



The European Health Data Space

Overview – Secondary use

SANTE C1

EHDS in a Nutshell – what is it about?

1. Primary use = use of data for the delivery of healthcare
 - Improving patients' access to their health data;
 - Ensuring seamless exchanges for continuity of healthcare.
2. Secondary use = use of data for research and public interest purposes
 - Making data available for research, policy-making etc. in a safe and secure way.
3. Requirements for electronic health record (EHR) systems
 - Creating a single market for electronic health records systems, supporting both primary and secondary use.

EHDS in a Nutshell – Secondary Use

How?

- Common European rules on who has to make which data available for which purposes and under which conditions
- No need for consent to access data, only 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.



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*

Additional Safeguards



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.

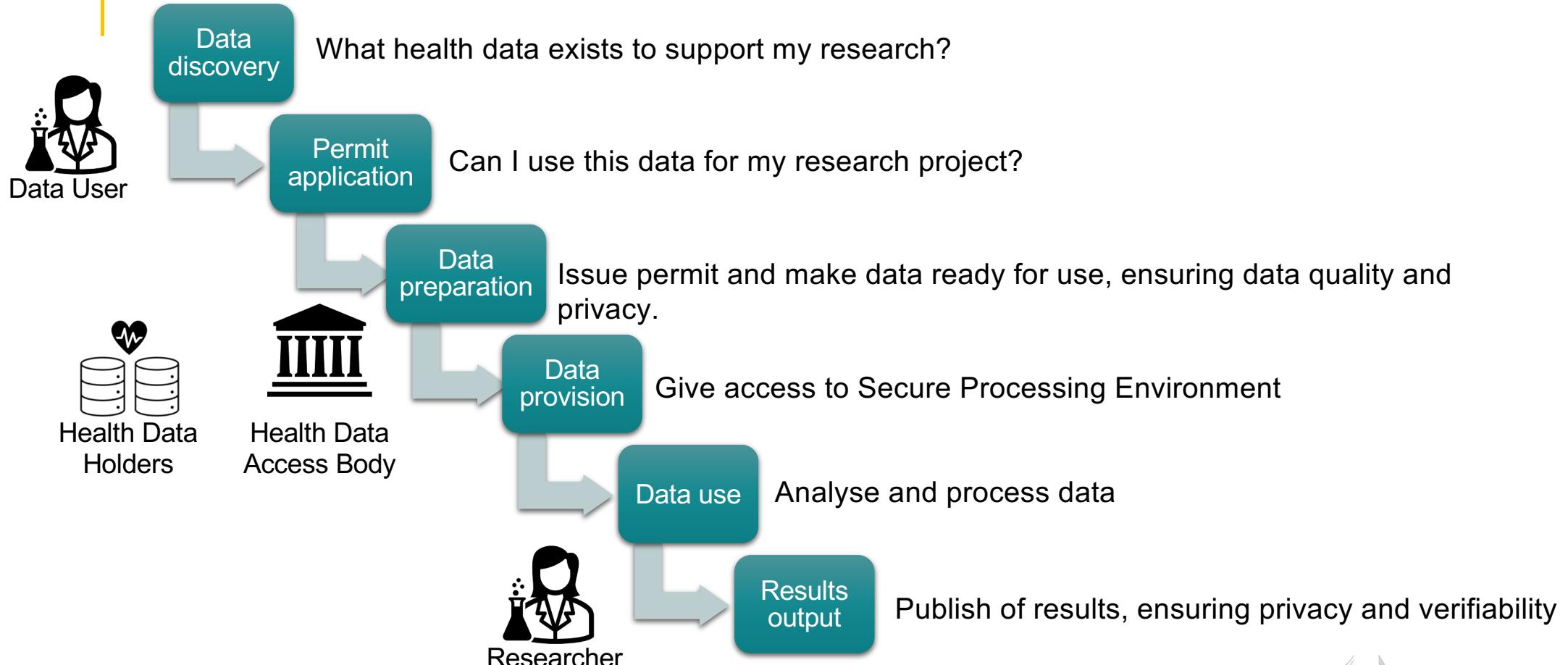
Public transparency on data processing activities and outcomes.

