EHDS Regulation - Interpreting Patient Rights

28 January 2025

EHDS Patient Forum
Athens Digital Health Week 2025

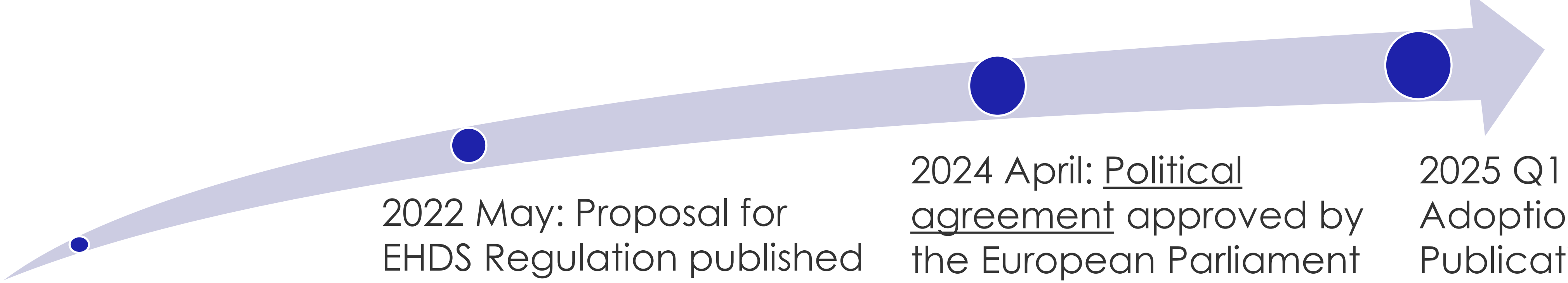
HIMSS

EHDS in a nutshell

HARNESSING THE POWER OF ELECTRONIC HEALTH DATA

- **Primary use** = use of data for the delivery of healthcare
  - Improving patients' access to their health data
  - Ensuring seamless exchanges for continuity of healthcare

- **Secondary use** = use of data for research and public interest
  - Making data available for research, innovation, planning and policy-making in a safe and secure way



2019 Dec: Mission to the Health Commissioner letter called for EHDS

2022 May: Proposal for EHDS Regulation published

2024 April: Political agreement approved by the European Parliament

2025 Q1: Adoption, Publication

Who will benefit from the EHDS ?

Healthcare professionals

- Faster access to patient's EHRs, including across borders
- Easier access to EHRs from different systems, greatly reducing the administrative burden.

Individuals / Patients

- Control over personal health data
- Security of data and privacy will be ensured

Researchers

- Know what data is available, where, and of what quality
- Access to large amounts of data cheaper and more effectively

Regulators / Policy-makers

- Easier and transparent access to health data for the benefit of public health, the overall functioning of healthcare systems

Industry

- Enter into new markets for EHRs in other Member States
- Benefit from data, enabling applied research and innovation.

GDPR: Patients' and researchers' rights

Right to be given a legal base for data processing

- Consent
- Contract
- Legal Obligation
- Care provision
- Public interest
- Vital interest

(Art. 6(1) and 9 (2))

Right to data portability

...When processed on basis of consent and automatic processing (Art 20)

Right to access and rectification

(Art 16)

Right to erasure

(to be forgotten)
(Art 17)

Right to restrict processing

(Art 18)

Right to object

(Art 21)

Right not to be subject to a decision based solely on automated processing

(Art 22 of GDPR)

Legal base for data re-use (Research)

- Explicit consent
- Public interest in public health or research
- National frameworks

(Art. 9 (2) and Art 89)

EHDS: Patients' rights and researchers' interests

Primary use of health data

Legal base for processing
- Legal base for primary use

Enhanced data access
- Immediate, free of charge
- Access for proxy
- Access service

