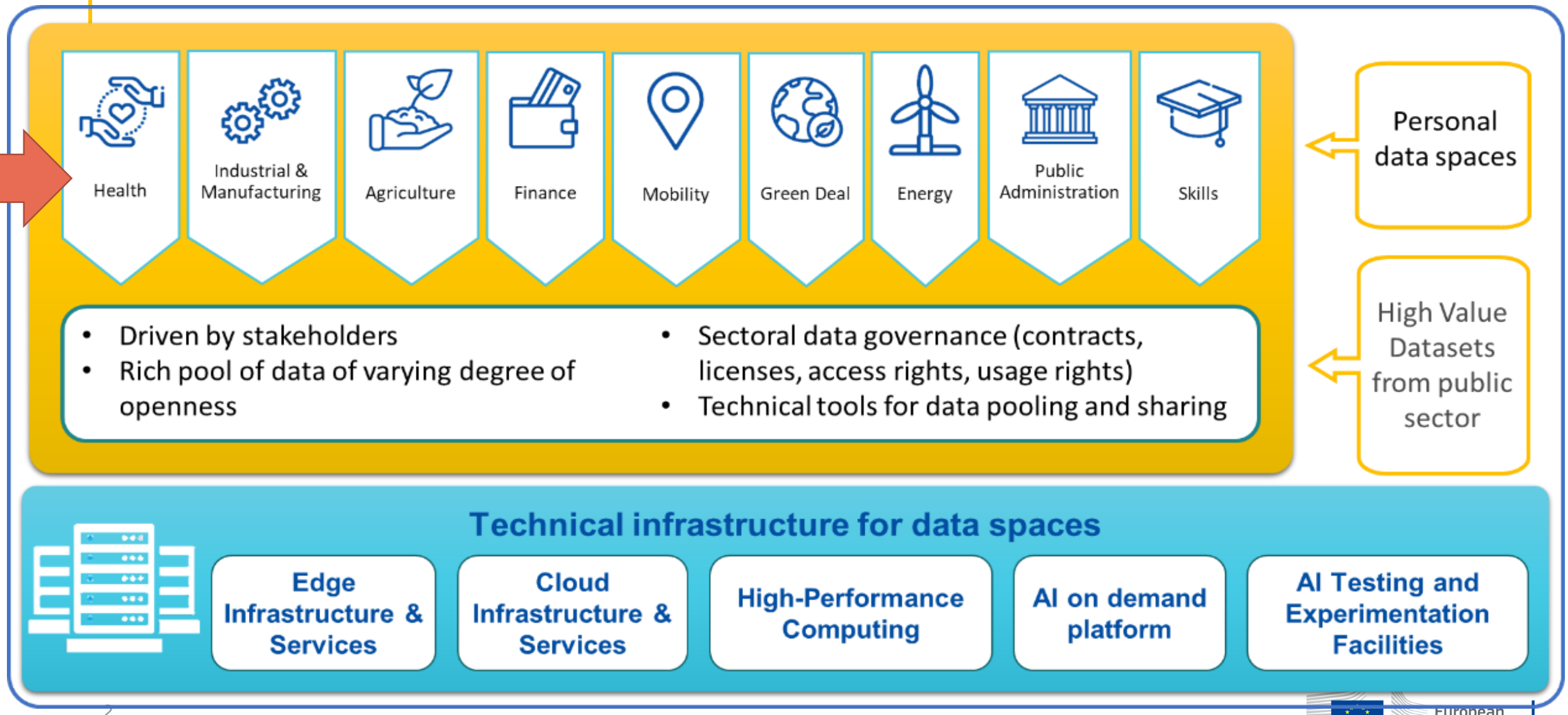
The European Health Data Space

Overview – Secondary use

Slovenian general assembly

SANTE C1

EHDS – the first sector specific European Data Space



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.

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?

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
- Common infrastructure: HealthData@EU
- Data catalogues of available datasets
- Permits for data use, common safeguards

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.

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

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**;

+

established in the EU

Having the right or obligation to process

or the ability to make these data available.

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.

European Commission

Prohibited and allowed purposes

- Making decisions detrimental to individuals or groups based on electronic health data, qualifying as decisions if they have legal, social, or economic impacts.
- Making employment-related decisions or offering less favorable terms in goods or services based on health data, including discriminatory decisions affecting insurance, credit, or loans.
- Conducting advertising or marketing activities.
- Developing products or services that could harm individuals, public health, or society, including illegal drugs, alcohol, tobacco, weaponry, or addictive products.
- Engaging in activities that conflict with ethical standards set by national law.

