PHIRI
Population Health Information Research Infrastructure

The future of European health (data) systems

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Health data

The EU's General Data Protection Regulation (GDPR) defines 'data concerning health' as

"*any personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status*" (Recital 35)

Concepts

- Special category of personal data acc. to GDPR Art 9

- Legal grounds for processing: consent, vital interests, or, in case of existing Union or Member State law: substantial public interest, healthcare, public health, scientific research (opening clauses)

- Personal vs non-personal data

- Anonymisation and pseudonymization

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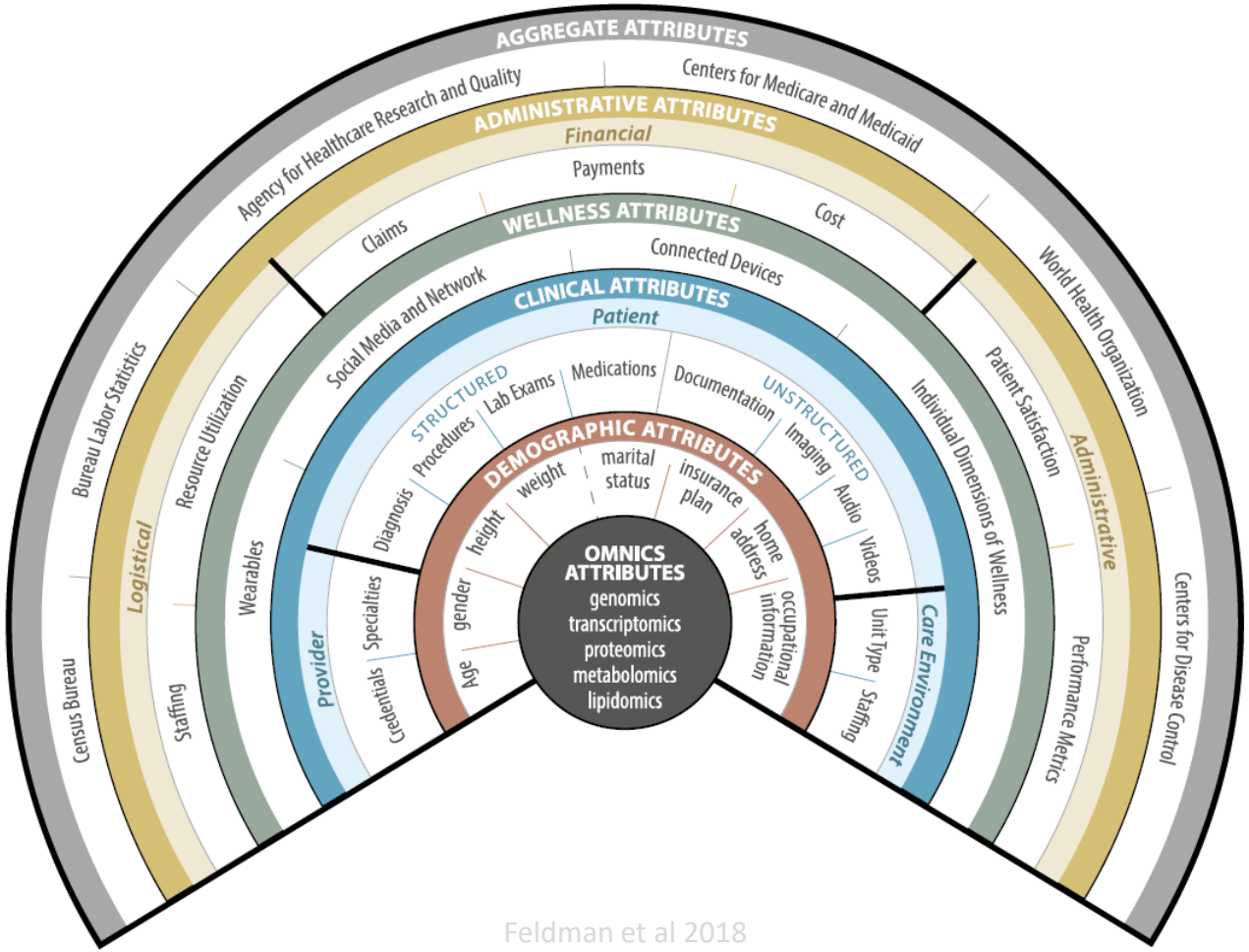
Health data – types