Data Addition
- Apps
- Personal notes

Transparency
- Access Log
- Annual report

Opt-out
- MS may provide opt-out for sharing EHRs with other care providers

Data Altruism

Secondary use of health data

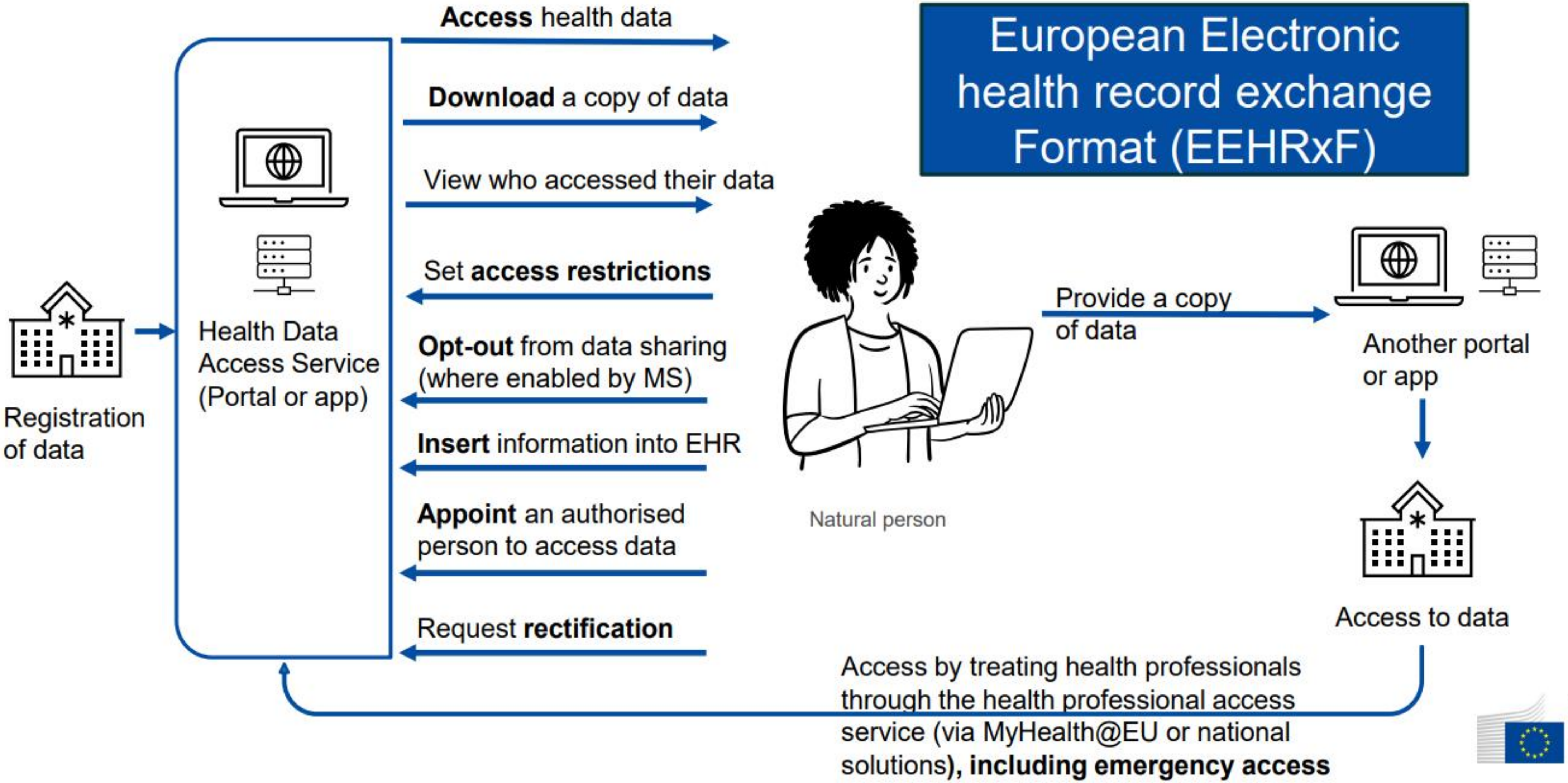
Legal base for re-use
- Legal base for secondary use
- Health Data Access Bodies
- Data access Permits

Data Quality Assurance
- Data catalogues
- Quality and utility labeling
- Enhanced data returned to HDAB

Opt-out
- Right to opt-out of secondary use

Transparency
- Access Log
- Annual report secondary use

Rights of natural persons in primary use



Registration of data

Health Data Access Service (Portal or app)

Access health data

Download a copy of data

View who accessed their data

Set **access restrictions**

Opt-out from data sharing (where enabled by MS)

Insert information into EHR

Appoint an authorised person to access data

Request **rectification**

Natural person

European Electronic health record exchange Format (EEHRxF)

Provide a copy of data

Another portal or app

Access to data

Access by treating health professionals through the health professional access service (via MyHealth@EU or national solutions), **including emergency access**

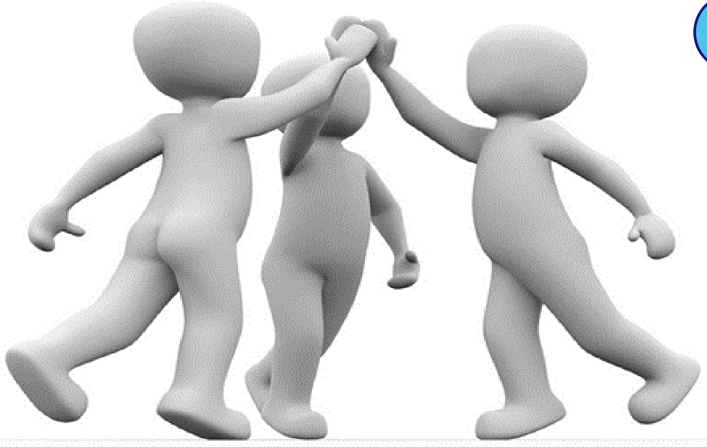
A change in rights, a change in perspective: new advocacy and engagement needs

From national focus to EU wide integration and interoperability

From data subject protection to active engagement

Introducing data altruism

From data protection to data usage



From data re-use as the exception to the norm

From DSAR to easy transparency on use, re-use and impact of re-use

From generic data controller to focused healthcare data controller and data holder support

Thank you

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