

The European Health Data Space and learning health systems



Martin Boeckhout

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European Health Data Space

#EHDS
#HealthUnion



European
Commission

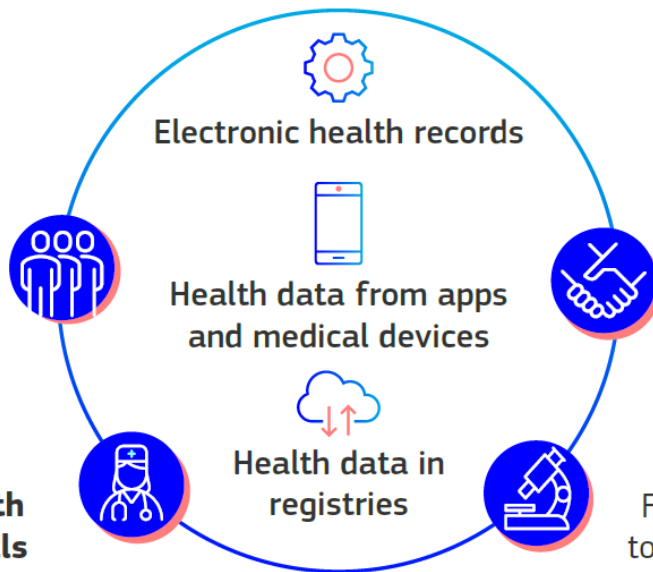
The EHDS: objectives

- 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



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

Empower individuals to control their health data



Unleash the power of the health data economy

Foster a single market for digital health services and products



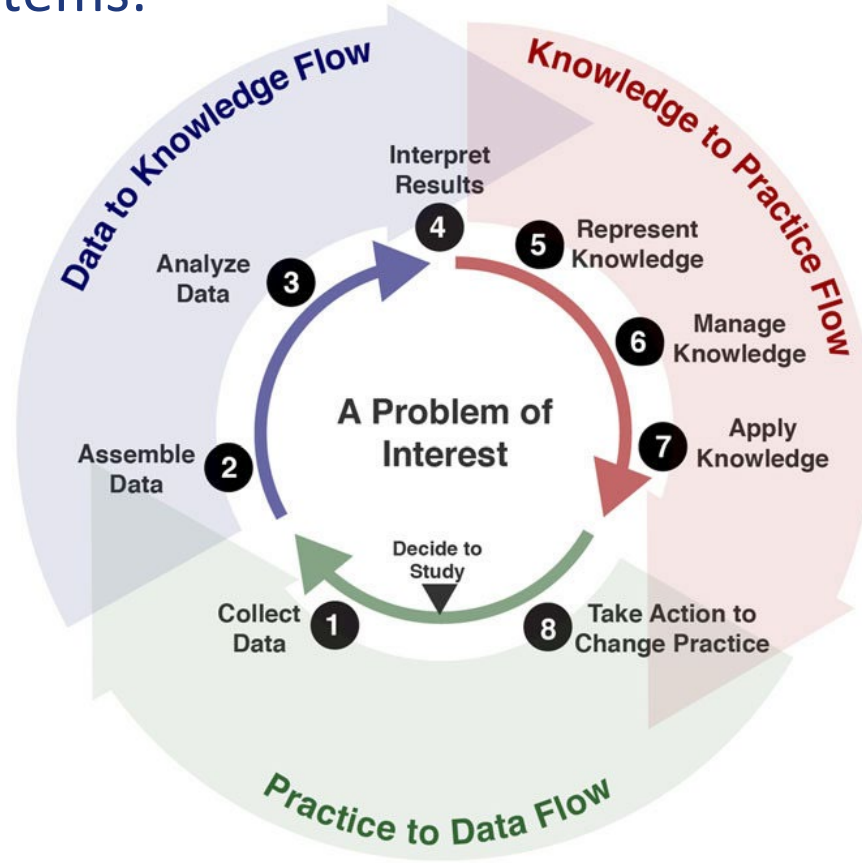
Ensure a consistent and efficient framework for the reuse of health data for research, innovation, policy-making and regulatory activities

Ensure interoperability and security of health data and a level playing field for manufacturers

