



European Health Data Space

CEFI

6 June 2023

Angel Martin (Digital health Advocacy EMEA, Johnson & Johnson)

Creating an EU health data ecosystem



The EHDS is [...] crucial to develop life-saving treatments, vaccines or medical devices and ensuring better access to healthcare and more resilient health systems.

– Health Commissioner Kyriakides

What is the European Health Data Space?

A health data ecosystem built through **legislation, infrastructure and governance**

Major system shift to unleash potential of data in:



Delivery of Care

Empowering patients on their health data and HCPs in delivery of care across EU borders



Electronic Health Records

Upgrade generation of high-quality data through common standards in Electronic Health Records Systems



Research & Innovation

Use of health data for R&D, innovation and personalised medicines

EHDS: a multi-layered structure

A health data ecosystem built through **legislation, infrastructure and governance**



Framework Legislation

- 2022-2024 (TBC)
- Principles / Scope
- Purpose, Data types, Conditions

Technical Legislation

- 2025-... TBC)
- Standard Definition
- Implementing rules

National Data Spaces and Infrastructure

- 2022-...
- National/Regional Spaces (aligned with the framework): new (BE, DE, ES...), existing (FI, DK, EE, FR)
- Interoperability, Connectivity and Infrastructure – how do we connect the Spaces

EHDS – a (r)evolution in health data



EHR systems governance

Establishes **mandatory regulatory scheme** for **Electronic Health Record Systems**, with requirements for interoperability, security, access to data and governance (including self-certification)



Harmonised technical standards

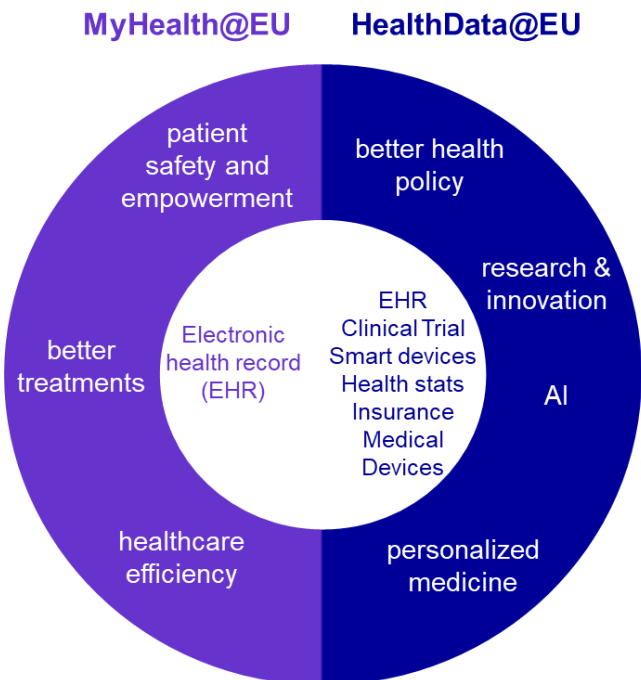
Commission selection of **standards and common specifications** to avoid interoperability, security, quality risks.



Empowering patients

Ensures **free access and control** of their electronic health records, with the **ability to edit or transmit the data**

The proposal



Access to data

Provides **common European purposes of access** for public and private actors. Includes **innovation of new products/ services**; training of algorithms in medical devices and digital health apps; and providing personalized healthcare



Provision of data

Provide access to health **data held by private entities** (incl Pharma or MedTech companies) for **secondary use**, including electronic health data entailing protected IP and trade secrets (measures to preserve confidentiality shall be taken).