Data Minimization and Purpose Limitation

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

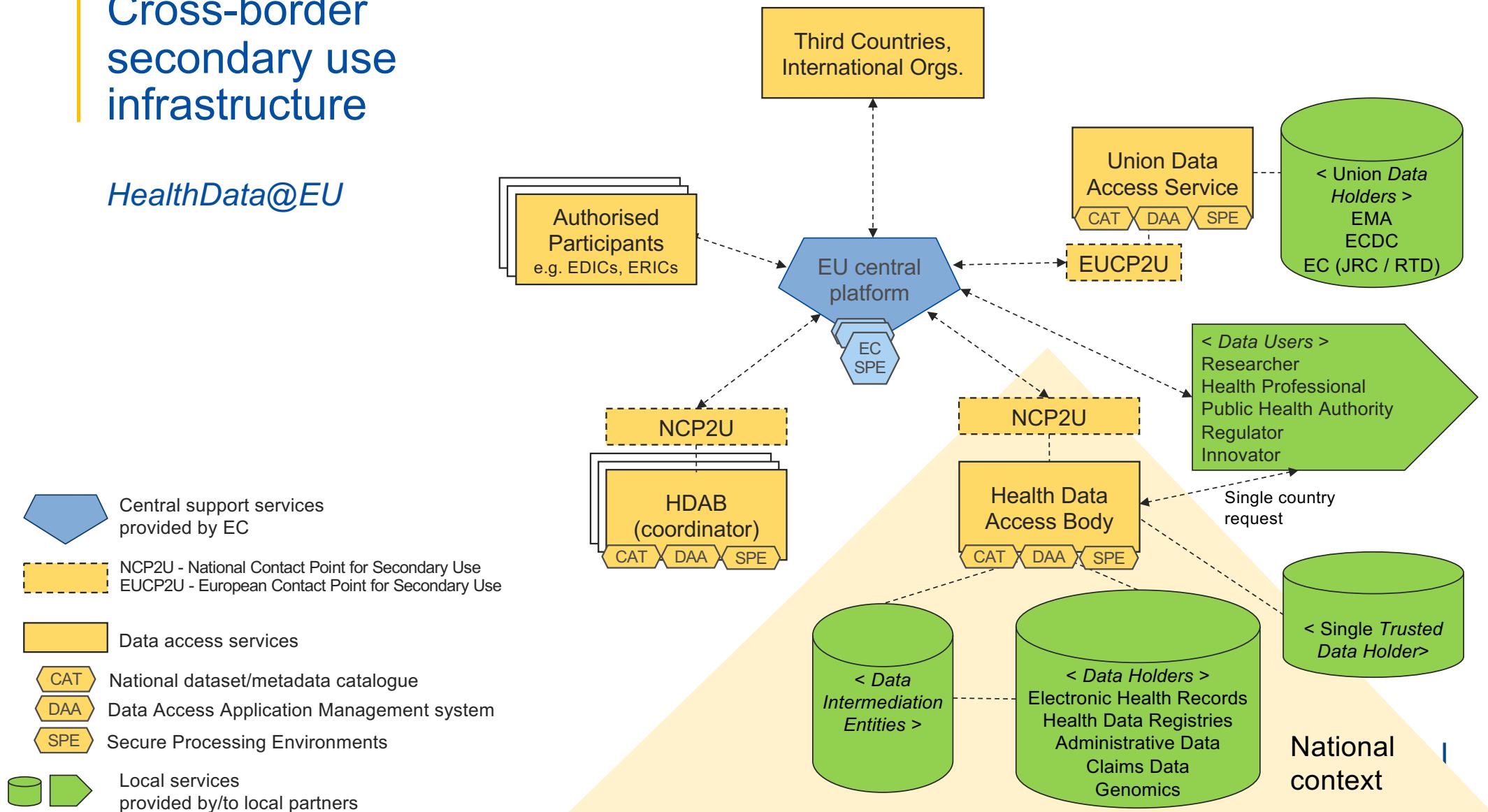
Pseudonymized data provided unless anonymized data suffices, with strict controls on de-identification.

