

European Health Data Space

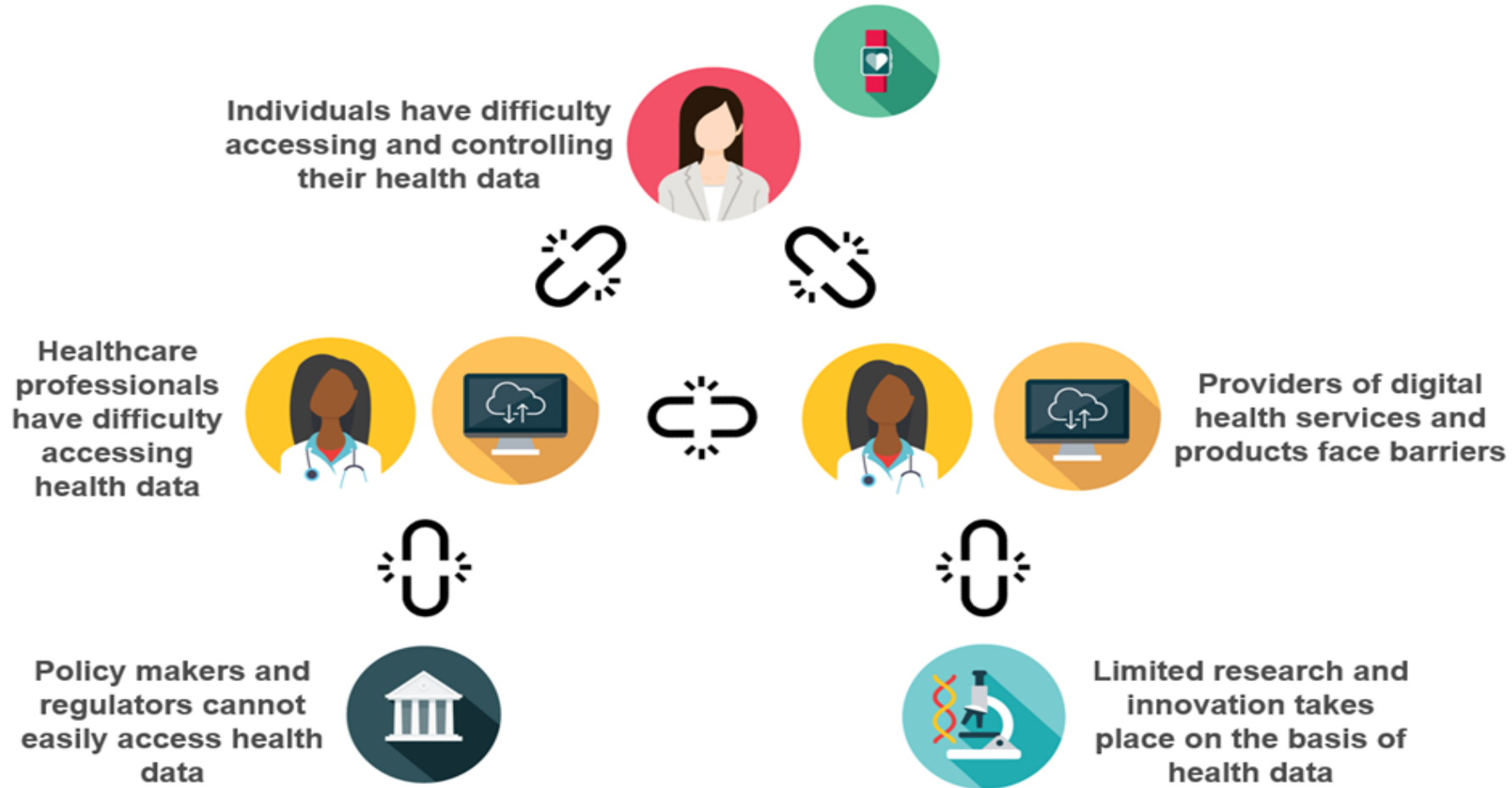
Harnessing the power of health data
for people, patients and innovation

