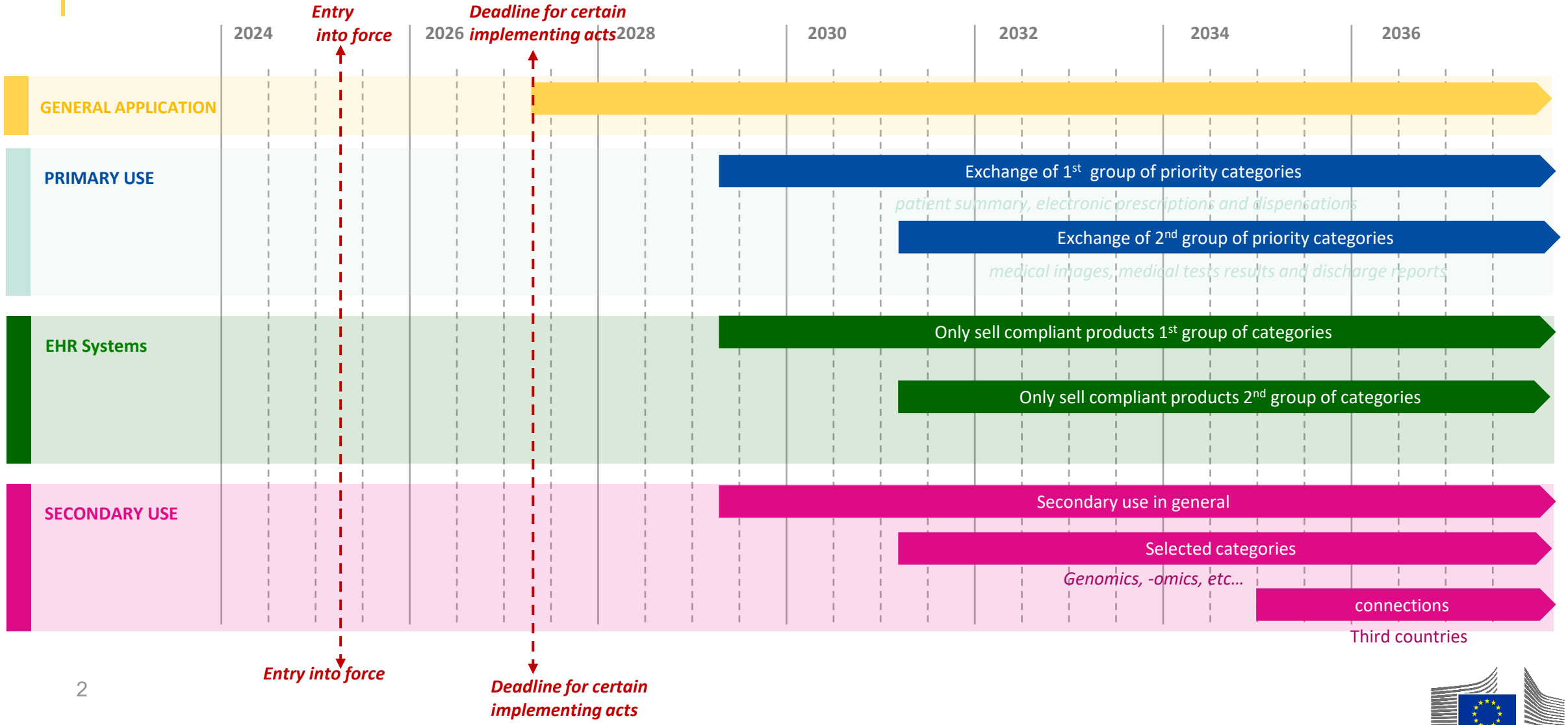
European Health Data Space

Status and next steps

European Commission

Article 105

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)

Adoption of implementing acts (and delegated acts)

- the European Electronic Health Record exchange Format (EEHRxF)
- Common specifications for EHR systems
- Digital testing environments for EHR systems
- MyHealth@EU, HealthData@EU
- secure processing environments
- EHDS Board

Adoption of implementing acts (and delegated acts)

- Cooperation with MS in drafting content of IA
- **Xt-EHR JA deliverables**
- Targeted consultation with MS, industry, and other relevant stakeholders