Feldman et al 2018

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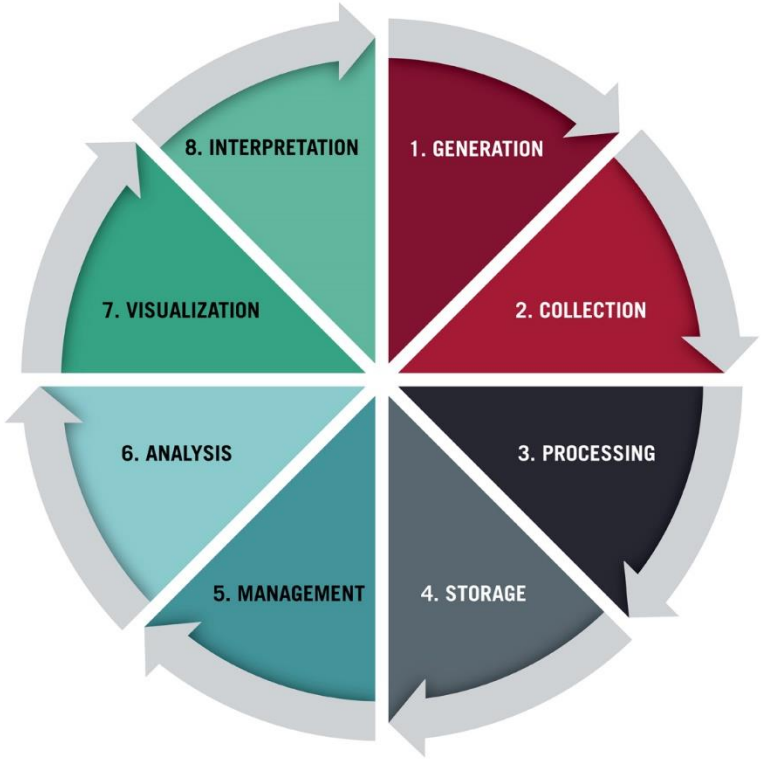
Health data – data life cycle



Stobierski 2021, https://online.hbs.edu/blog/post/data-life-cycle

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Health data - changes

Developments changing the health data landscape

- New data collection points: medical devices (sensors, apps..), internet of (medical) things
- Cheaper and faster availability of data (e.g. omics)
- Digital health and digital care pathways
- Imaging technology
- Artificial intelligence (language models, etc.)
- …

→ more data, more diverse data

→ new opportunities to use data (accessibility, analysis, etc.)

→ **Opportunity not only for healthcare, but also for public health and health policy**: cf. discussions around precision public health, public health data science

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Health data infrastructures

Health data infrastructures:

- Hospital information systems
- Laboratory software systems
- Radiology systems
- Health insurance claims management infrastructure
- Pharmaceutical information systems
- Clinical trials data infrastructures
- Public health registries and other registry data
- Private sector-held data (health apps)
- Etc.

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Health data infrastructures

Challenges:

- Data availability (legal grounds for processing, etc)
- Data accessibility (interfaces, access rules)
- Data quality (missing data, bias, etc)
- Data linkage (legal grounds, institutional interests)
- Timeliness and responsiveness

→ Interoperability along the care pathway, between healthcare sectors (inpatient-outpatient) and between healthcare and public health/health policy?

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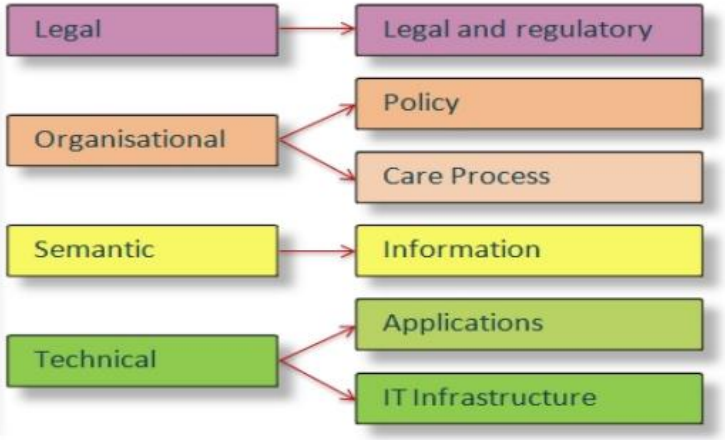
Health data - interoperability

European Interoperability Framework

Legal interoperability	e.g.: types of health data collected and processed in healthcare
Organisational interoperability	e.g. organization of care processes
Semantic interoperability	e.g. standards and terminologies (Snomed, ICD-10, etc.)
Technical interoperability	e.g. communication standards and IT infrastructure

Refined eHealth European Interoperability Framework (eHealth Network 2015):