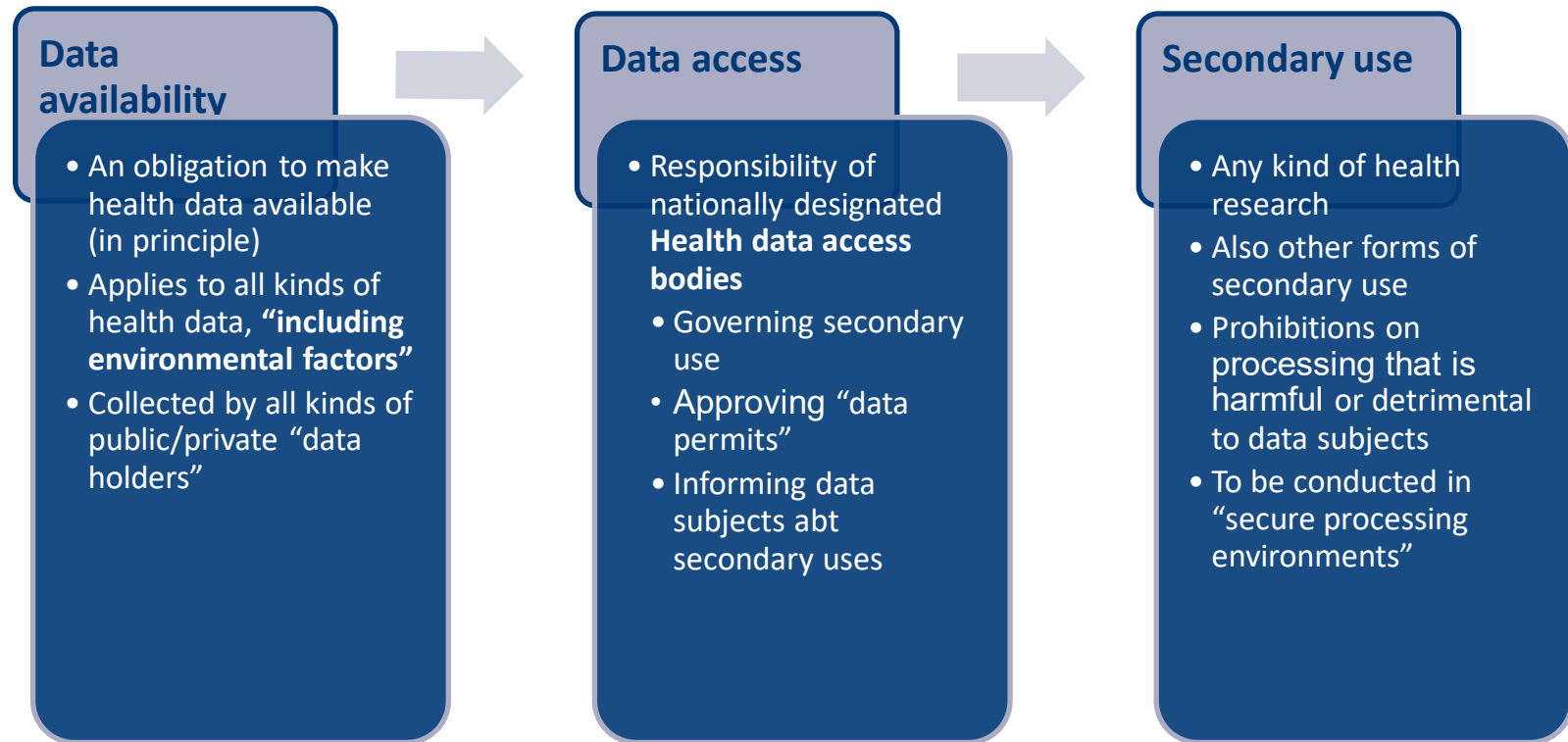


Figure 1 - Main objectives of the European Health Data Space

Learning health systems: a model



The EHDS & secondary use of health data for research



Data availability

- A push towards FAIRification, facilitating re-use “at source”, interoperability of health data – also for primary use
- Potentially: defragmentation of health data landscape
- The hard work of making data available for secondary use
- Primary & secondary use: two different authorities, policy areas



Data access

- Centralised, government-facilitated data access for secondary use
- In principle: a smooth, impersonal “data application process”
- In principle: no more locating, freeing up data from zillions of data controllers
- In practice: the hard work of learning from data = done in communities of practice around data, data streams, areas & problems of health & disease

“Secondary” data use

- Encompassing evaluating quality of care & scientific research
- Permitted “by default”, unless consent required by national law
- An opportunity to resolve GDPR & consent struggles – but only if *national* government acts
 - “Citizens in control” – but consent doesn’t always square with learning
 - Other safeguards: participatory governance, public interest exemptions?
- Data permits: a form of (ethics) review for research

“Data altruism consent”

Data altruism:

how the EU is screwing up
a good idea

By Winfried Veil



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DATA AND REGULATION

Will the European Health Data Space change data sharing rules?

Questions of consent and public interest research loom large

By Mahsa Shabani

This plan to construct a common space to

the coherence and complete health sector-specific EHDS health sector-nonspecific and data governance from the EU General Data Protection Regulation (GDPR) and the proposed Act (DGA).

The GDPR provides specific rules for the processing of data for scientific research including for scientific research investigations into the implementation of the

From “secondary use” to learning health: closing the loop?

- “Feedback loops” from research into practice:
 - Through “products and services”
 - Through dissemination of results (health data access bodies!)
- What about other *data-driven* feedback loops?
- Requires integrating health/care & research environments, infrastructures, communities of practice, ...

The EHDS and learning health systems: conclusion

EHDS offers many opportunities & incentives for data-driven health research – plus plenty challenges

Many of these will require (our) national government to act – not least on data protection

The EHDS framework does not fully “close the loop” of learning

Integration of research and care: ongoing work!

Initial response from Dutch health research (Health-RI, COREON and others)

- A stimulus for removing obstacles for re-use (cf. Health-RI)
- A push towards FAIR data stewardship, opening up data for research
- National health data access: build on ongoing efforts!
- National legislative reform is urgently needed
 - Cf. the Gedragcode & debate over consent and opt-out for re-use
- Data altruism is good, **data solidarity** needed as well – ideally nationally
- Data infrastructures for **research and care: bridging the gap**
- Strong **national coordination of efforts for re-use** needed: involve the field!

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HEAP PROJECT

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