Targeted consultation + MS involvement

- Open **public consultation** period

MS involvement

- **Regulatory Committee** meets to discuss the IA

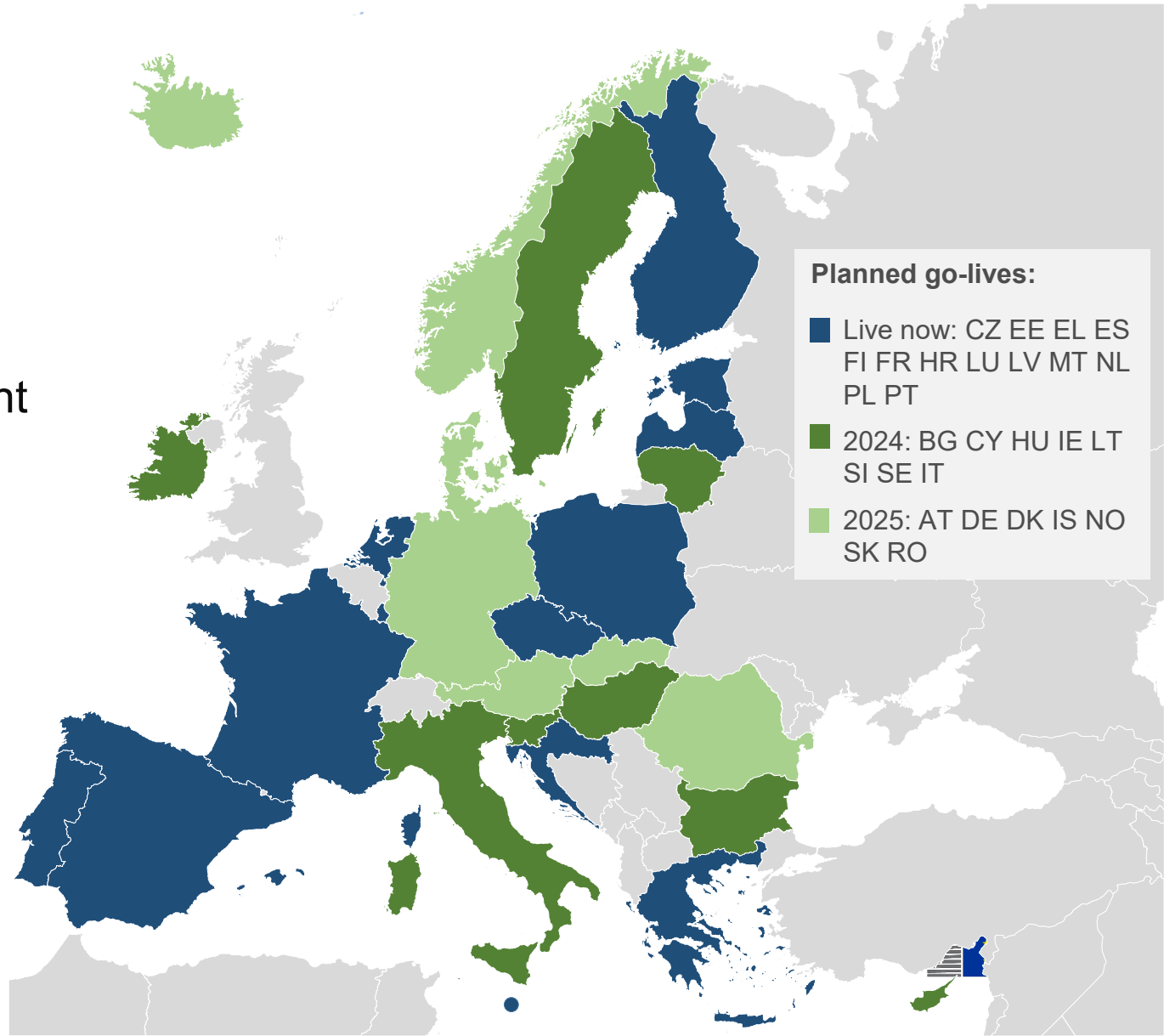
MS involvement

- Adopted IA published in the Official Journal of the EU

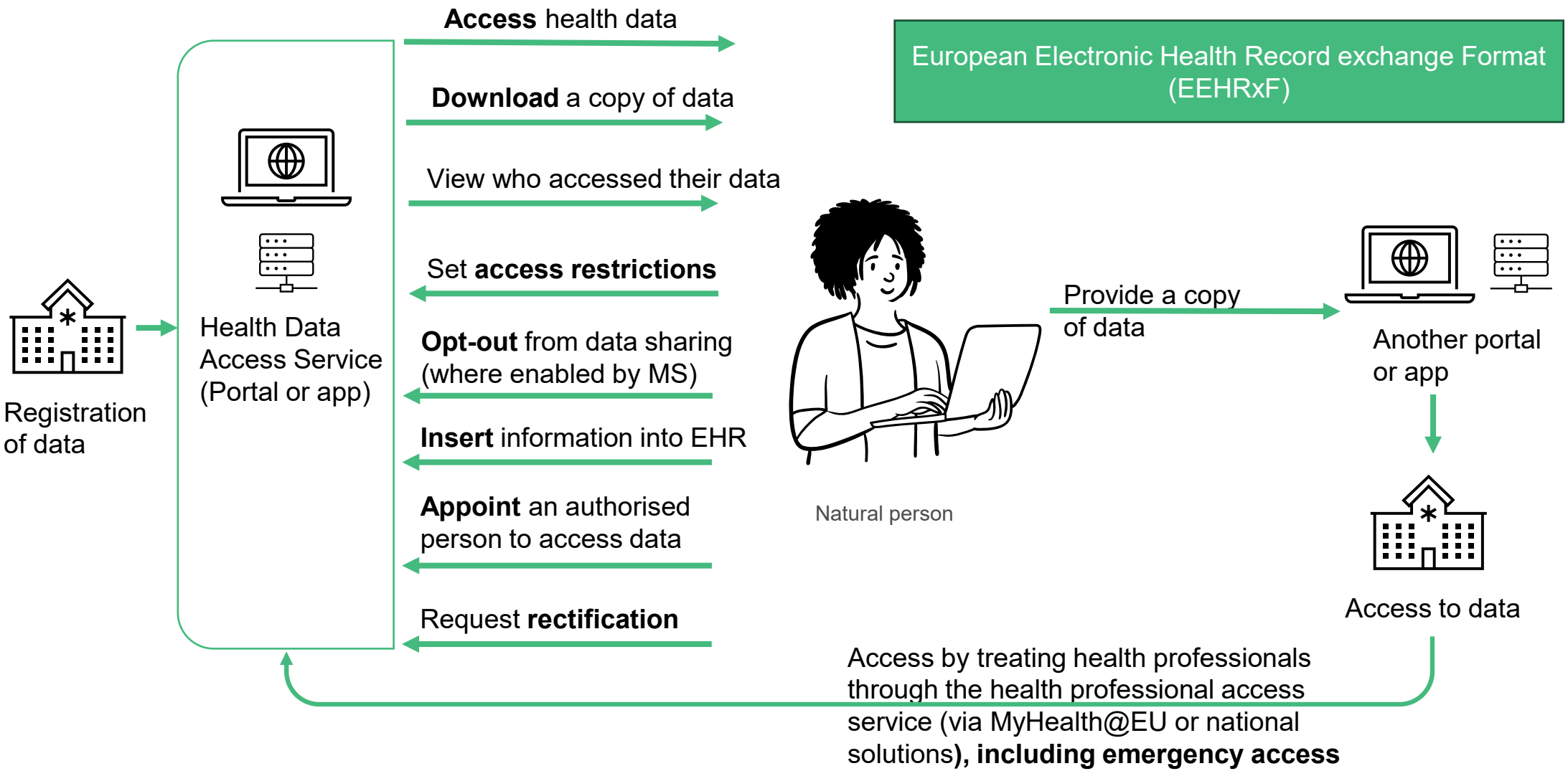
The process can take 4-6 months

Full rollout of cross-border infrastructures MyHealth@EU

- MyHealth@EU is the existing infrastructure that connects healthcare providers in 15 Member States.
- The current live services are: (1) Patient Summaries and (2) ePrescriptions.
- These services will be expanded to include (3) lab results, (4) hospital discharge reports and (5) medical images.
- Together they comprise the priority categories in EHDS.