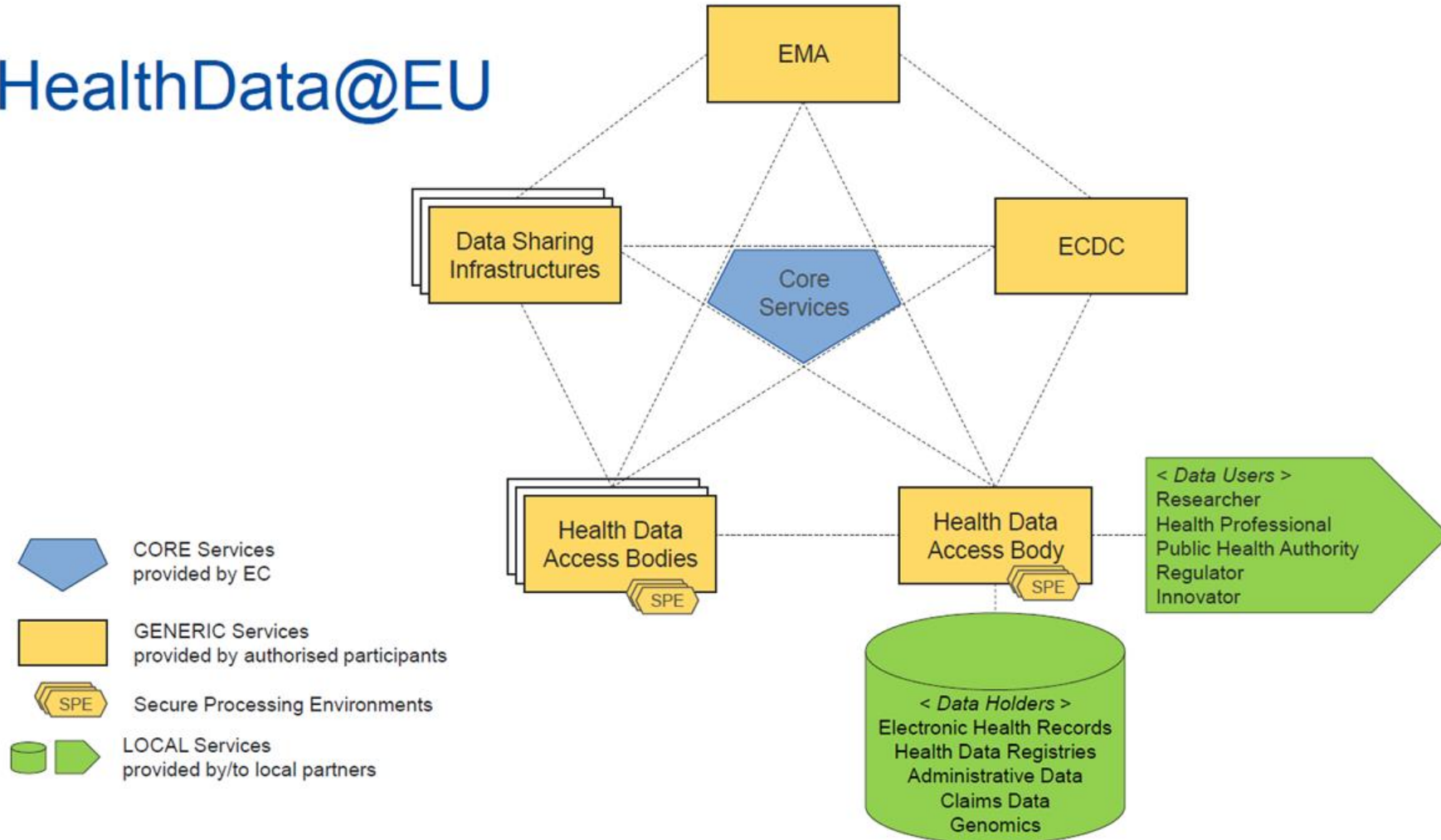


Data quality requirements

Datasets in EHDS may have a **data quality and utility label**, which will consider **requirements such as FAIR**, documentation, technical quality, quality management process, coverage and linkages.

EHDS Visualization

HealthData@EU



Data Types for secondary use

EHDS details the broad type of health data in scope for both access and provision and the purposes

Types of Data

- EHRs
- Determinants of health
- Pathogen genomic
- Administrative
- Genetic, genomic, proteomic
- Person-generated
- HCP identification
- Broad registries
- Specific registries
- Medical devices
- Research cohorts
- Biobanks
- Insurance status, education, lifestyle, wellness, behaviour
- Improved sets from EHDS use

Context of Data Generation

Collected for purposes of:

- healthcare
- public health
- research
- innovation
- policy making
- official statistics
- patient safety
- regulatory

Purposes for secondary use

EHDS details the broad type of health data in scope for both access and provision

Purposes for Public Actors

- a) public interest (e.g. protection against serious cross-border threats to health)
- b) support public sector bodies, incl regulatory authorities, to carry out their tasks
- c) produce official statistics
- d) education or teaching activities

Purposes for Private Actors

- e) scientific research
- f) development and innovation activities for products or services
- g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications
- h) providing personalised healthcare

Prohibited Uses

- (a) decisions detrimental to a person
- (b) decisions to exclude people from benefit of insurance contract;
- (c) advertising or marketing activities for HCPs or natural persons;
- (d) providing access to 3rd parties not mentioned in data permit;
- (e) developing products/ services harming individuals and societies

IP Rights: References in Legislative Text

Art 33(1) – Data types in scope

Data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter:

[...]

