

EHDS – and patient control of health data



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Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the European Health Data Space

(Text with EEA relevance)

{SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final} -
{SWD(2022) 132 final}

3 May 2022

EHDS Regulation in short...

- Both primary and secondary use of health data
- Efficient and secure sharing of data across national borders
- At the same time facilitate, for example, research on health data and strengthen (the individual's) control over their own health data
- Primary use: Certain amounts of information (among other things according to X-eHealth, and future projects within EU4Health)
- Secondary use: Specific purposes and extensive (data categories) (Joint Action TEHDAS)
- Medical record systems and health apps
- Good proposal - but many question marks and challenges



EHDS...

...will create a common space where **natural persons** can easily control their electronic health data.

It will also make it possible for researchers, innovators and policy makers to use this electronic health data in a trusted and secure way that preserves privacy.

Primary use
(healthcare, social care)

Secondary use **digheten**
(e.g. research)

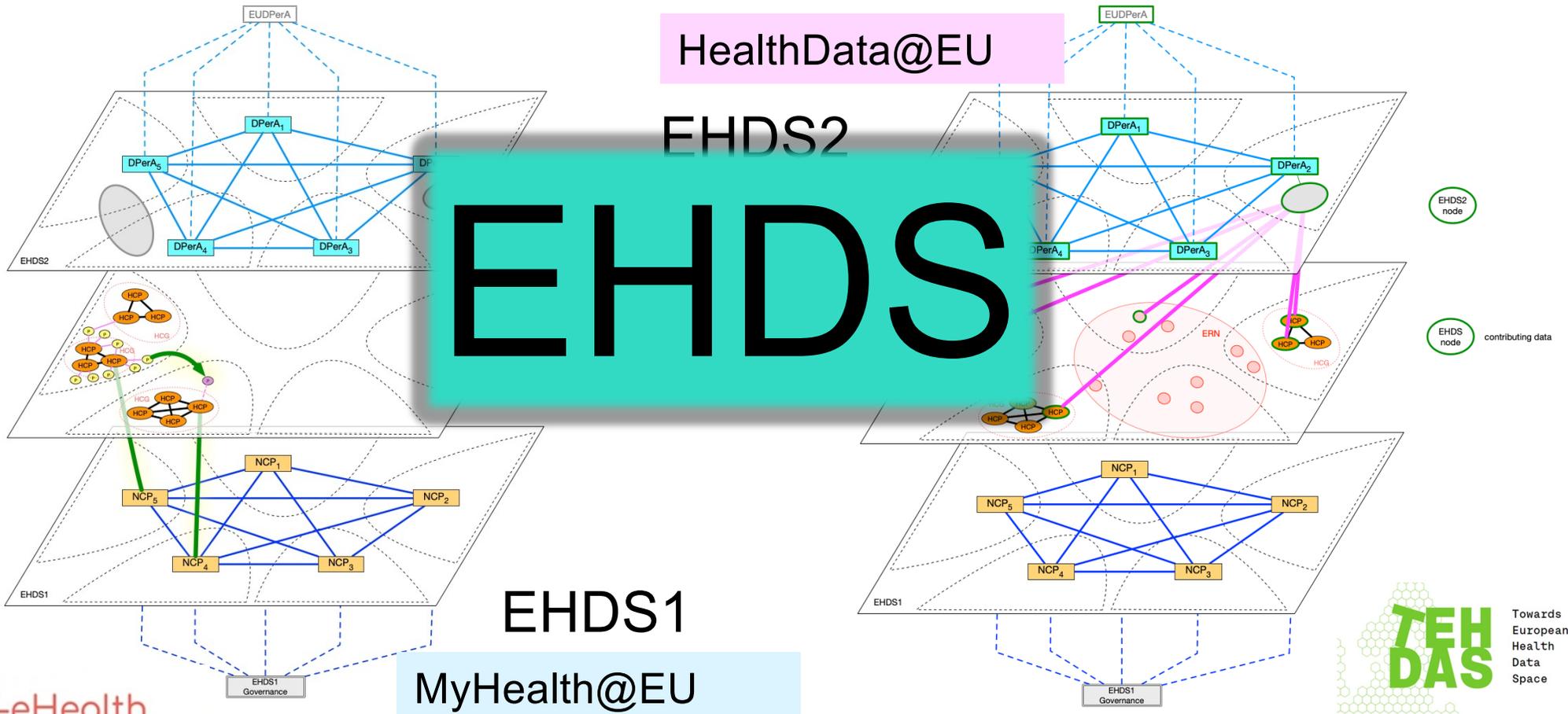
HealthData@EU

EHDS2

EHDS

EHDS1

MyHealth@EU



Proposal EHDS Act

- Chapter I – General provisions
 - Chapter II – Primary use of electronic health data
 - Chapter III – EHR systems and wellness applications
 - Chapter IV – Secondary use of electronic health data
 - Chapter V – Additional actions
 - Chapter VI – European governance and coordination
 - Chapter VII – Delegation and Committee
 - Chapter VIII – Miscellaneous
 - Chapter IX – Deferred application and final provisions
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Proposal EHDS Act

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The general objective is to ensure that natural persons in the EU have increased control in practise over their electronic health data.

- Therefore, the EHDS sets essential requirements specifically for EHR systems in order to promote interoperability and data portability of such system, which would allow natural persons to control their electronic health data more effectively.
- The EHDS will help to attain the Commission's vision for EU's digital transformation by 2030, the Digital Compass aim of providing 100% of natural persons with access to their medical records and Declaration of Digital Principles.

Electronic health data

according to EHDS:

- *Personal electronic health data* means data concerning health and genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services, processed in an electronic form.
 - *Non-personal electronic health data* means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679
 - *Electronic health data* means personal or non-personal electronic health data.
