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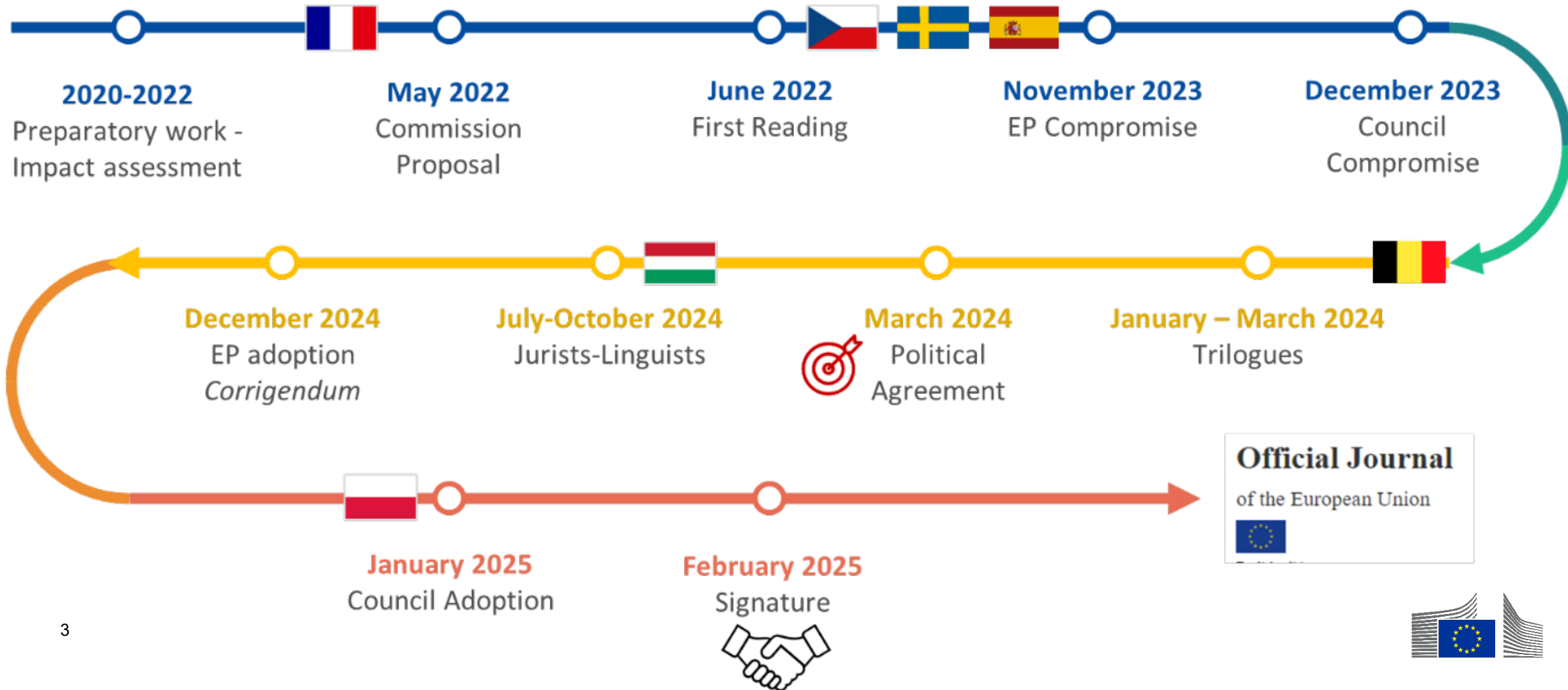
Main expertise: Digital health – Policy, legal and technical development of the European Health Data Space framework



European Health Data Space

Petr Cermak, EC DG SANTE C1

EHDS Roadmap



EHDS in a Nutshell – what is it about?

