - **I**nteroperable
  - **R**eusable

- **Enhance reusability of data**

- **Extract maximum benefit for patients from digital data sources**

- **Allow automatic processing (e.g. ETL, AI / machine learning)**

This can aid the "democratization" of medicine:

making health technologies& data (globally) accessible, improving healthcare, fostering innovations, supporting patients