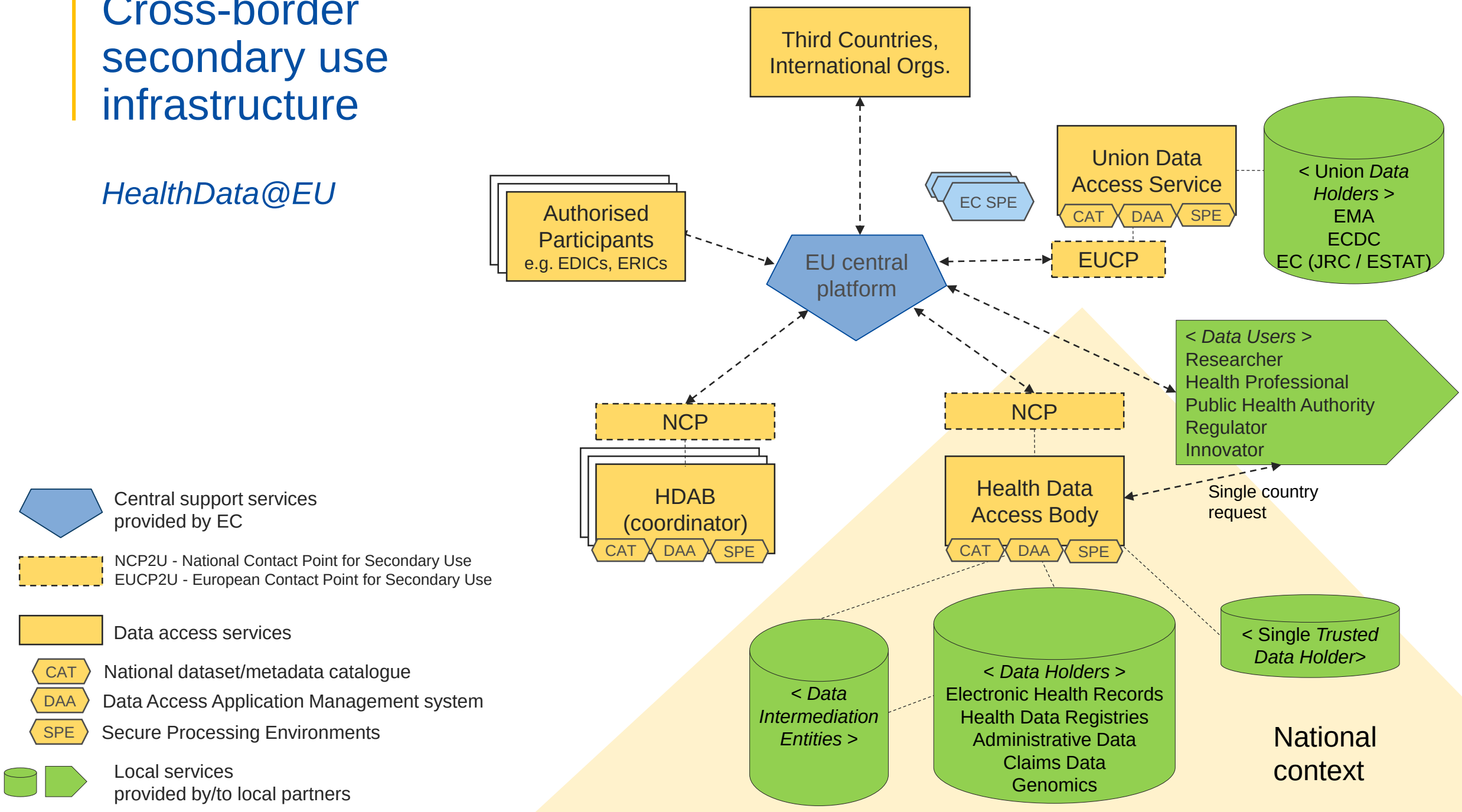
Reserved for public sector bodies *and Union institutions, offices, and agencies carrying out tasks under Union or national law, including third-party data processing on their behalf.*

- **Public interest in the area of public and occupational health**, such as activities for protection against serious cross-border threats to health and public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices;
- **Policy making and regulatory activities** to support public sector bodies or Union institutions, agencies and bodies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;
- **Statistics**, such as national, multi-national and Union level official statistics defined in Regulation (EU) No 223/2009 related to health or care sectors;

- **education or teaching activities** in health or care sectors at the level of vocational or higher;
- **scientific research** related to health or care sectors, **contributing to public health** or health technology assessment, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices, **with the aim of benefitting the end-users** including : development and innovation activities for products or services; training, testing and evaluating of algorithms, including in medical devices, in-vitro diagnostic medical devices, AI systems and digital health applications ;
- **improving delivery of care, treatment optimization and providing healthcare**, based on the electronic health data of other natural persons.