Data User Journey

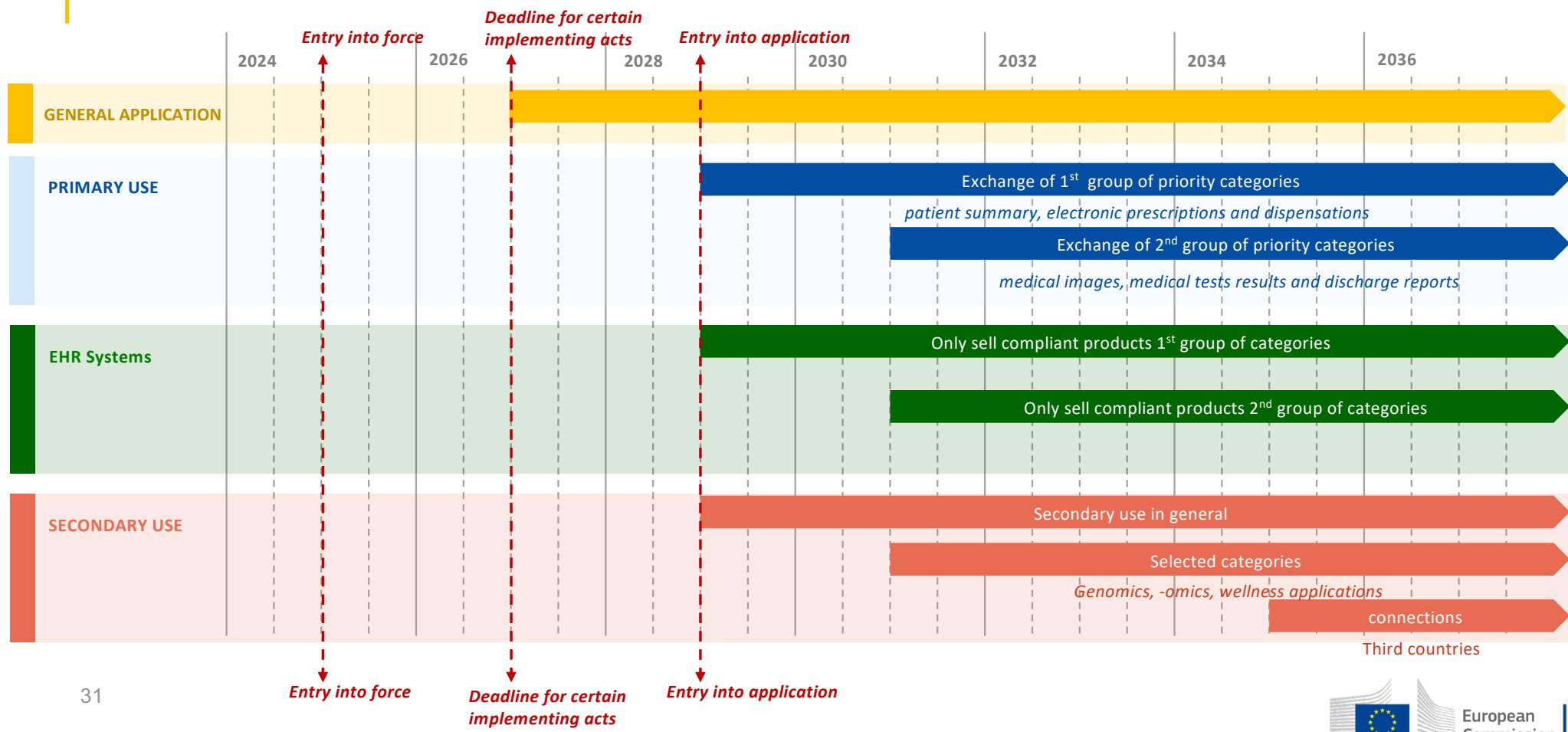


Cross-border secondary use infrastructure

