Erasmus School of Law

Collective Governance of Health Data: Towards More Democratic and Inclusive Models

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WHO CONTROLS YOUR
HEALTH DATA?

SPECTRUM OF EU HEALTH DATA LAW AND GOVERNANCE

CONSENT

EU General Data Protection Regulation

NO CONSENT

European Health Data Space Regulation (EHDS)

European Health Data Space (EHDS)

- Structure
  - Strengthening of fundamental rights of data subjects (e.g. access to EHR)
  - Primary uses of EHR / FAIR Data
  - EHR systems and wellness applications
  - **Secondary uses of data**

Secondary uses of electronic health data

Primary and secondary use

Primary

- *primary use' means the processing of electronic health data for the provision of **healthcare, in order** to assess, maintain or restore the state of health of the natural person to whom those data relate, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social, administrative or reimbursement services;*

Secondary

- *'secondary use' means the processing of electronic health data for the purposes set out in Chapter IV of this Regulation**, other than** the **initial purposes for which they were** collected **or produced;***

Health data holder and health data user

"***health data holder***' *means any natural or legal person, public authority, agency or other body in the healthcare or the care sectors, including reimbursement services where necessary, as well as any natural or legal person developing products or services intended for the health, healthcare or care sectors, developing or manufacturing wellness applications, performing research in relation to the healthcare or care sectors or acting as a mortality registry, as well as any Union institution, body, office or agency, hat has either: (i) the right or obligation, in accordance with applicable Union or national law and in its capacity as a controller or joint controller, to process personal electronic health data for the provision of healthcare or care or for the purposes of public health, reimbursement, research, innovation, policymaking, official statistics or patient safety or for regulatory purposes; or (...)*

'health data user' *means a natural or legal person, including Union institutions, bodies, offices or agencies, which has been granted lawful access to electronic health data for secondary use pursuant to a data permit, a health data request approval or an access approval by an authorised participant in HealthData@EU;*

A little bit of history

Article 9(2)i-j GDPR: research exemption for processing without consent: public interest in the area of public health or e.g. scientific research.

No definition of research but… Recital 159 GDPR: included privately funded research.

EHDS

1. A New Paradigm for Secondary Uses of electronic Health Data for Scientific Research.
2. EHDS forms a governance framework for health data use in the EU.
3. Focuses on creating a space for health data sharing for secondary purposes, including scientific research (and **algorithmic training**).
4. Proposes a paradigm shift from consent-based to public and general interest-based regulation for health data usage.

Minimum categories of electronic health data for secondary use

1. Health data holders shall make the following categories of electronic health data available for secondary use in accordance with this Chapter:

(a) electronic health data from EHRs;

(b) data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health;

(c) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;

(d) data on pathogens that impact human health;

(e) healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements;

(f) human genetic, epigenomic and genomic data;
(g) other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;
(h) personal electronic health data automatically generated through medical devices;
(i) data from wellness applications;
(j) data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;
(k) data from population-based health data registries such as public health registries;
(l) data from medical registries and mortality registries;

(m) data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council (35), Regulation (EU) 2017/745 and Regulation (EU) 2017/746;
(n) other health data from medical devices;
(o) data from registries for medicinal products and medical devices;
(p) data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results;
(q) health data from biobanks and associated databases.

Purposes for secondary use

(a) the public interest in the areas of public or occupational health, such as ***activities to*** protect against serious cross-border threats to health, public health surveillance or ***activities*** ensuring high levels of quality and safety of healthcare***, including patient safety,*** and of medicinal products or medical devices;
(b) ***policy-making and regulatory activities*** to support public sector bodies or Union institutions, bodies, offices or agencies***,*** including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;
(c) ***statistics as defined in Article 3, point (1), of Regulation (EU) No 223/2009, such as*** national, multi-national and Union-level official statistics, related to health or care sectors;

(d) education or teaching activities in health or care sectors ***at vocational or higher education level***;

(e) scientific research related to health or care sectors ***that*** contributes to public health or ***health technology assessments,*** or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices***, with the aim of benefiting end-users, such as patients, health professionals and health administrators, including:***

(i) development and innovation activities for products or services;

(ii) training, testing and evaluation of algorithms, including in medical devices***, in vitro diagnostic medical devices***, AI systems and digital health applications ;

(f) ***improvement of the delivery of care, of the optimisation of treatment and of the provision of healthcare***, based on the ***electronic*** health data of other natural persons.