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Article 1

Subject matter and scope

1. This Regulation establishes the European Health Data Space (EHDS) by providing for rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of electronic health data.

2. This Regulation:

(a) strengthens the rights of natural persons in relation to the availability and control of their electronic health data

Article 3

Rights of natural persons in relation to the primary use of their personal electronic health data

- **right to access** their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form
 - **right to receive an electronic copy**, in the European electronic health record exchange format (EEHRxF)
 - Member States **may restrict** the scope of this right whenever necessary for the protection of the natural person based **on patient safety and ethics**
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Article 3 (continued...)

Rights of natural persons in relation to the primary use of their personal electronic health data

- may **insert** their electronic health data in their own EHR or in that of natural persons whose health information they can access. That information shall be **marked** as inserted by the natural person or by his or her representative.
- right to **rectification** under Article 16 of Regulation (EU) 2016/679
- right to **give access to** or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder.

Article 3 (continued...)

Rights of natural persons in relation to the primary use of their personal electronic health data

- right that, where the data holder and the data recipient are located in **different Member States** the data holder shall **transmit** the data (according to Article 5) in EEHRxF and the data recipient shall read and accept it.
- right to **restrict access** of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.
- right to obtain information on the healthcare providers and **health professionals that have accessed** their electronic health data in the context of healthcare. The information shall be provided immediately and free of charge through electronic health data access services.

- ...under **MyHealth@EU**, natural persons will be able to effectively share their personal electronic health data in the **language** of the country of destination when travelling abroad or take their personal electronic health data with them when moving to another country.
- The implementation of actions for natural persons' control of and access to personal electronic health data for the provision of healthcare (Chapter II) will require **EUR 110 million**.
- ...include operations of the European digital health platform services for MyHealth@EU, Member States audits for National Contact Points for Digital Health as part of MyHealth@EU, support for uptake of international standards and support for patients' access to health data through MyHealth@EU.