Three legs:

1. Primary use = use of data for the delivery of healthcare
2. Requirements for electronic health record (EHR) systems
3. Secondary use = use of data for research and public interest purposes



EHDS in a Nutshell – Primary Use

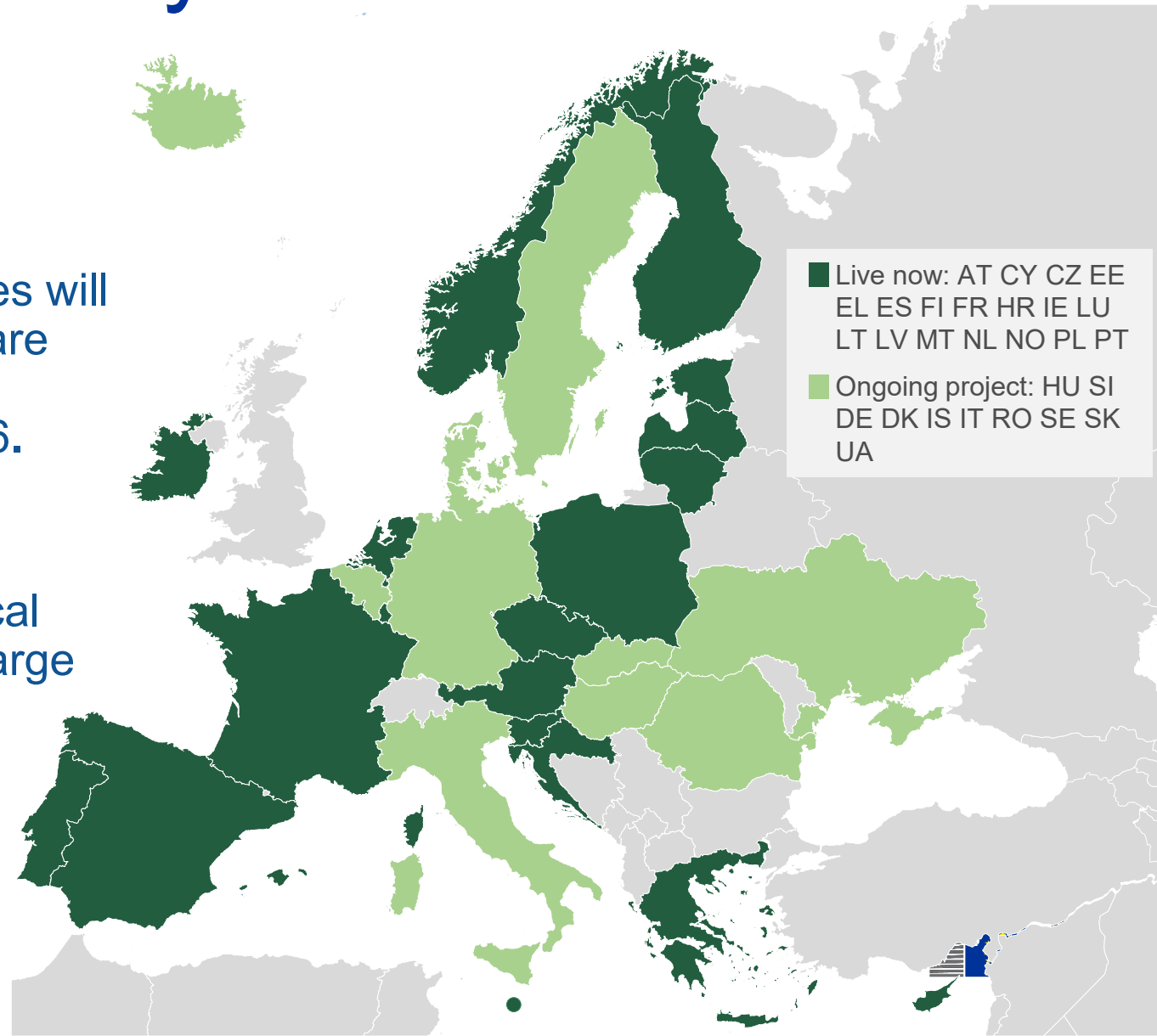
Primary use

- Strengthening patients' rights on defined categories of their own data;
 - Patient summary (include vaccination data);
 - Electronic prescription and dispensation;
 - Medical imaging studies and related reports;
 - Medical test results and related reports;
 - Discharge reports.
- Patient- and health professional-facing services to access data;
- Building on existing voluntary MyHealth@EU infrastructure, not touching upon national rules on provision of care / management of healthcare systems.