Rights of natural persons in primary use



Priority categories

European Electronic Health Record exchange Format (EEHRxF)

Group 1

- Patient summaries
- Electronic prescriptions
- Electronic dispensations

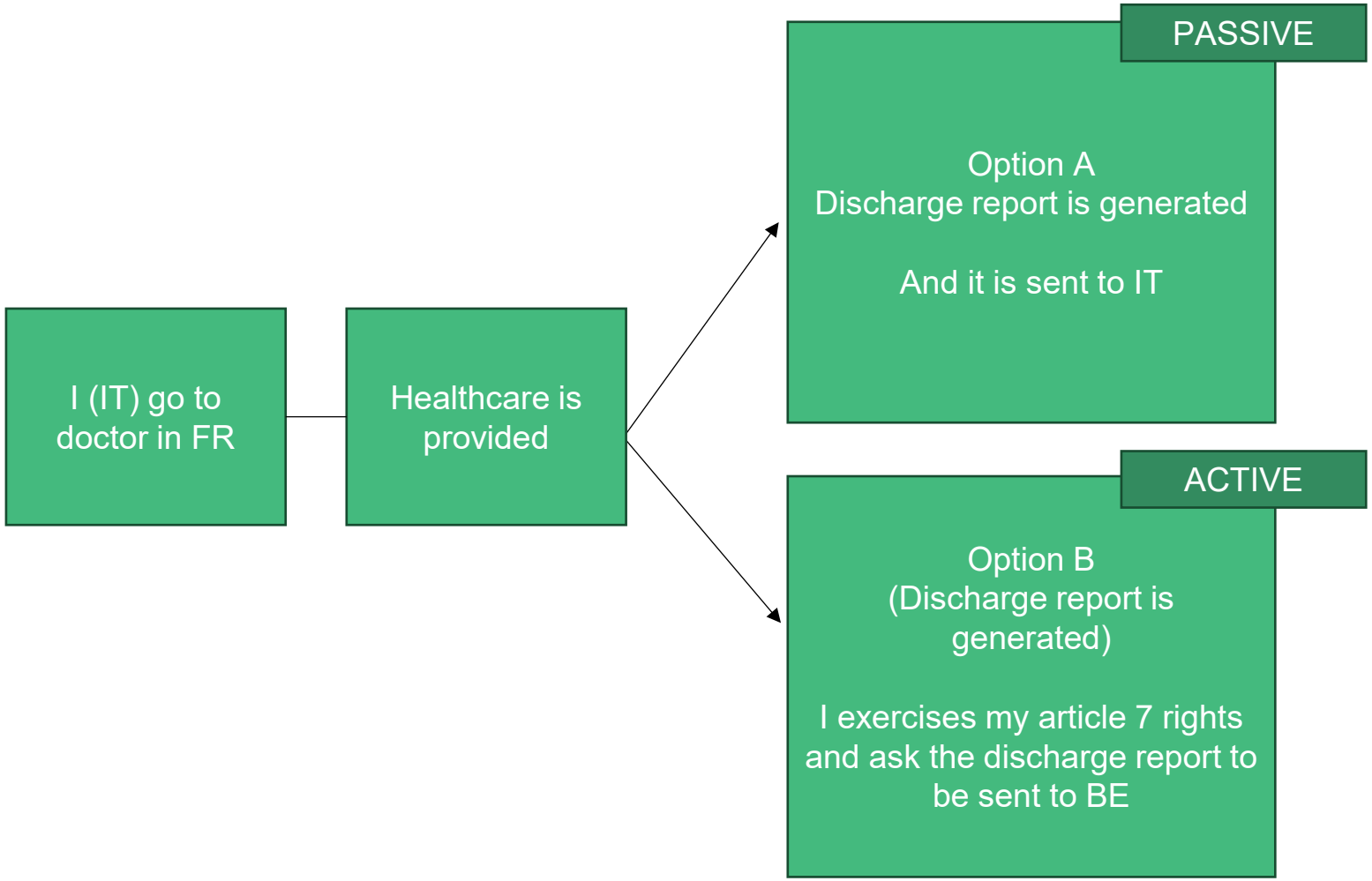
4 years

Group 2

- Medical imaging studies and related imaging reports
- Medical test results, including laboratory test and related reports
- Discharge reports

