The European Health Data Space

Overview

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Update on the EHDS regulation

EHDS is signed



Strasbourg, 11 February 2025

Signature & publication in OJ

Signature 12th of February 2025
Publication in the OJ 5th of March

26th of March 2025: Start of the transition period towards entry into application of the provisions



Updated Digital Health website !!!

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EHDS in a Nutshell – what is it about?

1. Primary use = use of data for the delivery of healthcare.
   - Ensuring patients' right to access their health data wherever they are in Europe;
   - Ensuring seamless exchanges of health data for continuity of care.

2. Secondary use = use of health data for a different purpose than the one they were initially collected for.
   - Making data available for research, innovation, policy-making etc. in a secure and streamlined way.

3. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health record systems, supporting both primary and secondary use with the European Electronic Health Record exchange format.

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2 Secondary Use

What are the benefits for whom?
Who will have to make which data available?
How can users apply for access to data?
What are the safeguards?
What infrastructures will provide support?

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EHDS in a Nutshell – Secondary Use

Secondary use = reuse of data for research and policy making

How?

- Common European rules on who has to make which data available for which purposes and under which conditions
- No need for patient consent to access data, possibility for citizens to opt-out from the reuse of their health data

Safeguards

Secure Processing Environment (SPE)



Data access only to **authorised users.**

State-of-the-art measures to prevent unauthorized data modification, access, or removal.

Download of personal data strictly prohibited.

Only aggregated results and fully anonymized data can be extracted.

Additional Safeguards



Allowed and prohibited purposes.

Legal and organizational measures to protect intellectual property and personal data.

Obligations to **inform individuals about data use** and their rights under data protection laws.

Public transparency on data processing activities and outcomes.

Natural persons shall have the right to opt-out from the secondary use of their health data

at **any time** + **without stating reasons**

this right is reversible

through an easily accessible and understandable mechanism

*with the possibility for MS to have rules to ensure that for **selected purposes of public interest**, on **a case-by-case basis** and under **strict conditions**, also data of opted-out people may be made available*

Data Minimization and Purpose Limitation

Access limited to data adequate, relevant, and necessary for specific, approved purposes.

Pseudonymized data provided unless anonymized data suffices, with strict controls on de-identification.

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Data holders : who is in scope ?



- Any natural or legal person, public authority, agency or other body in the **health or care sectors**; including reimbursement services when necessary;
- Any natural or legal person **developing products or services** intended for the health, healthcare or care sectors; developing or manufacturing wellness applications;
- Any natural or legal person **conducting research** related to the healthcare or care sectors;
- Any natural or legal person acting as a **mortality registry**;
- As well as any institution, body, office or agency of the Union;

+

Having the right or obligation to process

or the ability to make these data available.

established in the EU

Exemptions

Individual researchers and natural persons

Micro-enterprises as per Recommendation 2003/361/EC

National provisions

Possibility for MS to extend obligations to exempted entities.

Possibility for MS to designate intermediary entities to fulfill these duties.

Notification to the Commission of any relevant national legislation.

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Data categories

electronic health data from **EHRs**;

healthcare-related **administrative data**, including dispensation, claims and **reimbursement** data

human **genetic, epigenomic and genomic** data;

other **human molecular** data such as proteomic transcriptomic, metabolomic, lipidomic and other omic data;

automatically generated personal electronic health data, through **medical devices**;

data from **wellness applications**;

other health data from medical devices.

Data on factors impacting health, including **socio-economic, environmental and behavioural determinants** of health;

Aggregated data on **healthcare needs**, **resources** allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;

Pathogen data, impacting on human health

population-based health data **registries** (public health registries);

data from medical registries and **mortality registries**;

data from registries for medicinal products and medical devices;

health data from **biobanks** and associated databases.