Secondary use of health data according to EHDS:

Chapter IV EHDS:

Data holders shall make the following categories of electronic data available for secondary use

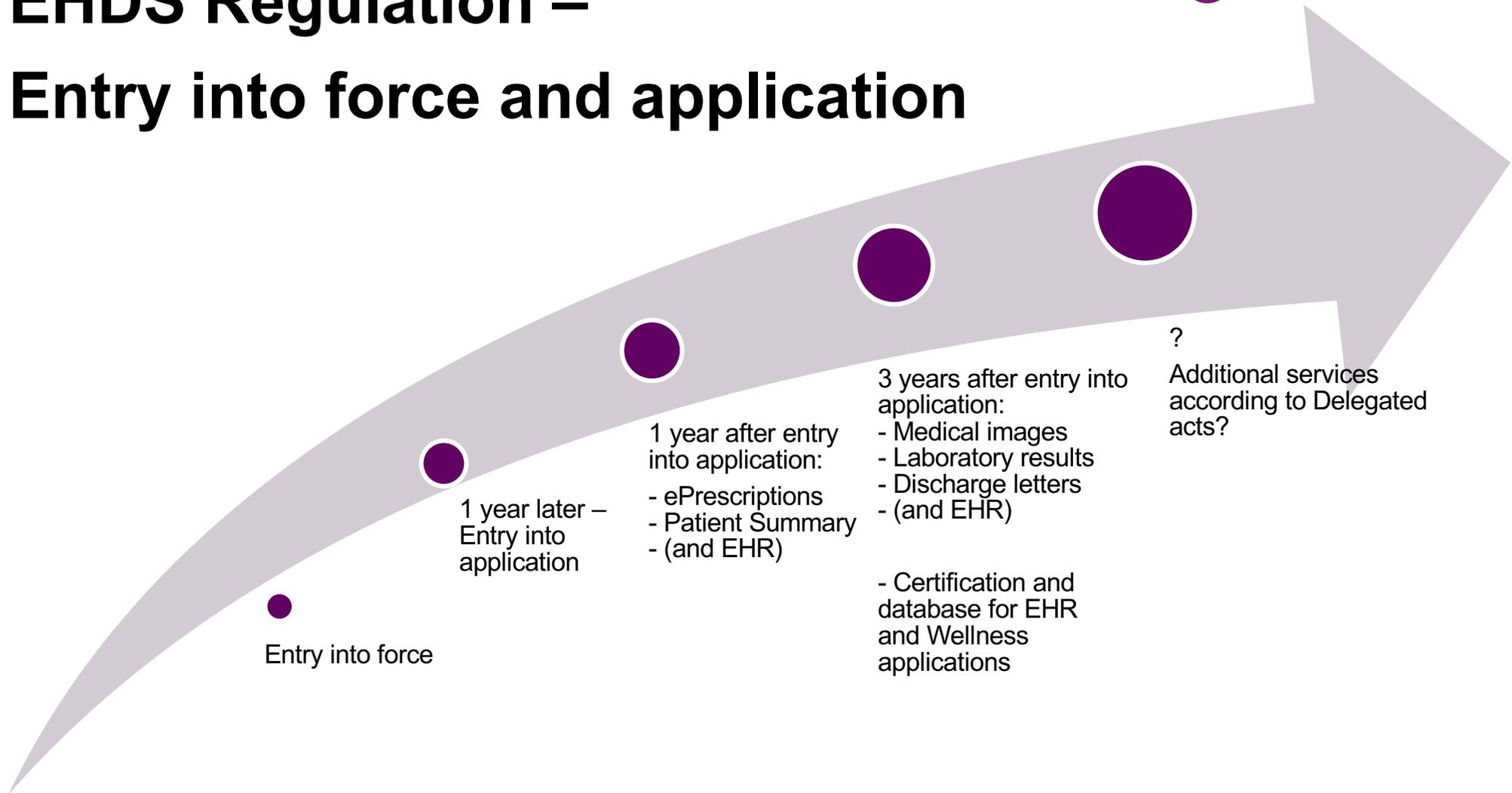
- a) EHRs
- b) data impacting on health, including social, environmental behavioural determinants of health
- c) relevant pathogen genomic data, impacting on human health
- d) health-related administrative data, including claims and reimbursement data
- e) human genetic, genomic and proteomic data
- f) person generated electronic health data, including medical devices, wellness applications or other digital health applications
- g) identification data related to health professionals involved in the treatment of a natural person
- h) population wide health data registries (public health registries)
- i) electronic health data from medical registries for specific diseases
- j) electronic health data from clinical trials
- k) electronic health data from medical devices and from registries for medicinal products and medical devices
- l) research cohorts, questionnaires and surveys related to health
- m) electronic health data from biobanks and dedicated databases
- n) electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health
- o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data permit.