6 years

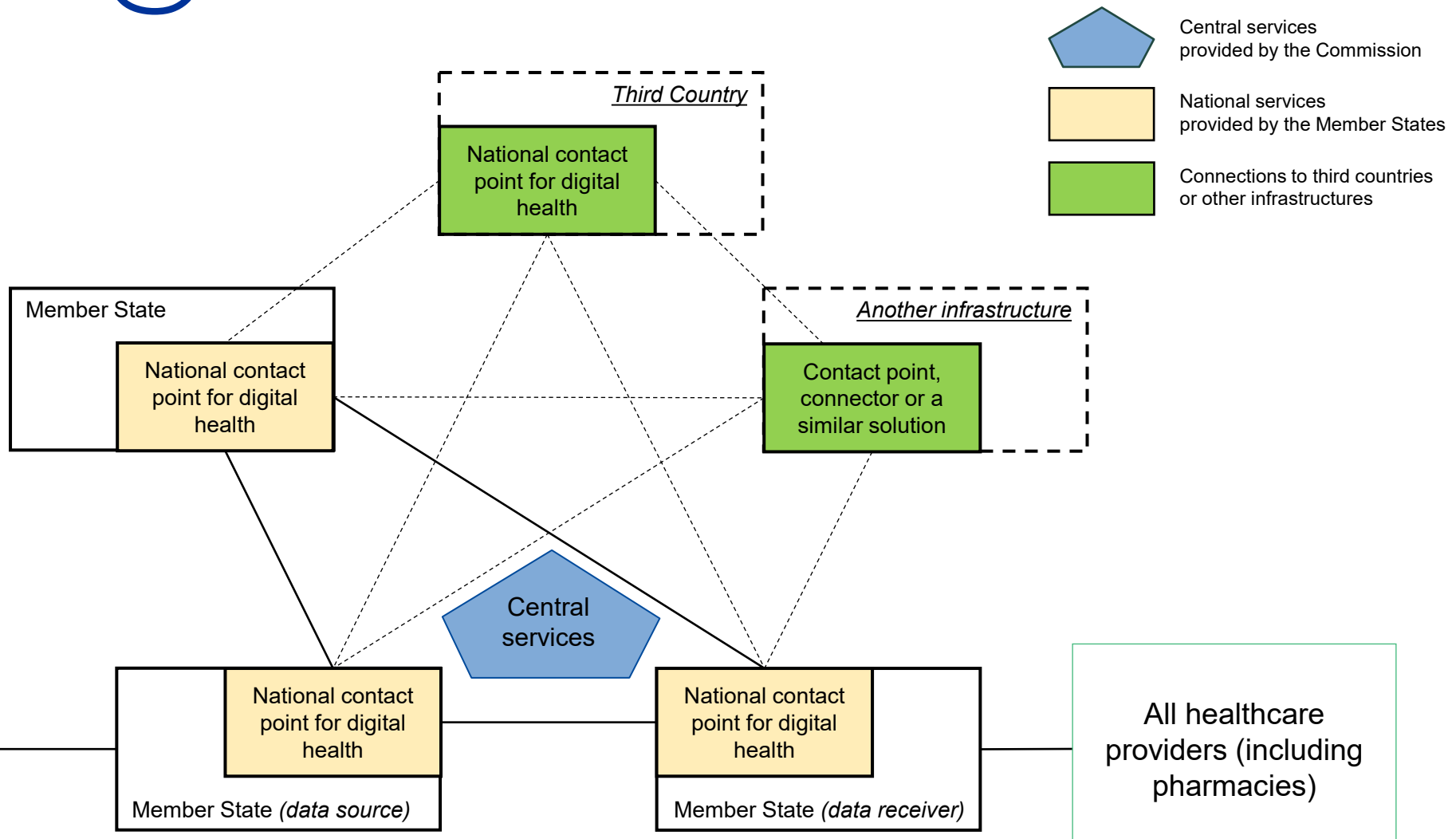
New layers of data exchange



In both cases the document gets sent from NCP B to NCP A / NCP C

NCP A or C either knows that it should go to a certain GP and sends there, or just stores it and whoever needs it can retrieve