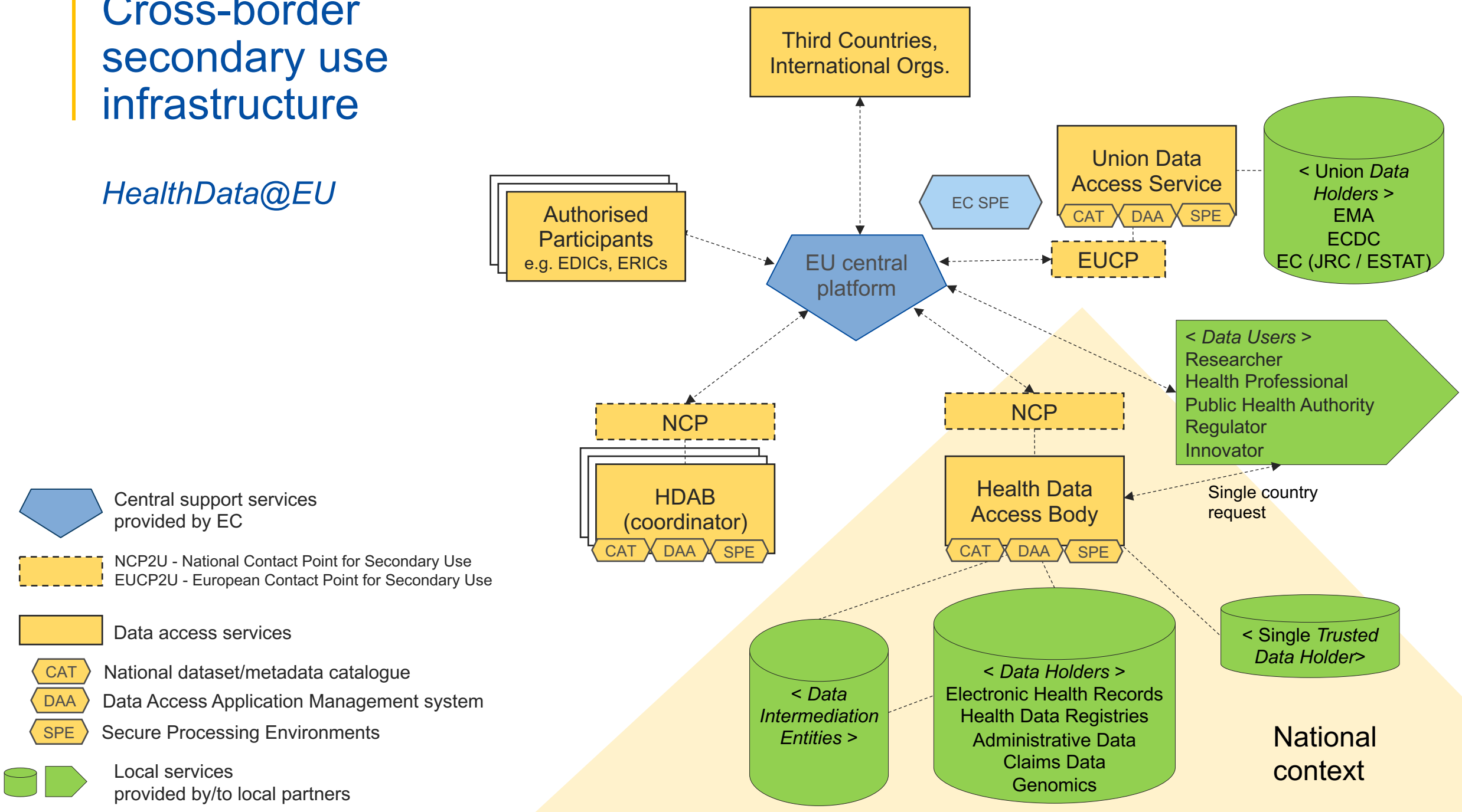
data from **clinical trials**, **clinical studies** and clinical investigations subject to Regulation (EU) 536/2014, Regulation [SOHO], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively;

data from **research cohorts, questionnaires** and surveys related to health, after the first publication of results

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Cross-border secondary use infrastructure

HealthData@EU



User journey of a researcher on Ewing's sarcoma (3 in 1 M)

Data user

Data discovery — What health data exists to support my research?

Central Services → Central EU metadata catalogue → Metadata records from 27 member states

Data access application — Can I use this data for my research project?

Multi-country data access application

Data preparation — Issue permit and make data ready for use, ensuring data quality and privacy.

Health Data Holders

Health Data Access Body

Data provision — Give access to Secure Processing Environment

Central Services → Gather datasets from 27 member states in the EC SPE for analysis.