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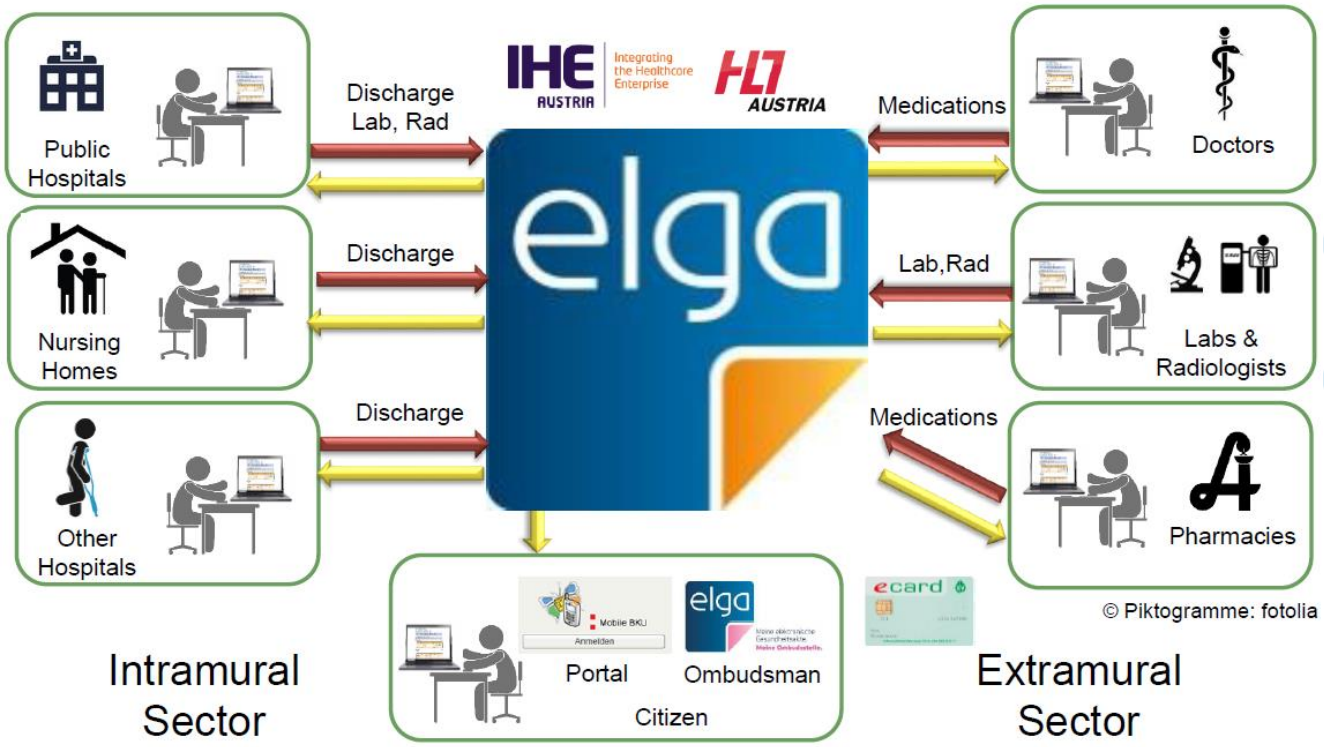
Case study: Austria

The Austrian health data infrastructure – two examples:

- National electronic health records through ELGA



Source: ELGA GmbH

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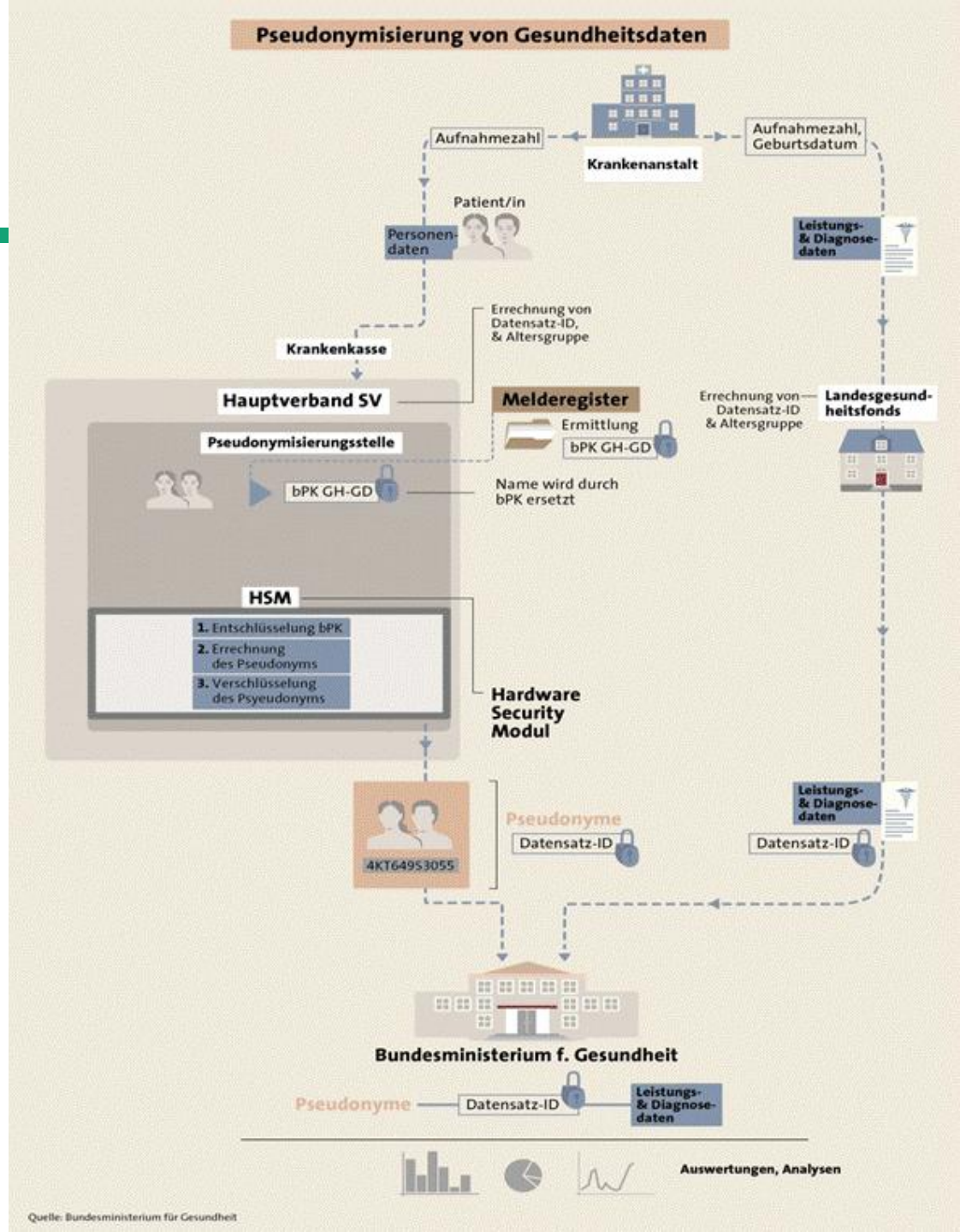
Case study: Austria