InteropEHRate final conference

28 September 2022



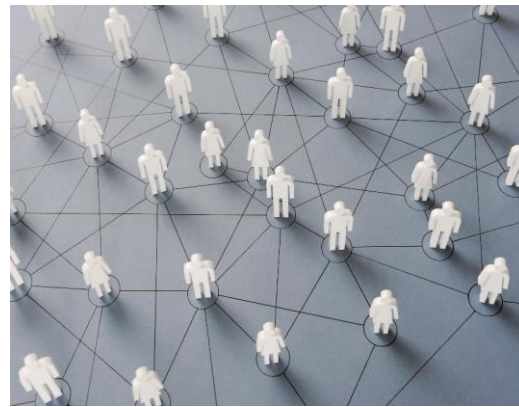
Main challenges in harnessing the power of health data



Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

Empower individuals to access and control their personal health data



Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)



EHDS – links with other legal proposals and initiatives

GDPR

EHDS builds upon GDPR rights and further develops some of them

European Health Union

EHDS will boost the work of EU Cancer plan, HERA, Pharmaceutical Strategy for Europe

Data Governance Act, Data act

EHDS complements and provides more tailor-made rules for the health sector

EU cybersecurity framework (NIS directive)

EHDS complements and provides more tailor-made rules for the health sector

Artificial Intelligence Act

EHDS supports and complements training of AI, interoperability of AI and EHR systems and data quality

Medical Device Regulations

If manufacturers claim interoperability of devices with EHR systems –EHDS requirements apply

European Health Data Space (EHDS)

OBJECTIVES

Effective use of health data

SCOPE & EXPECTED IMPACT

Use of health data
(primary,
MyHealth@EU)

- Empower individuals to control their data
- Standardization and mandatory certification of EHR systems
- Voluntary labelling of wellness apps
- European Electronic Health Record Exchange Format

Single market for health data, data protection, free movement of people, digital goods and services

Re-use of health data
(secondary,
HealthData@EU)

- Health data access bodies
- Purposes for use and forbidden use
- Data permits, secure environments, no identification

Facilitated Research & Innovation

Better Policy Making

MEANS

Legal / Governance

Quality of data

Infrastructure

Capacity building/digitalisation (MFF)

The scope of EHDS

Strengthens the rights of individuals in relation to greater control over their electronic health data:

Access, share health data with health professionals nationally or cross-border, add information, rectify errors, restrict access, know what health professional accessed data, issue and accept health data in a common European format, strengthen interoperability.

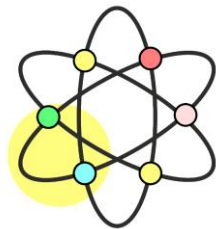


Rules for electronic health record systems (EHR systems)