SPE

Data use — Analyse and process data

Data User

Results output — Publish results, ensuring privacy and verifiability

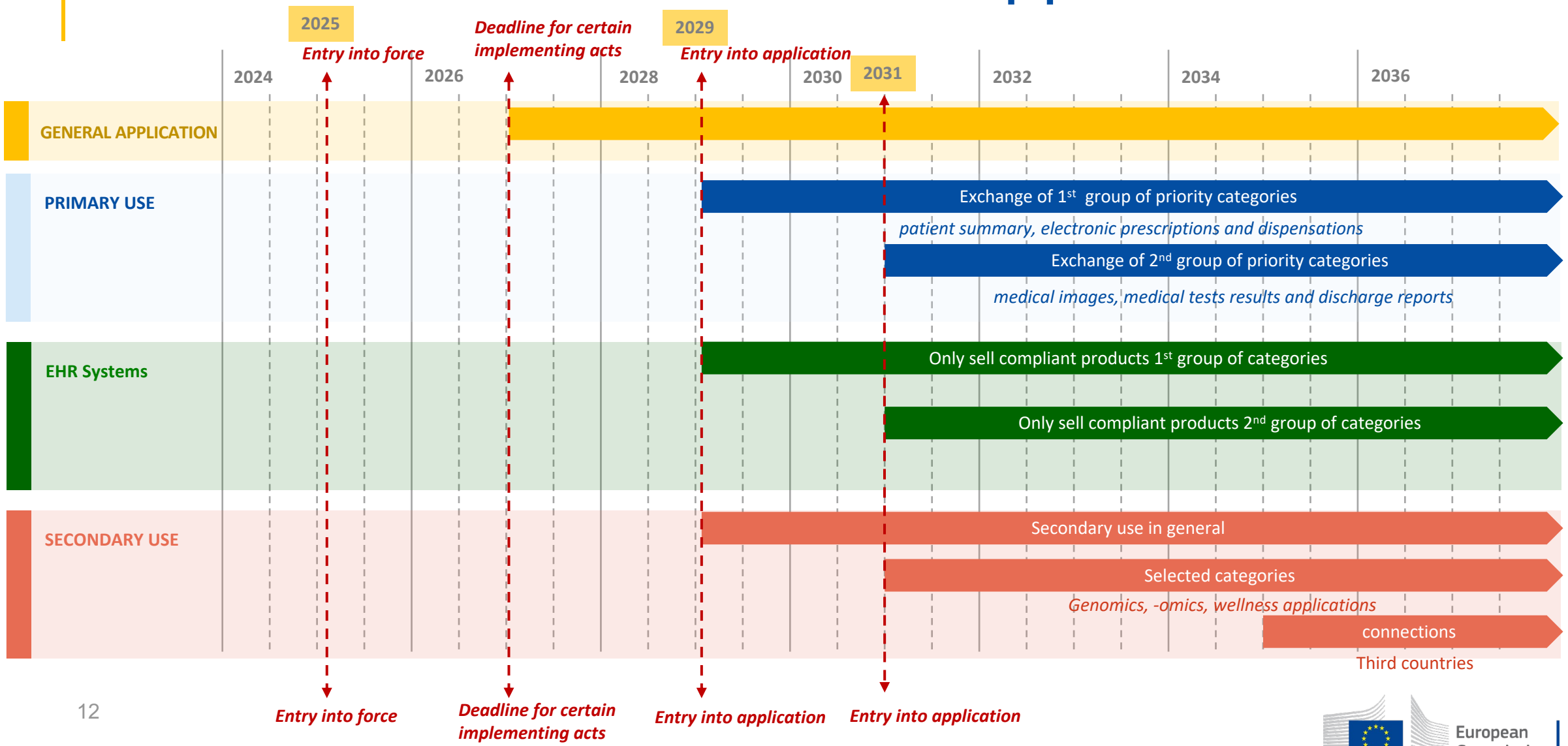
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Timelines and implementation

By when will all of this happen?
How do we get there?

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EHDS – Overall timeline for application



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Interplay with EOSC

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EOSC - Health Data Task Force

- EOSC can support the EHDS implementation with the provision of services and tools to support data holders, HDABs and data users.
  - Improving data quality at source
  - Provision of compliant Secure Processing Environments
  - Compass for services, datasets and tools that have been developed as part of research projects and research or data infrastructures

Thank you!

Scan the QR code to learn more about the EHDS!

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