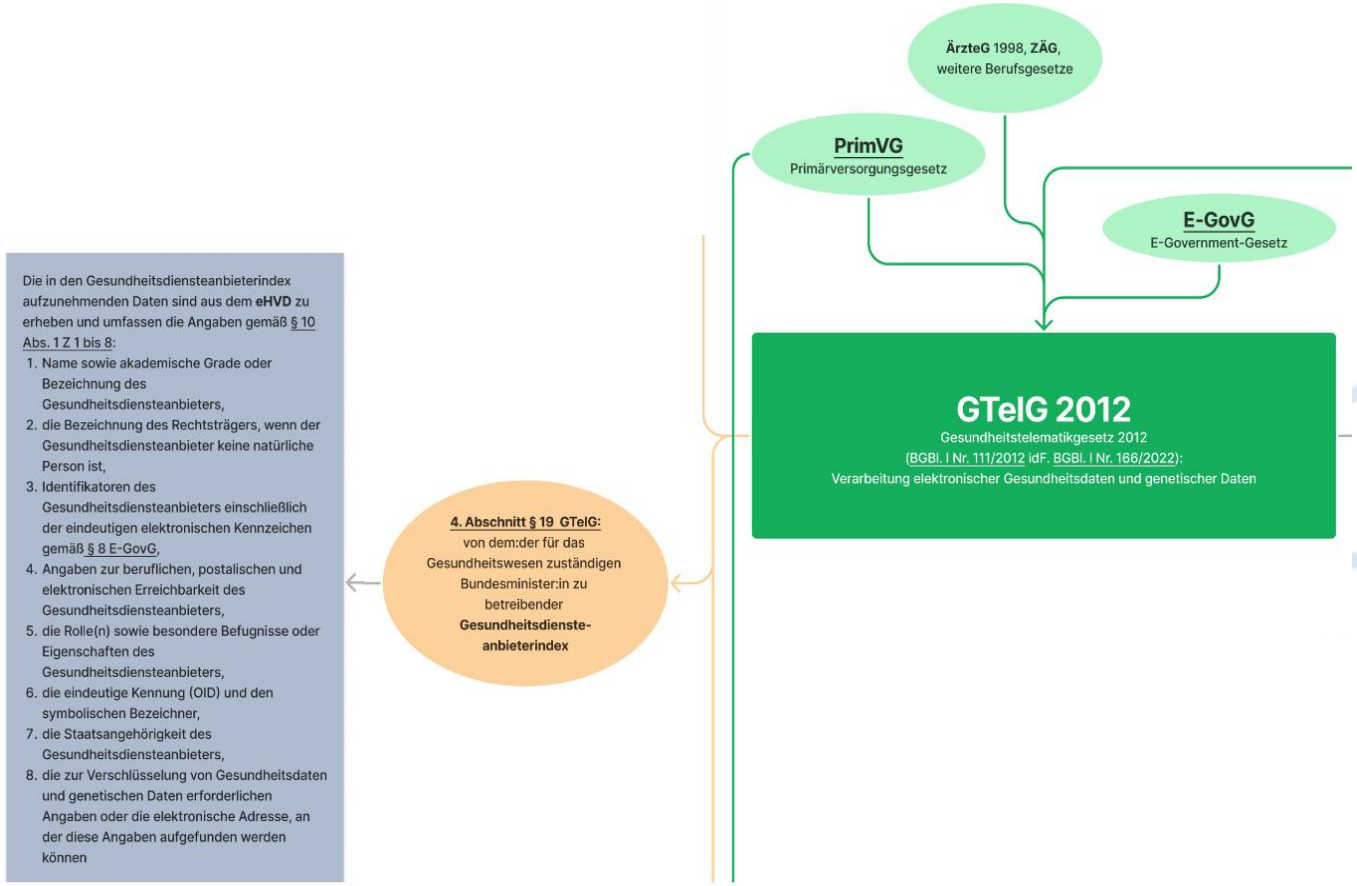
The Austrian health data infrastructure – two examples:

- National electronic health records through ELGA
- Pseudonymisation of health data for systems planning



Source: Vereinbarungsumsetzungsgesetz 2017 – VUG 2017, https://www.parlament.gv.at/dokument/XXV/I/1333/fname_571666.pdf

Case study: Austria



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Case study: Austria

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Health data as a policy problem

Policy challenge

Imagine the Austrian government is thinking about boosting health data sharing

Should Austrian health policy support health data sharing..,

- in general
- for specific conditions (Covid-19), actors (university research) etc?
- limit/prohibit it,
- or do nothing about it?