But…

Recital 61: *In particular, the secondary use of health data for research and development purposes should contribute to benefiting society in the form of new medicines, medical devices, and healthcare products and services at affordable and fair prices for Union citizens, as well as to enhancing access to and the availability of such products and services in all Member States.*

Recital 52: ***Member States should no longer be able to maintain or introduce under Article 9(4) of Regulation (EU) 2016/679 further conditions, including limitations and specific provisions requesting the consent of natural persons, with regard to the processing for secondary use of personal electronic health data under this Regulation.***

Opt-out

However, for certain purposes with a strong link to the public interest, such as activities for protection against serious cross-border threats to health or scientific research for important reasons of public interest, it is appropriate to provide for a possibility for Member States to establish, taking into account their national context, mechanisms to provide access to personal electronic health ***data of natural persons who have exercised their right to opt out, to ensure that complete datasets can be made available in those situations. Such mechanisms should comply with the requirements established for secondary use under this Regulation. Scientific research for important reasons of public interest could for example include research addressing unmet medical needs, including for rare diseases, or emerging health threats.***

Prohibited secondary use

1. Taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data
2. Taking decisions in relation to a natural person or group pf personal in relation to job offers, offering less favorable terms in the provisions of goods or services.
3. Developing products or services that may harm individuals
4. Advertising
5. Carrying out activities in conflict with ethical provisions laid down in national law

Duties of data holders and data users

Data holders:
Make data available

Data users:
Make public the results

Objectives and Challenges

- Objectives:
  - Facilitate access to health data for research, innovation, and public health.
  - Enable secondary use of health data while maintaining societal benefit.
- Challenges:
  - Definitional clarity on 'scientific research' and 'public interest.'
  - Potential for increased commercial use over societal benefit.

EHDS Framework Under GDPR

• GDPR allows processing sensitive data for scientific research under certain conditions.
• EHDS expands on this by:
  - Overriding individual consent for broader public interest.
  - Including activities like algorithm training and innovation as 'scientific research.'

Beyond the GDPR and the EHDS?