*(j) electronic health **data from clinical trials**;*

Art 33(4) – Data types in scope

*“Electronic health data entailing protected intellectual property and trade secrets from private enterprises **shall be made available for secondary use**. Where such data is made available for secondary use, **all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken.**”*

Art 37(1) –Health Data Access Bodies

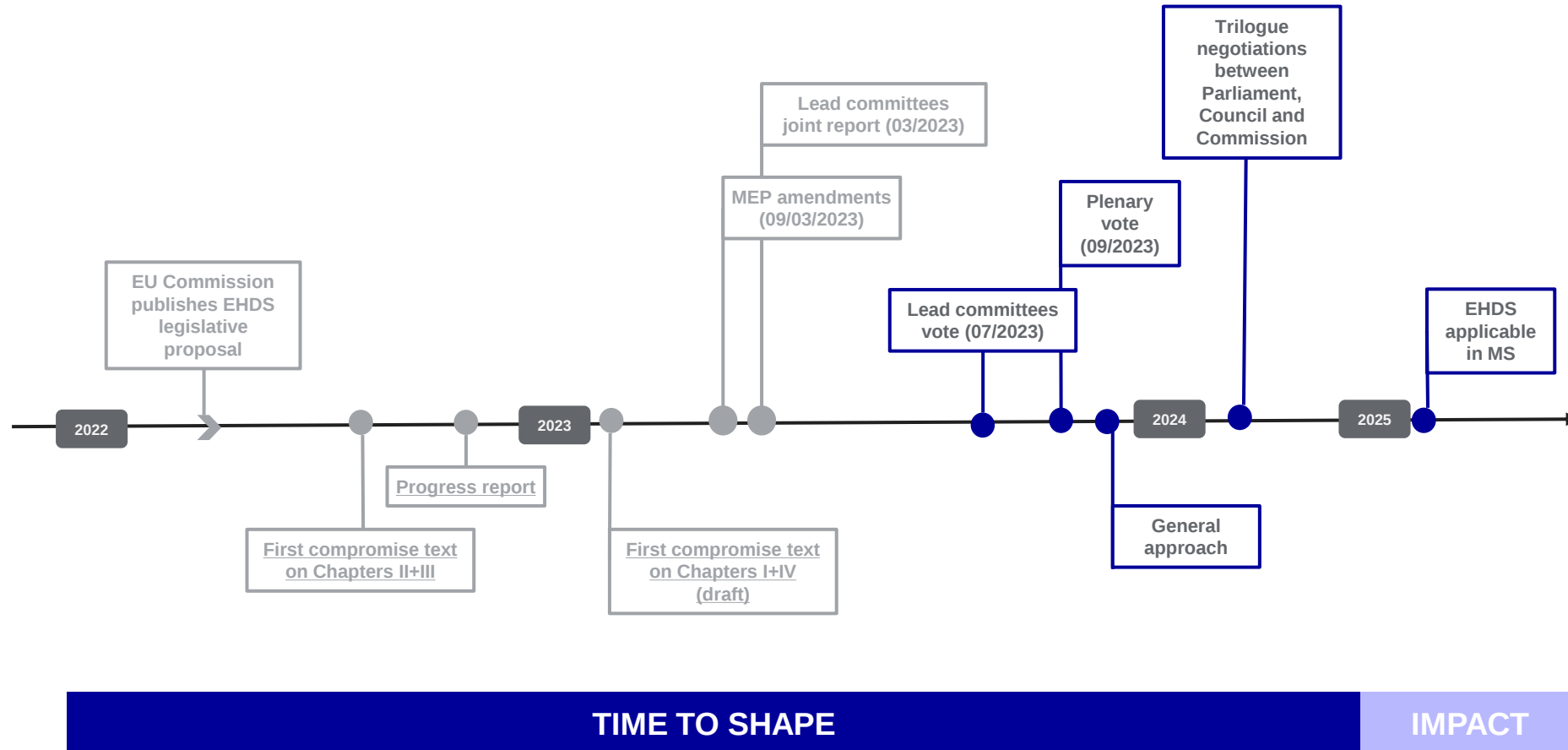
Health data access bodies shall carry out the following tasks:

[...]

(f) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets;

Timeline for Adoption

The time to act is **now**



Opportunities & Risks

Opportunities

- Harmonized data access and sharing & better data interoperability and quality supporting innovation
- Promote a data culture in health systems, fostering data-driven healthcare and patient empowerment across Europe, raising the bar and harmonizing
- Helping existing and new collaborations - improving comparability and interoperability and thus the power of analytics

Risks

- Undermining IP and trade secrets & unclear IP from innovations obtained by EHDS data (ternary use)
- Fragmented interpretation across countries, unclear interplay with other legislation (GDPR), and insufficient funding for implementation
- Compliance obligations for data holders

Links to Other Policies & Legislations

EHDS has strong links to both past and current legislation and policy proposals

GDPR, Data Governance Act & Data Act

EHDS builds upon and develops GDPR rights, and complements horizontal data legislations by providing tailor-made rules for 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 notify interoperability of devices with EHR systems, EHDS requirements apply

EU Cybersecurity Framework (NIS 2.0 Directive)

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

European Health Union

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

TEHDAS Joint Action

Supports in building EHDS by developing principles for crossborder secondary use of health data