Cross-border secondary use infrastructure

HealthData@EU



User journey of a researcher

Data user

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

National datasets catalogue → Metadata records from genomic dataset and hospital (EHR) dataset

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

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

Health Data Holders

Health Data Access Body

Health Data Access Body → Linkage of datasets at individual level.

SPE

Data provision — Give access to Secure Processing Environment

Data use — Analyse and process data

Data User

Results output — Publish results, ensuring privacy and verifiability

European Commission

Timelines and implementation

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

Update on the regulation

Signature & publication in OJ

Signature 12th of February 2025

Publication in the OJ 5th of March

High-level conference to celebrate the adoption of the EHDS regulation

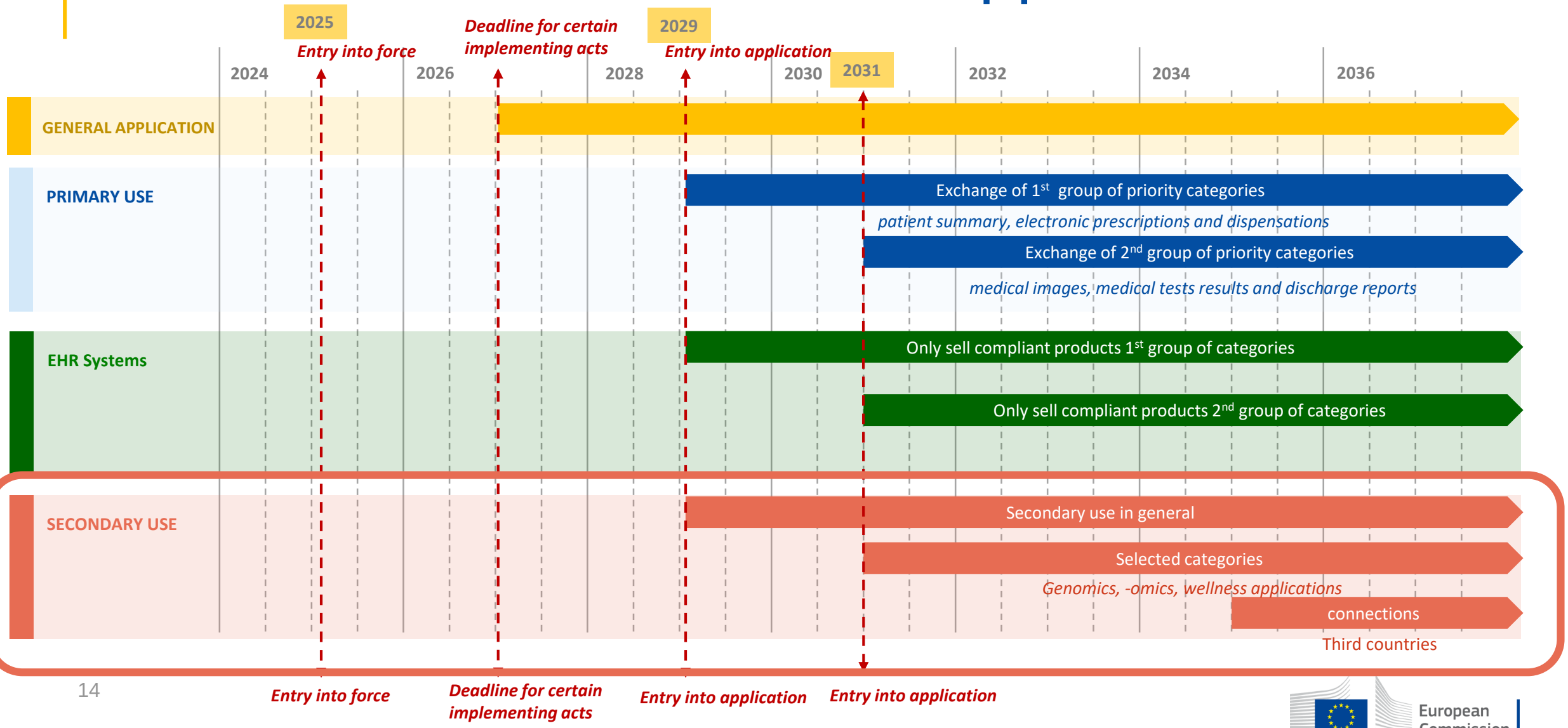
18th of March
Co-organised with the Polish Presidency in Brussels