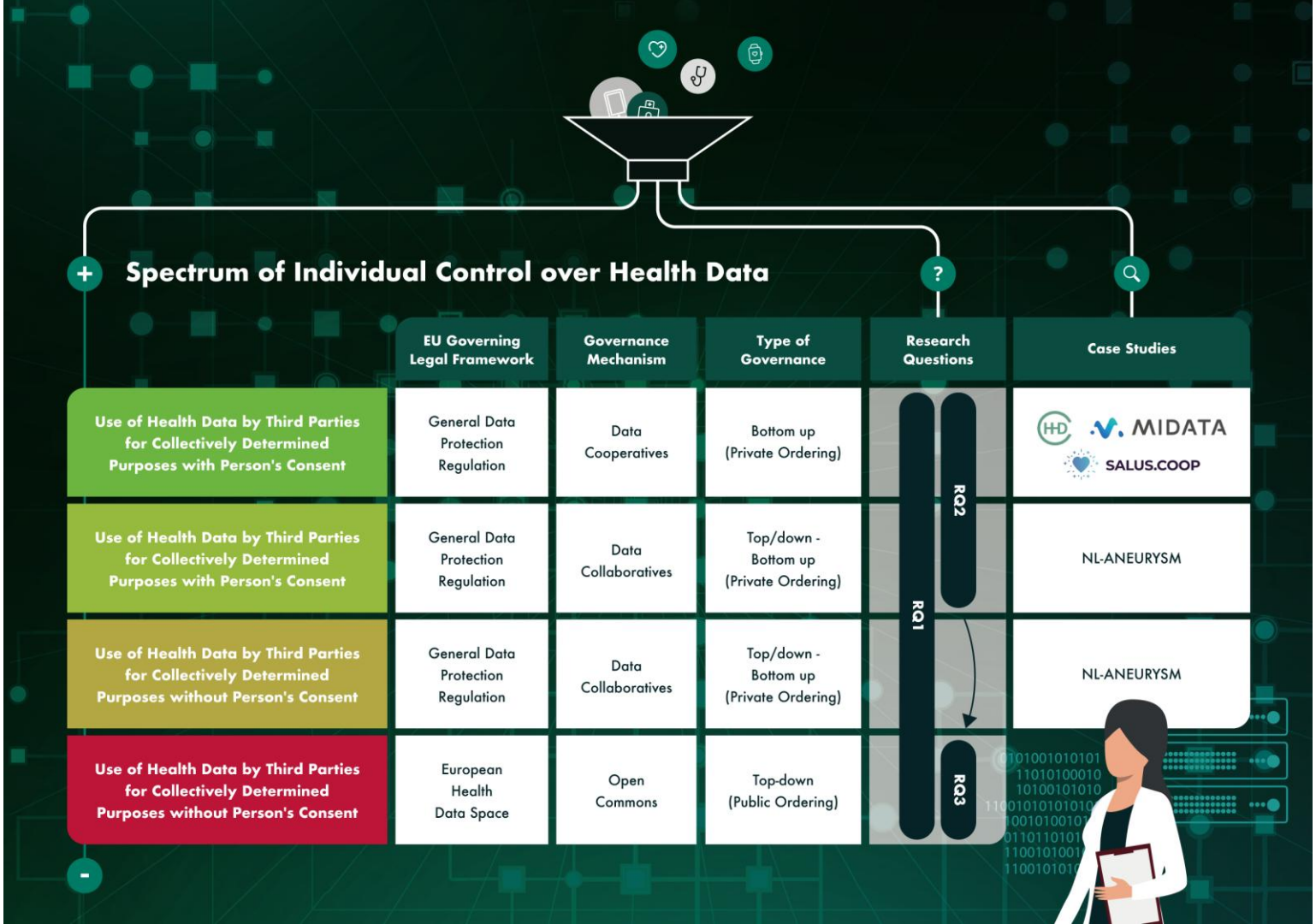
ALTERNATIVE GOVERNANCE MODELS

HEALTH DATA COOPERATIVES

Individuals pool their health data

HEALTH DATA COLLABORATIVES

Institutions share health data with each other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Spectrum of Individual Control over Health Data
?
EU Governing Legal Framework
Governance Mechanism
Type of Governance
Research Questions
Case Studies
Use of Health Data by Third Parties for Collectively Determined Purposes with Person's Consent
General Data Protection Regulation
Data Cooperatives
Bottom up (Private Ordering)
HD
MIDATA
SALUS.COOP
Use of Health Data by Third Parties for Collectively Determined Purposes with Person's Consent
General Data Protection Regulation
Data Collaboratives
Top/down - Bottom up (Private Ordering)
NL-ANEURYSM
Use of Health Data by Third Parties for Collectively Determined Purposes without Person's Consent
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Use of Health Data by Third Parties for Collectively Determined Purposes without Person's Consent
European Health Data Space
Open Commons
Top-down (Public Ordering)
RQ1
RQ2
RQ3
-

RESEARCH HYPOTHESIS

European Health Data Space Regulation (EHDS) and data coops/collaboratives stem from the idea of the commons.

EHDS: Open commons—anyone can access and use data.

Data coops/collaboratives: Common-pool resources—restricted access and collective governance.

What are the commons?

Common Pool Resources Commons

- Elinor Ostrom's framework (IAD)
- Commons inside but property outside.
- Collective property
- Originally: natural resources
- Self-governance bottom-up arrangements

Open Commons

- Carol Rose (inherent public property), but also Benkler, Lessig, Boyle, Frischmann.
- Symmetric freedom to operate
- Outside the property regime
- Built top-down, socially or carved-out the property regime
- **Characteristics: (i) Efficient allocation not a problem, (ii) positive externalities in the social value of the resource, (iii) input for other resources, (iv) resource provisi… in different settings**

EHDS: an open commons?

Open Commons:

a Efficient allocation of the resource, once provisioned, ..., is not a paramount management concern; this includes (1) nonrival resources, (2) partially congestable resources and so on.
b Significant positive externalities are involved in the social value of the resource set.
c The resource is used as input into goods, services, innovations, or other sources of value.
d The resource is provisioned in a diverse set of market, public or social processes.

Governance and the Commons

• EHDS as an 'incomplete open commons' for health data.
Commons:

• Relies on symmetric access to data but lacks clear rules on public interest definition.

• Challenges of managing access, free-riding, and benefit sharing.

Recommendations for EHDS

- Define 'public interest' and 'general interest' clearly.
- Establish mechanisms for:
  - Sharing results and outputs of data usage.
  - Redistributing benefits from private uses to the public domain.
- Adopt data solidarity as a framework for ethical and equitable governance.

Preliminary conclusion

- EHDS represents a significant shift in health data governance.
- Presents opportunities for innovation and societal benefit but requires improved regulation.
- Strong need to rely on alternative models, like data cooperatives and collaboratives for the collective governance of health data for secondary use.

Thank you