MyHealth@EU (primary use of health data)

- 17 Member States are live (+Norway)
- The number of connected Member States will grow rapidly in the years ahead - there are plans for most Member States and EEA countries to join **MyHealth@EU** by 2026.
- Currently there are 2 services: Patient Summary and ePrescription
- This is being expanded to include Medical imaging, Medical test results and Discharge reports



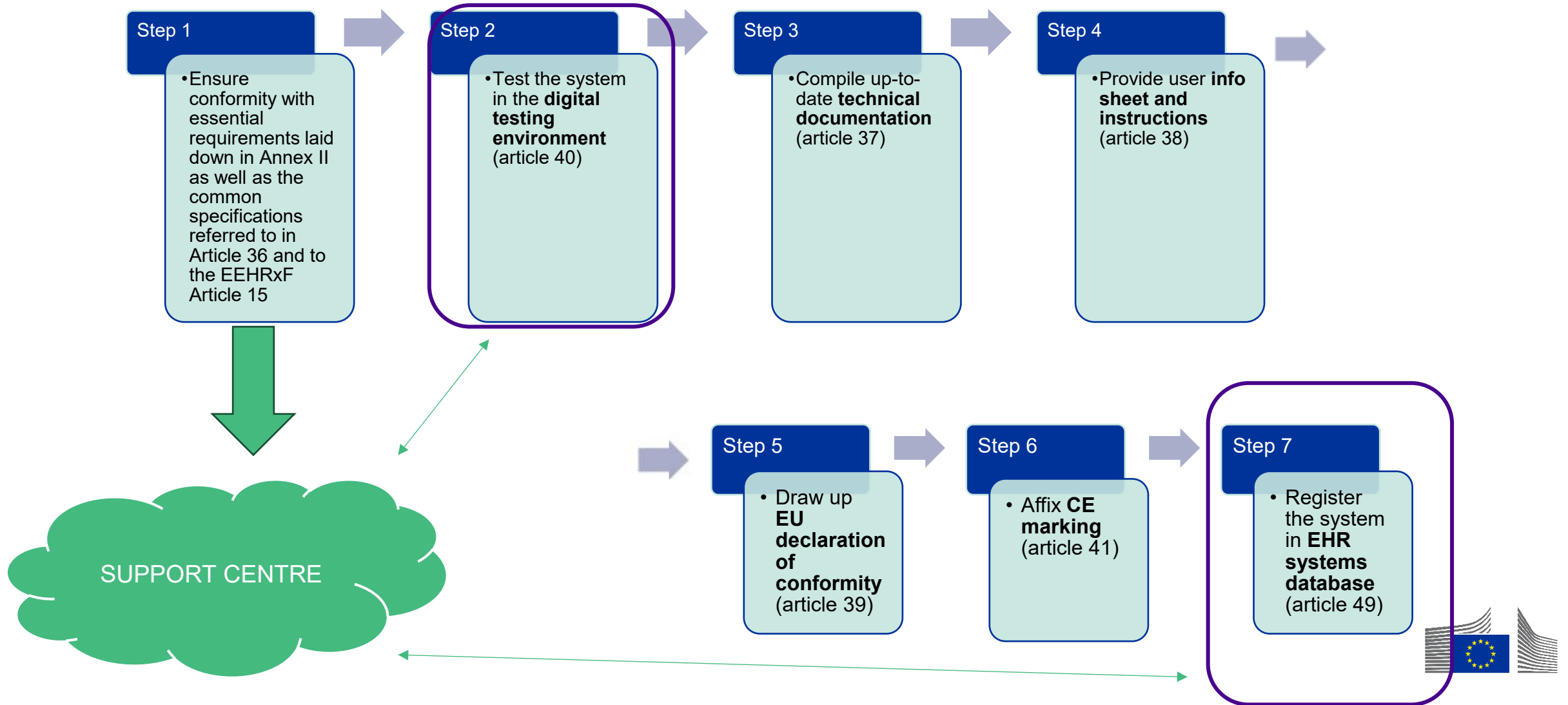
EHDS in a Nutshell – EHR systems

How?