If you were to decide on and design a policy response, how would you proceed? What steps are necessary?

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Health data as a policy problem

Policy challenge – additional questions

If data is shared for secondary use..,

- how to prepare stakeholders for transparency?
- how to ensure data quality?
- how to limit misinterpretation?

If you were to decide on and design a policy response, how would you proceed? What steps are necessary?

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Health data infrastructures

Functions of **health information systems** (WHO 2017); „[E]nsure the production, analysis, dissemination and use of reliable and timely data by decision-makers at all levels of the health system […]“

- Generate individual-level, facility-based and population-based data from multiple sources: public health surveillance platforms, medical records, civil registration data, household surveys, censuses, health service coverage and health system input data
- Detect, investigate, communicate and contain events that threaten public health security
- Synthesize information and apply this knoweldge

„A good HIS improves both demand for and supply and use of data“ (ibid.)

→ Health data infrastructures as a precondition for functioning HIS

Examples: for surveillance (incl variant screening etc), contact tracing, quality assessment, accounting and planning, research (clinical trials), public health surveys, disease registries

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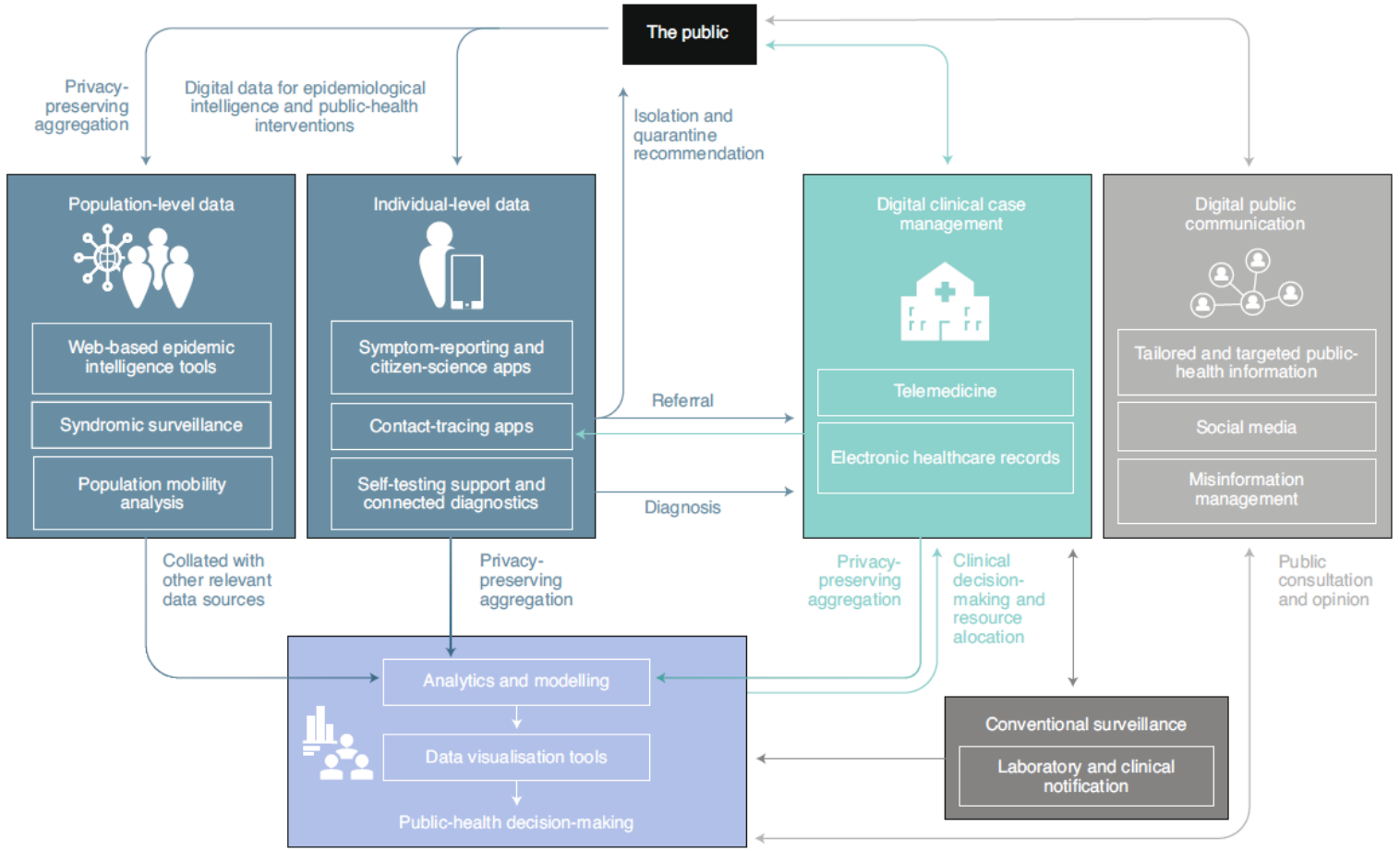
The future



Budd et al. 2020

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The future

New and improved

- Data collection opportunities
- Data transfer standards (HL7 FHIR, REST APIs etc.)
- Data infrastructure technologies (clouds, containerisation, distributed ledger systems, etc.)
- Analysis approaches (AI etc.)
- Governance mechanisms and access infrastructures