Full rollout of cross-border infrastructures MyHealth@EU



Data categories

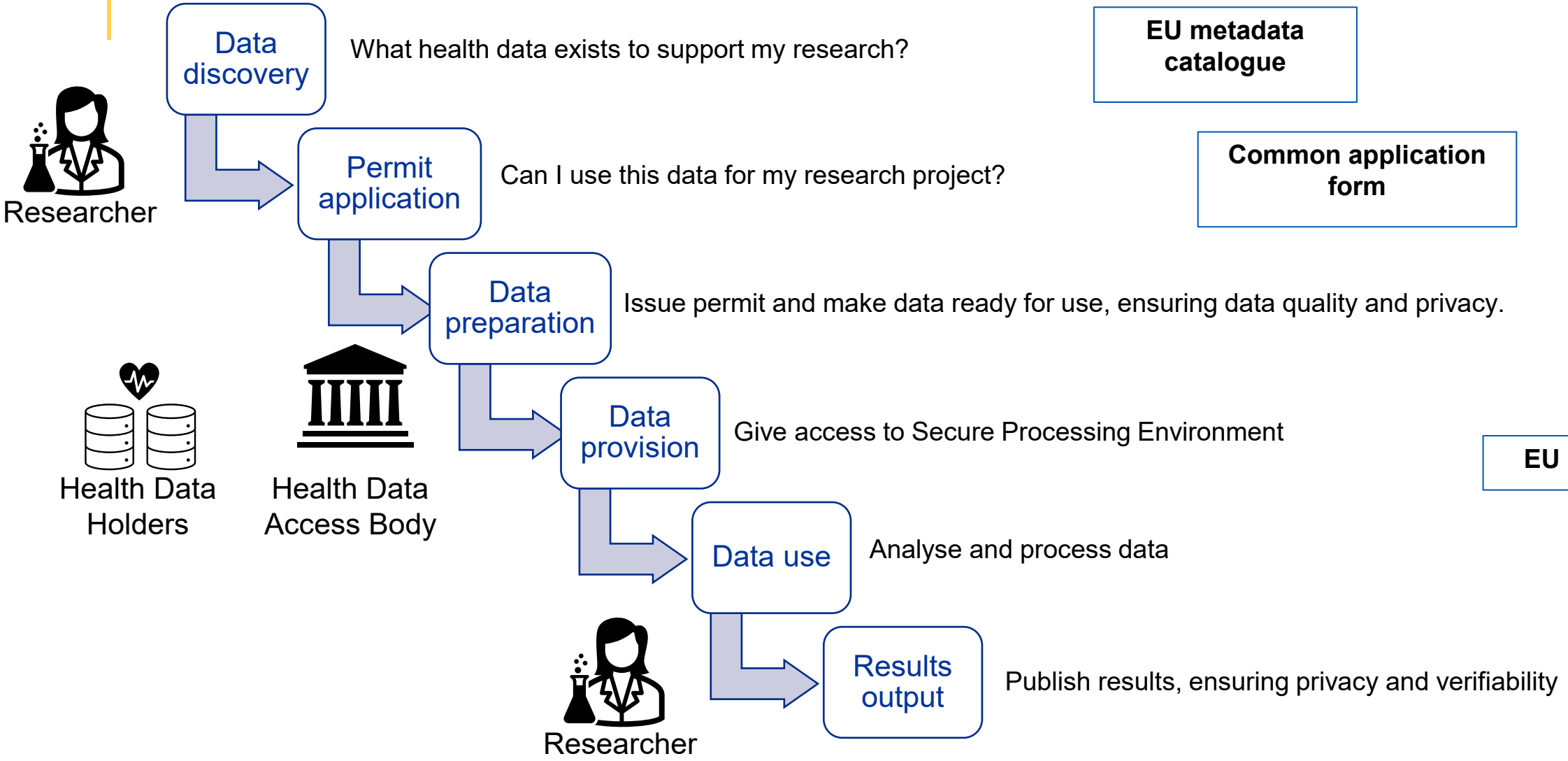
Priority group 1:
- Patient summaries
- ePrescriptions and eDispensations

Priority group 2:
- Medical test results: laboratory, other diagnostics, related reports
- Medical imaging: studies and reports
- Discharge reports