- Product legislation for two components of EHR systems: interoperability and logging;
- Full harmonisation for those two components;
- Approach based on new legislative framework for product legislation, incorporating recent developments from other product legislation.



Certification of EHR systems (simplified)



EHDS in a Nutshell – Secondary Use

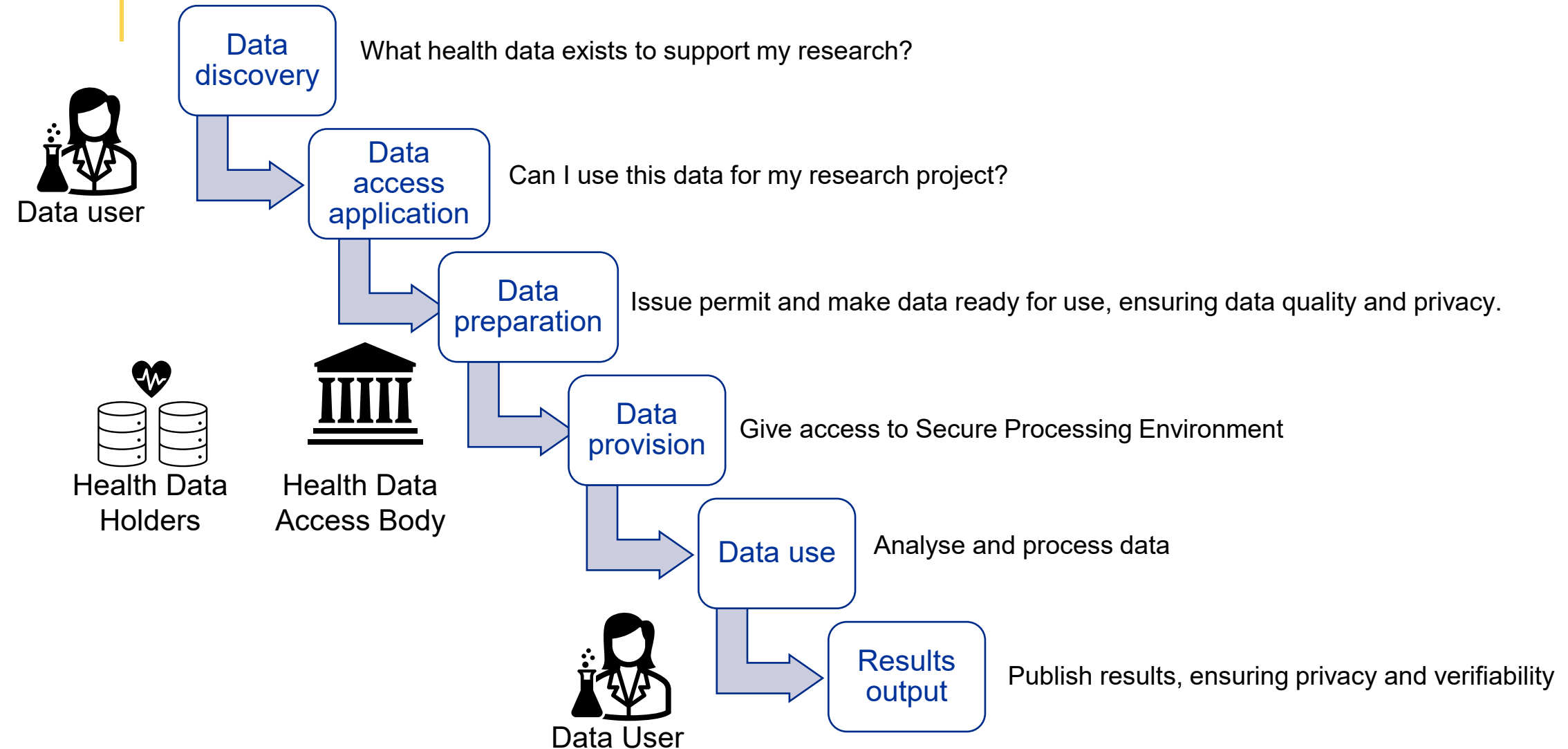
How?