Article 35

Prohibited secondary use of electronic health data

- (a) **taking decisions detrimental** to a natural person based on their electronic health data; in order to qualify as “decisions”, they must produce legal effects or similarly significantly affect those natural persons
- (b) **taking decisions** in relation to a natural person or groups of natural persons to **exclude them** from the benefit of an **insurance** contract or to modify their contributions and insurance premiums
- (c) **advertising or marketing activities** towards health professionals, organisations in health or natural persons
- (d) providing access to, or otherwise making available, the electronic health data to **third parties** not mentioned in the data permit
- (e) **developing products or services** that may **harm individuals and societies** at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality.

EHDS Regulation – Entry into force and application



EDPB/EDPS*

- ...the handle of **unexpected findings** by health data access bodies towards natural persons...
- ...unlike in the primary use, for which the Proposal allows natural persons to **restrict the access** to their personal data, the same option is **not afforded** with regard to **secondary use** of data.
- “[h]ealth data access bodies shall **not be obliged** to provide the specific **information** under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the **use of their data** for projects subject to a data permit (...)”...appears to undermine the rights of natural persons to privacy and to the protection of personal data.

**European Data Protection Board/European Data Protection Supervisor*

EDPB/EDPS

- relevant to ensure that data subjects with limited ability to access and use digital services are **not forced to rely on third parties** to exercise their fundamental rights and, consequently, are **not obliged to expose their privacy** and personal data to other natural persons to be able to request access to their data,
 - concept of **authorisation**...about general proxy services of access might not be sufficient to **ensure that the data subjects was not coerced** in any way to provide access to their data on their behalf to other natural persons of their choice.
 - such broad concept of authorisation without any safeguards opens the door to a **possible abusive use** of the right of access to electronic health data.
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EHDS negotiations and Swedish EU presidency



Sveriges EU-ordförandeskap 2023

Våren 2023 är Sverige ordförande i Europeiska unionens råd, även kallat ministerrådet. Ordförandeskapet innebär att Sverige under sex månader kommer att planera och leda arbetet i ministerrådet samt företräda rådet i förbindelserna med övriga EU-institutioner.



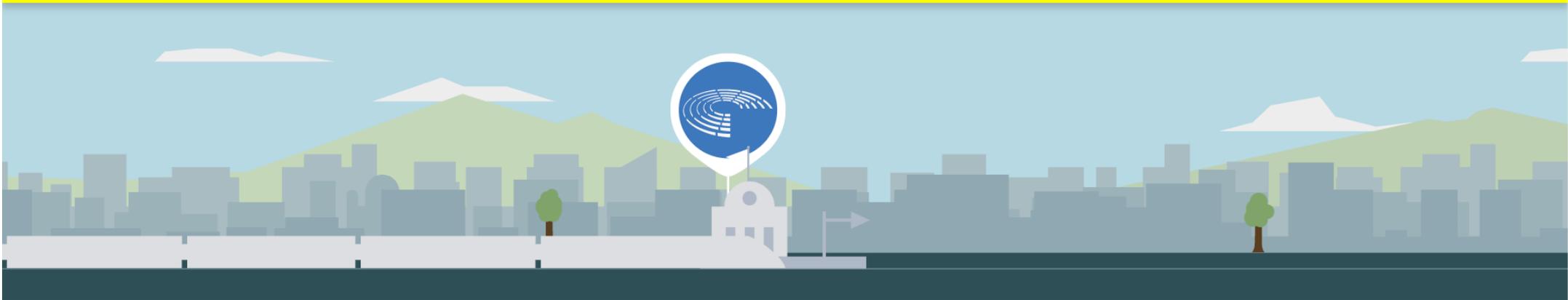


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Thank you!

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