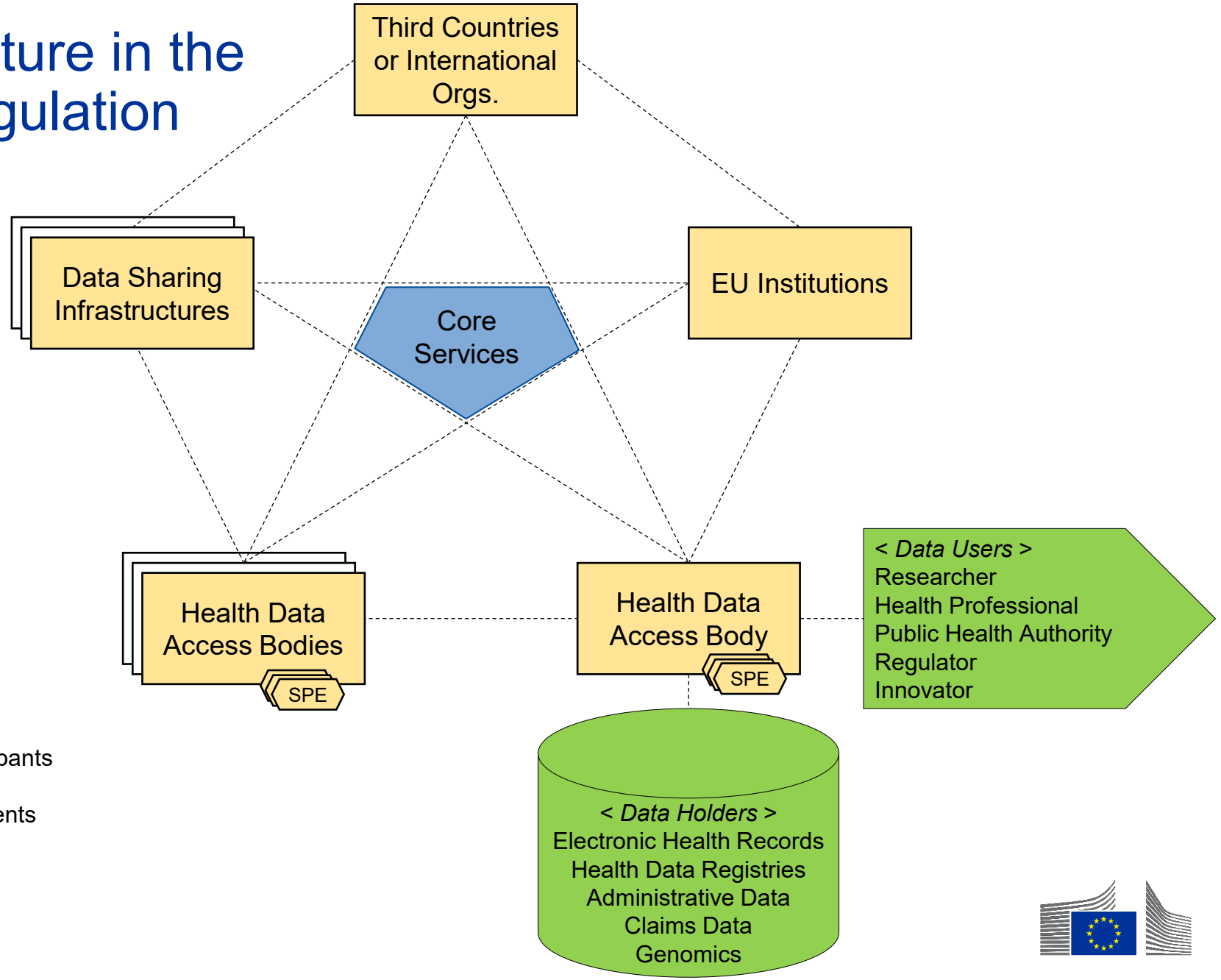
Additional data categories:
May be exchanged where supported

Data suppliers:
all healthcare providers.