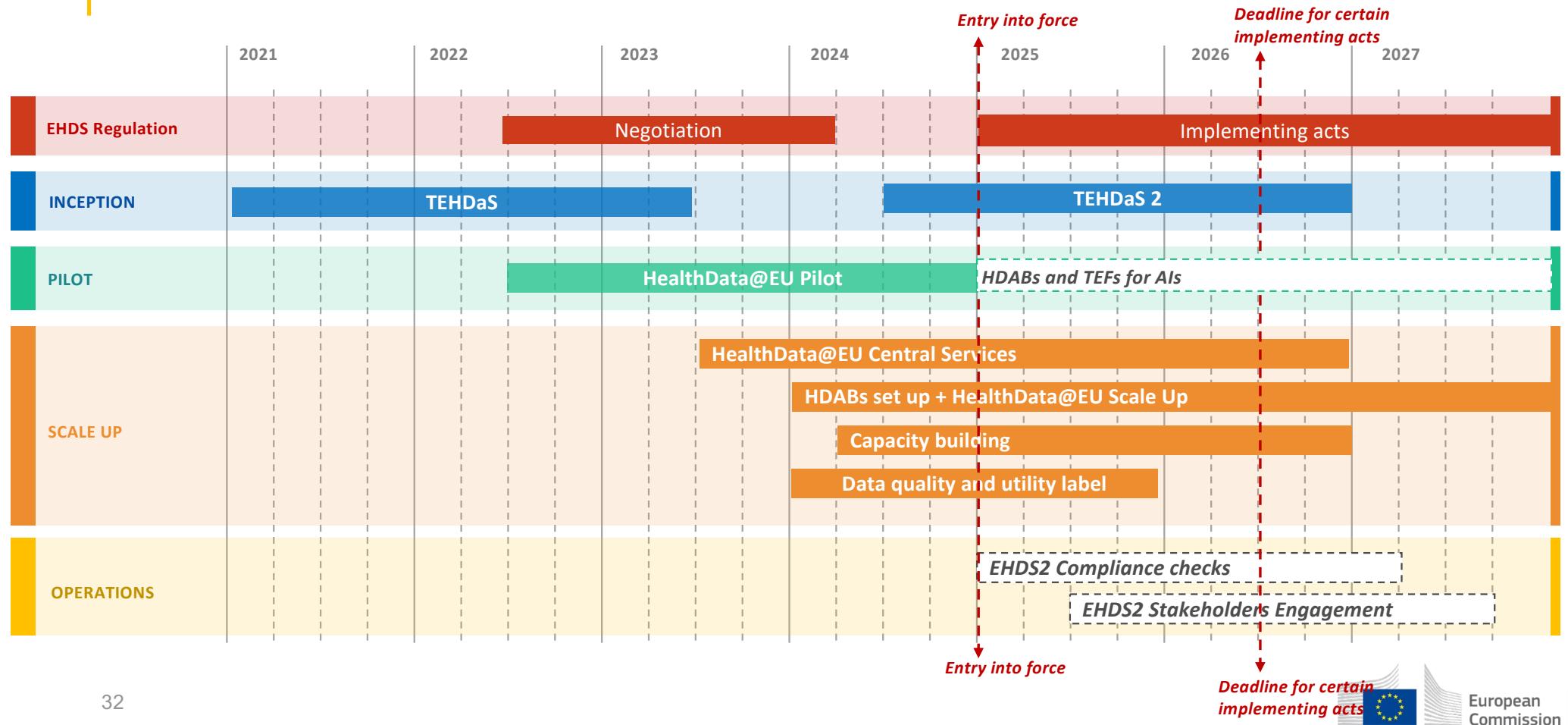
HealthData@EU



EHDS – Overall timeline for application



EHDS2 – Roadmap



Thank you!