Entry into force

26th of March
Start of the **transition period** towards entry into application!!!

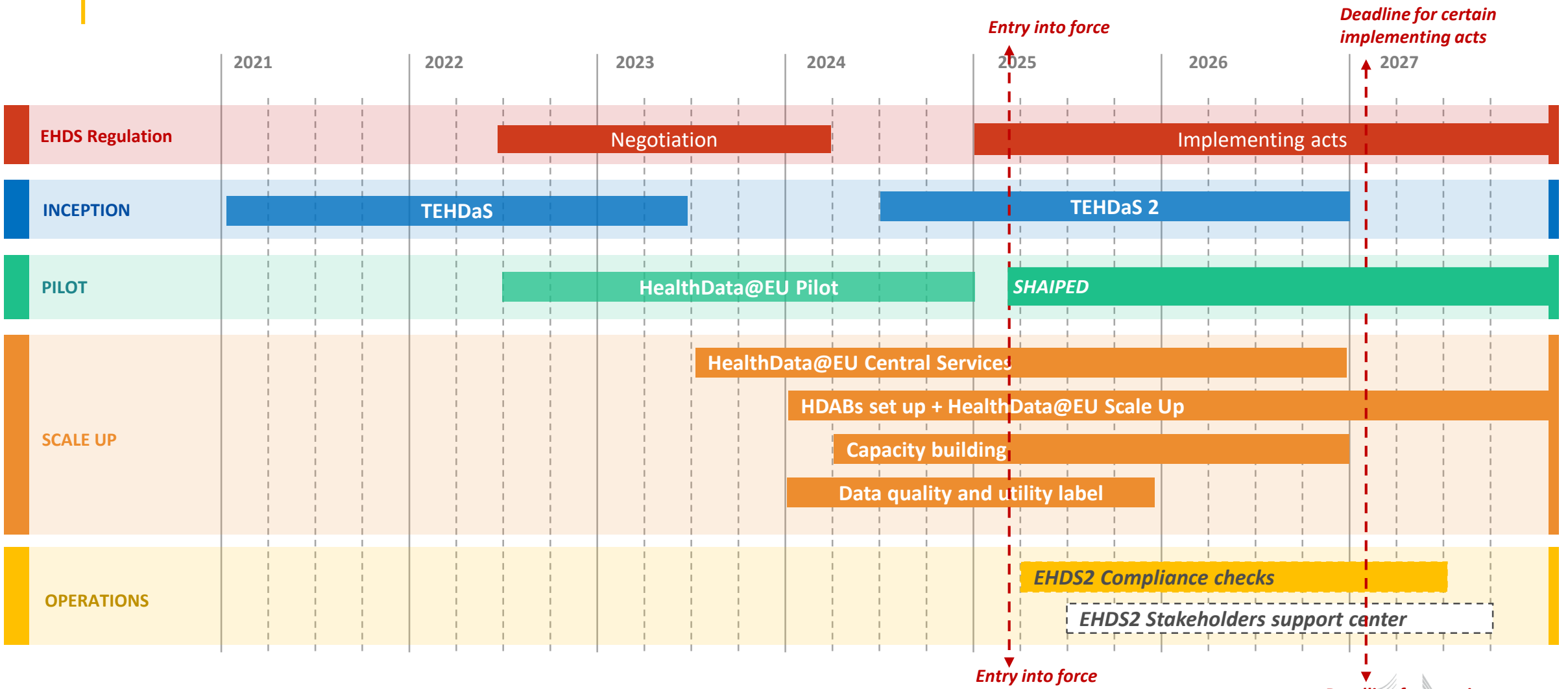
European Commission

EHDS – Overall timeline for application



European Commission

EHDS2 – Roadmap



European Commission

Thank you!