→ Towards the **European Health Data Space**

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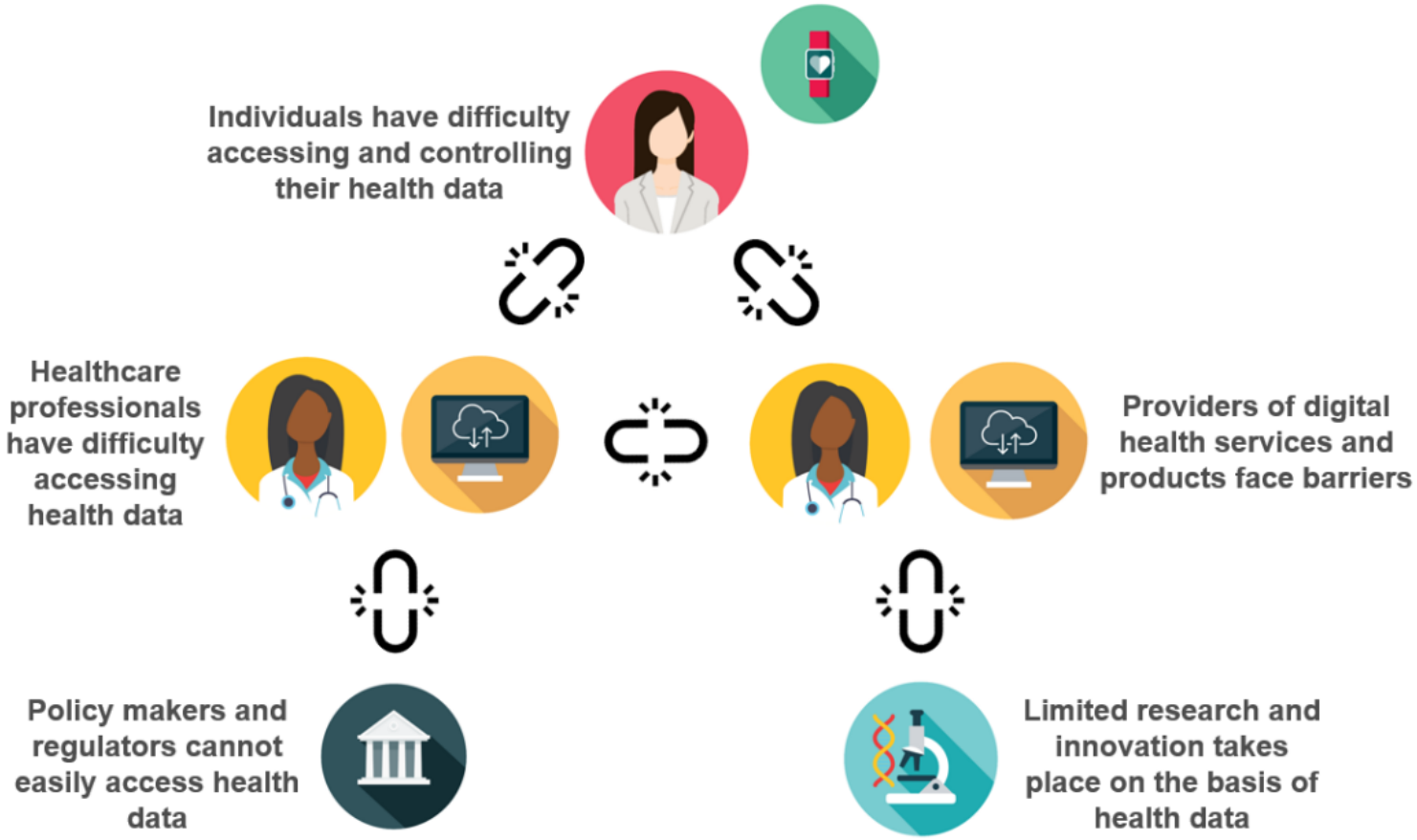
European Health Data Space



European Commission 2022

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Health data: EU policy

Council of the European Union

PUBLIC

Brussels, 18 March 2024
(OR. en)

7553/24

Interinstitutional File:
2022/0140(COD)

LIMITE

SAN 139
PHARM 41
COMPET 293
MI 279
DATAPROTECT 134
CODEC 741
IA 81

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	8571/22 ADD1-8
Subject:	Proposal for a Regulation on the European Health Data Space - Analysis of the final compromise text with a view to agreement