- Common European rules on who has to make which data available for which purposes and under which conditions
- Common infrastructure
- Data catalogues of available datasets
- Permits for data use, common safeguards

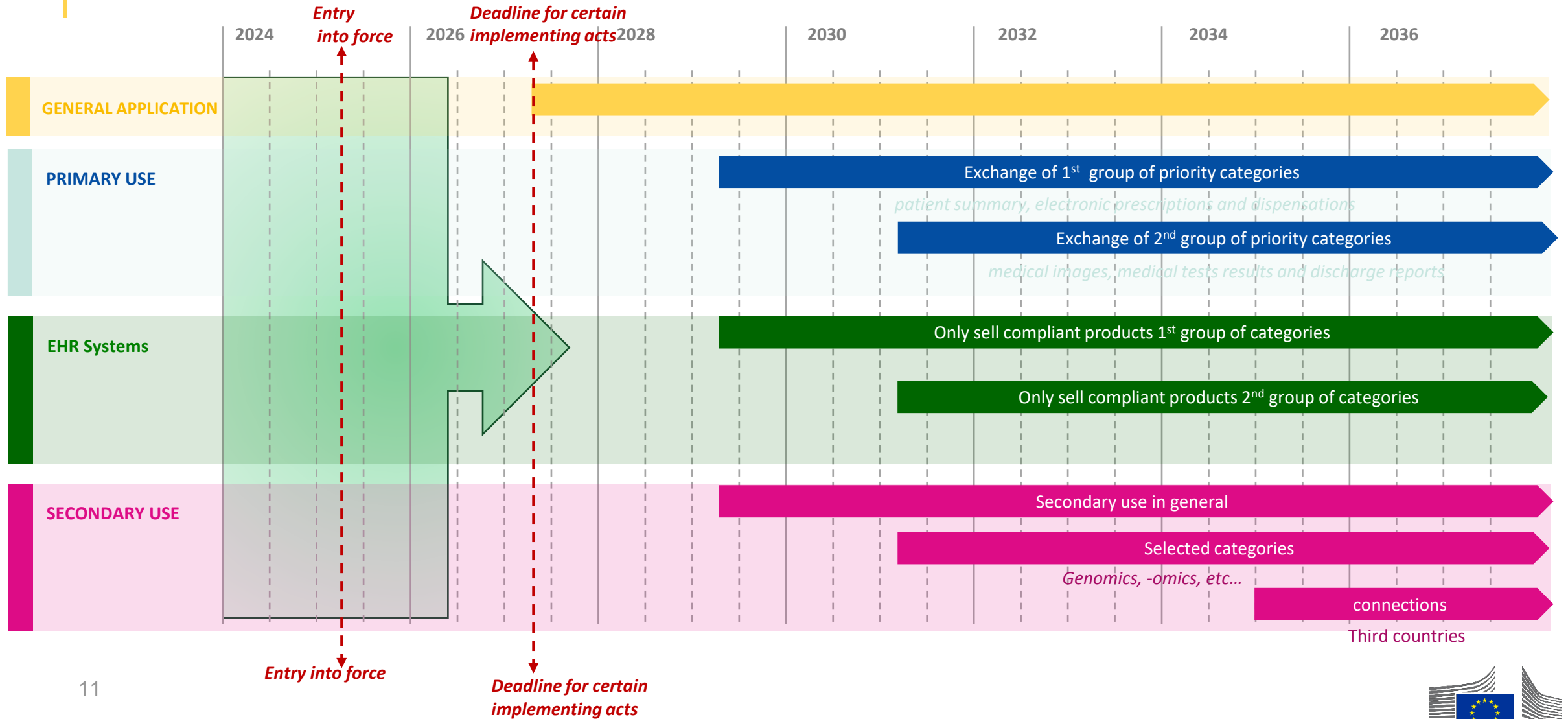
Vaccination registries are included in data categories for secondary use



User journey



EHDS – Overall timeline for application



Phases of implementation

- **Phase 1: Design and development**
 - 2 years - from now to March 2027 (adoption of key IA)
- **Phase 2: Consolidation and deployment**
 - 2 years - from March 2027 to March 2029 (following the adoption of key IA until entry into application of key provisions)
- **Phase 3: Operation and maintenance**
 - From March 2029 onwards (following the entry into application of remaining parts)



Thank you



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