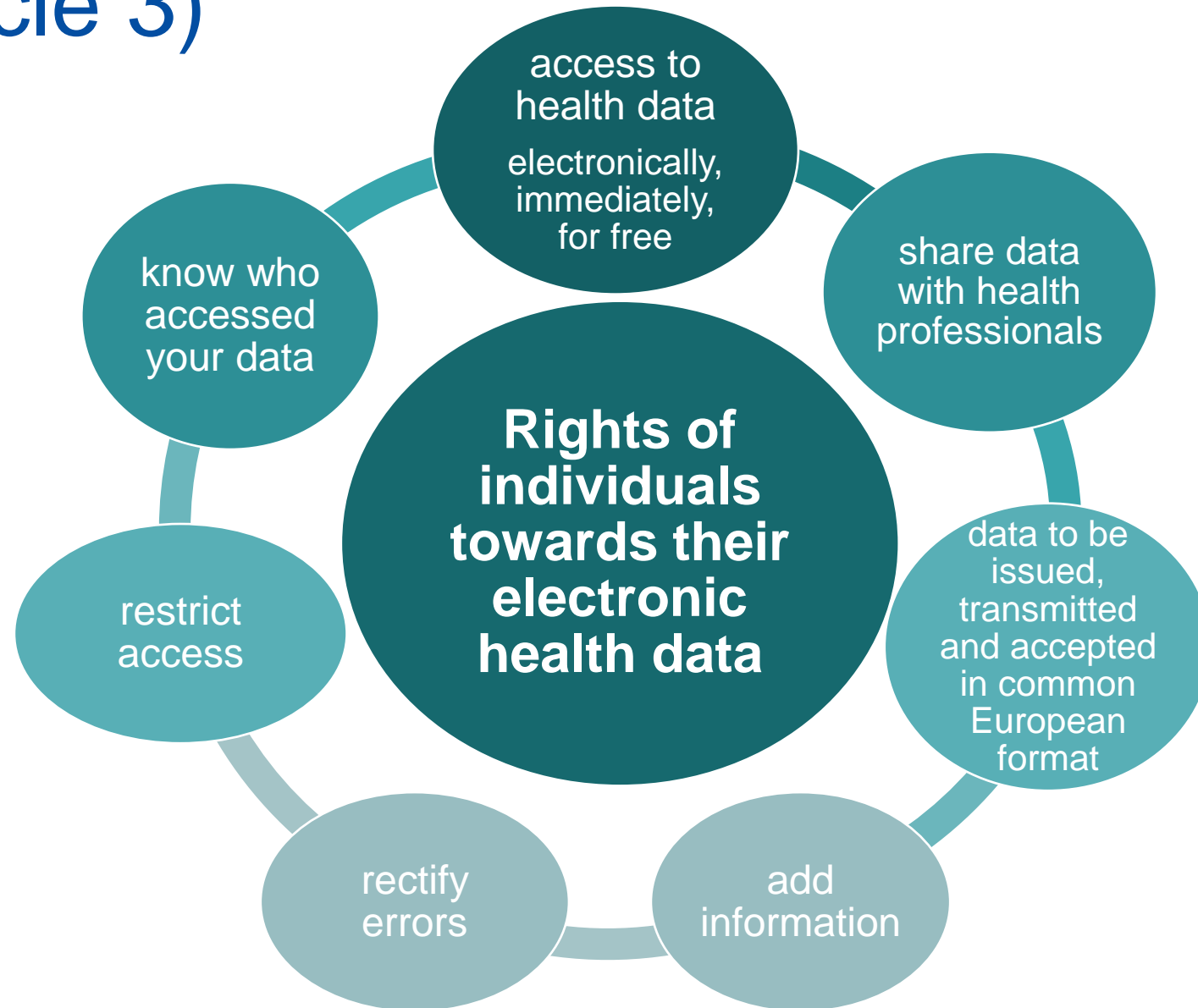
Rules and mechanisms supporting the secondary use of electronic health data

Mandatory cross-border infrastructures for primary and secondary use of health data

- MyHealth@EU
- HealthData@EU



Rights on individuals towards their health data (article 3)



Data altruism in the health sector (article 40)

Under the Data Governance Act (DGA):

General requirements for the registration of recognised data altruism organisations (*data altruism activities, objectives of general interest, non-for-profit/independent entity, etc.*).

These requirements apply also for data altruism organisations in the health sector.

EHDS proposal adds one requirement:

When such organisations process health data using a **secure processing environment**, it shall also comply with the requirements in the EHDS proposal (article 50).

Why? To ensure the **same security level** as in an environment provided under the responsibility of a Health Data Access Body (HDAB)

Benefits



Individuals

- Accessing and sharing health data
- More efficient healthcare
- Avoid unnecessary tests
- Support medical decisions
- Improve health outcomes



Healthcare providers

- Savings in hospital expenditure, improved decision making, better patient care
- Remote care and advice via telemedicine



Researchers, policy makers, regulators

- Access to more data
- Better decision making
- Research and development



Industry

- Access to data
- Research, development
- Larger markets for EHR systems

Individuals: strengthened security

Primary use

Builds upon EU-cybersecurity legislation

Security/interoperability criteria for EHR systems + CE marking

Security audits for the MyHealth@EU (primary use) infrastructure

Strong authentication for patient and health professionals

Only persons entitled to access the data can get access to individual's data

Secondary use

Data processed in secure processing environments, compliant with high standards of privacy and (cyber)-security.

No personal data can be downloaded

Users cannot identify individuals

Audits of participants in HealthData@EU

Thank you