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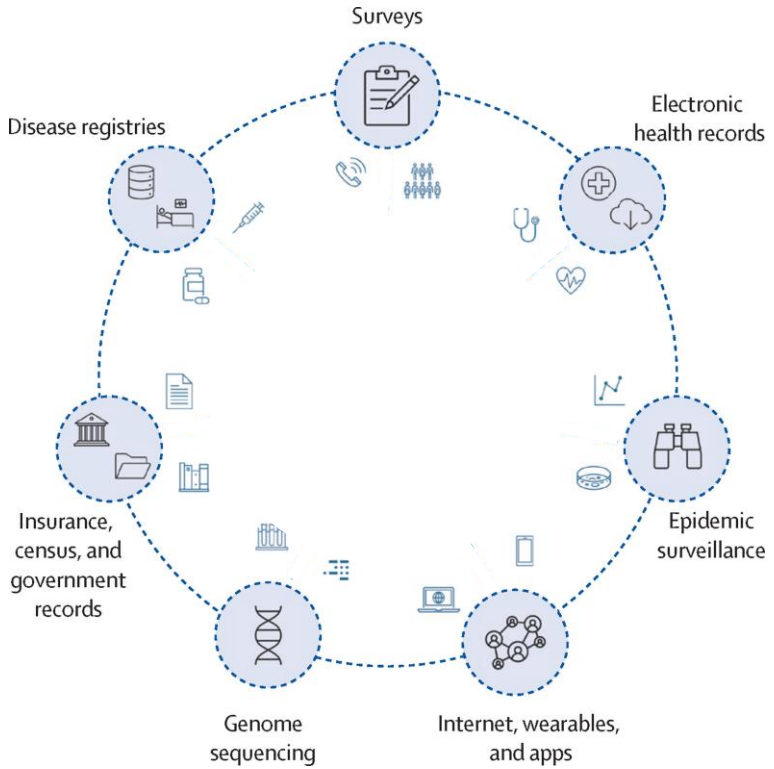
Health data: EU policy



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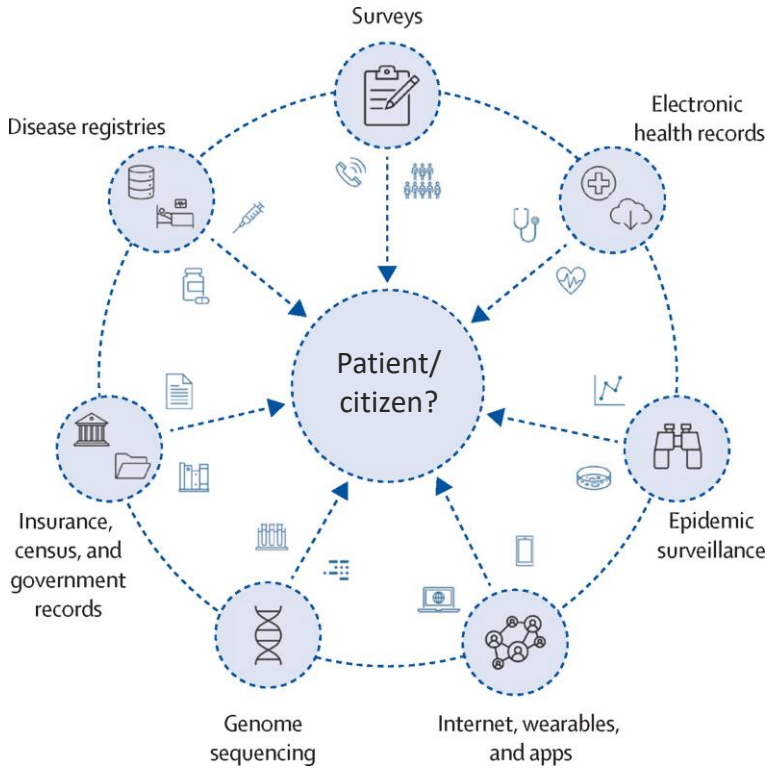
Health data: EU policy



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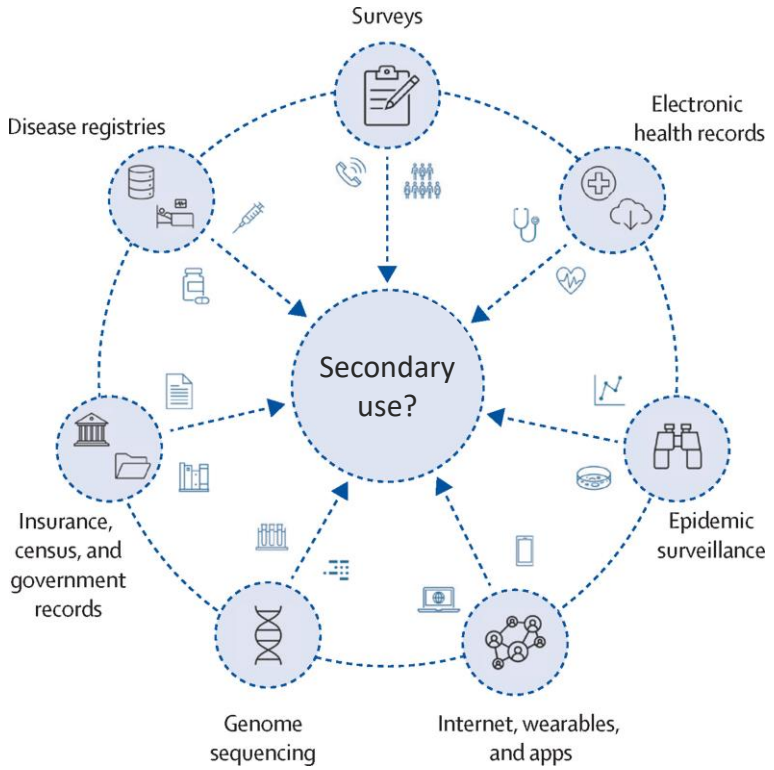
Health data: EU policy



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European Health Data Space

EU Regulation, proposed May 2022, political agreement reached in March 2024

Governing **primary use**:

- right of patients to decide on the use of their health data (Art 3)
- novel sets of standardized health data (patient summary, etc Art 5)
- electronic health record exchange format / interoperability (Art 6)
- cross-border availability

Governing **market access** of electronic health record systems (Art 13ff)

Governing **secondary use**: to be facilitated for

- Categories of health data (Art 33)
- Legitimate secondary use purposes (Art 34)
- Prohibited secondary use purposes (Art 35)
- Health Data Access Bodies (Art 36)

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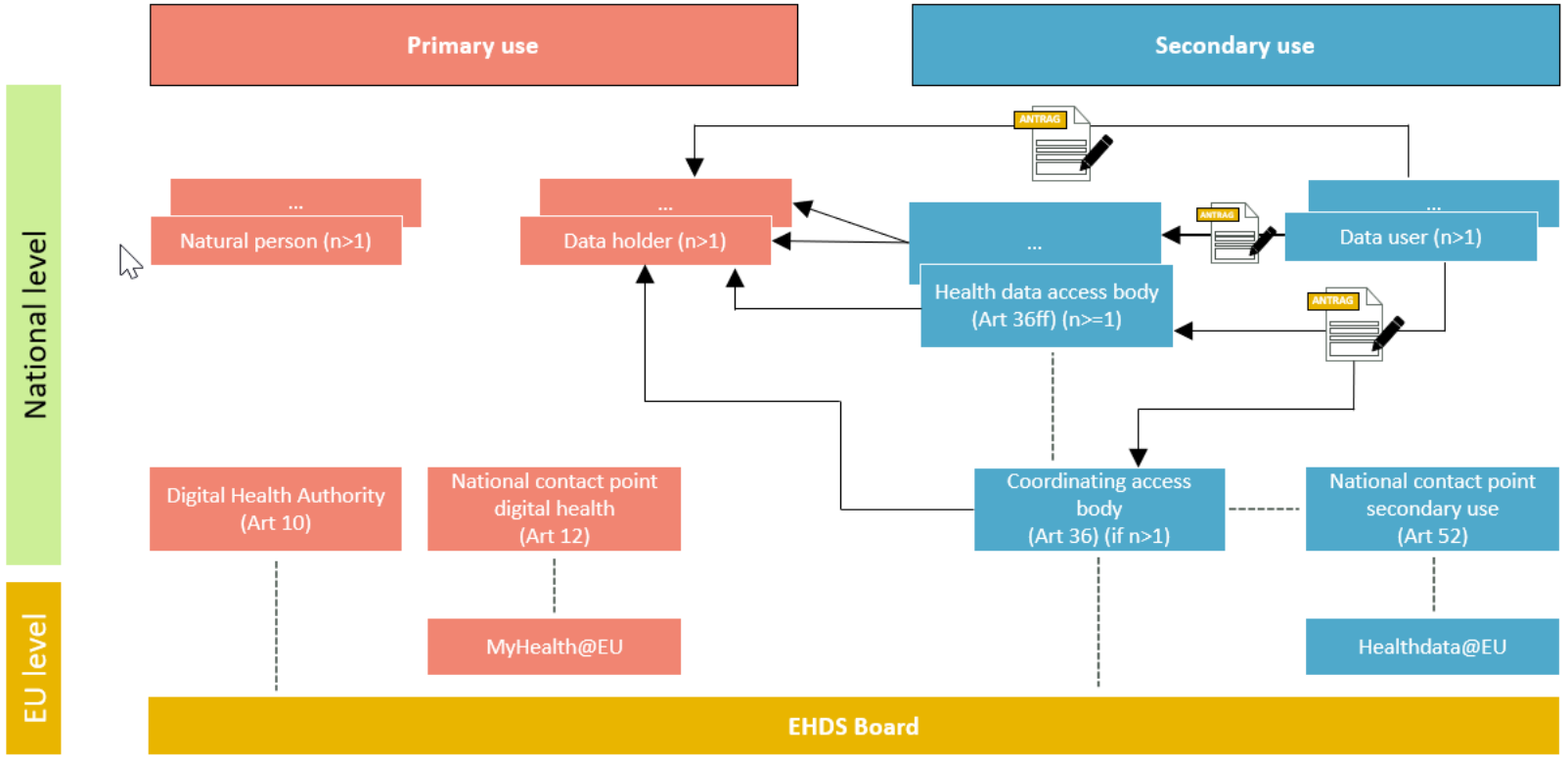
The European Health Data Space



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European Health Data Space

Some noteworthy discussion points:

- rights of natural persons and data protection
  - Opt-out primary use
  - Opt-out secondary use
- private sector data, intellectual property rights and trade secrets
- ethics/ensuring public value
- role of the access bodies

→ Your take?

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Wrap up

Designing health data infrastructures

- From reactive to proactive
- From case-by-case to modular, systemic and scalable
- From data duplication to automatised interfaces and on-demand availability
- Ensuring data protection and security
- Ethics, public value and accountability

EHDS as a paradigm change, but ‚homework' to be done nationally

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Thank you!

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