3. Full rollout of cross-border infrastructures HealthData@EU



HealthData@EU
High-Level Architecture in the proposed EHDS regulation

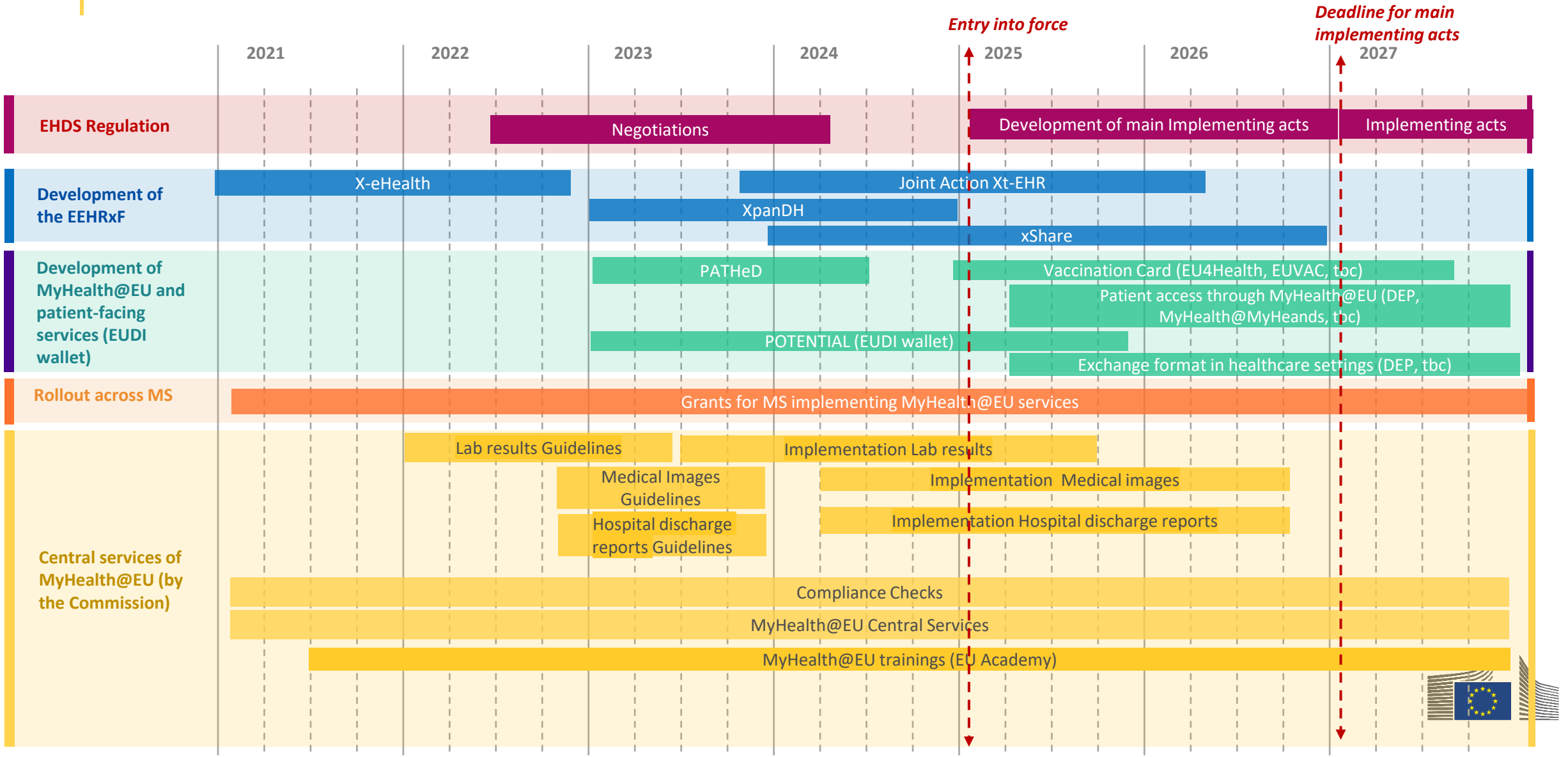


Roll-out of new IT systems and related processes

MyHealth@EU central services	NEW HealthData@EU central services	NEW Database for EHR systems	NEW European digital testing environment	NEW Union health data access service	NEW EU-level secure processing environments
• Secure communication infrastructure • Configuration, terminology, testing services • Community and stakeholder management with eHMSEG • Analysis, development, testing and deployment • NEW data categories and services in scope • NEW Interoperable cross-border identification and authentication mechanism	• Secure cross-border infrastructure • Analysis, development, testing and deployment • Cross-border gateway • EU Dataset catalogue • Common application form • Transparency Portal • Authentication mechanism • Central services helpdesk • Community and stakeholder management	• To be provided as a service • Requirements for EHR systems registration (to be included in a delegated act)	• Community of test centres • Technical specifications (to be included in an implementing act) • Open-source software	• Tasks and services of HDAB where data holders are EU institutions • Analysis and development • Operation and maintenance	• SPE for datasets from EU institutions and from more than one national contact point • Analysis and development • Operation and maintenance

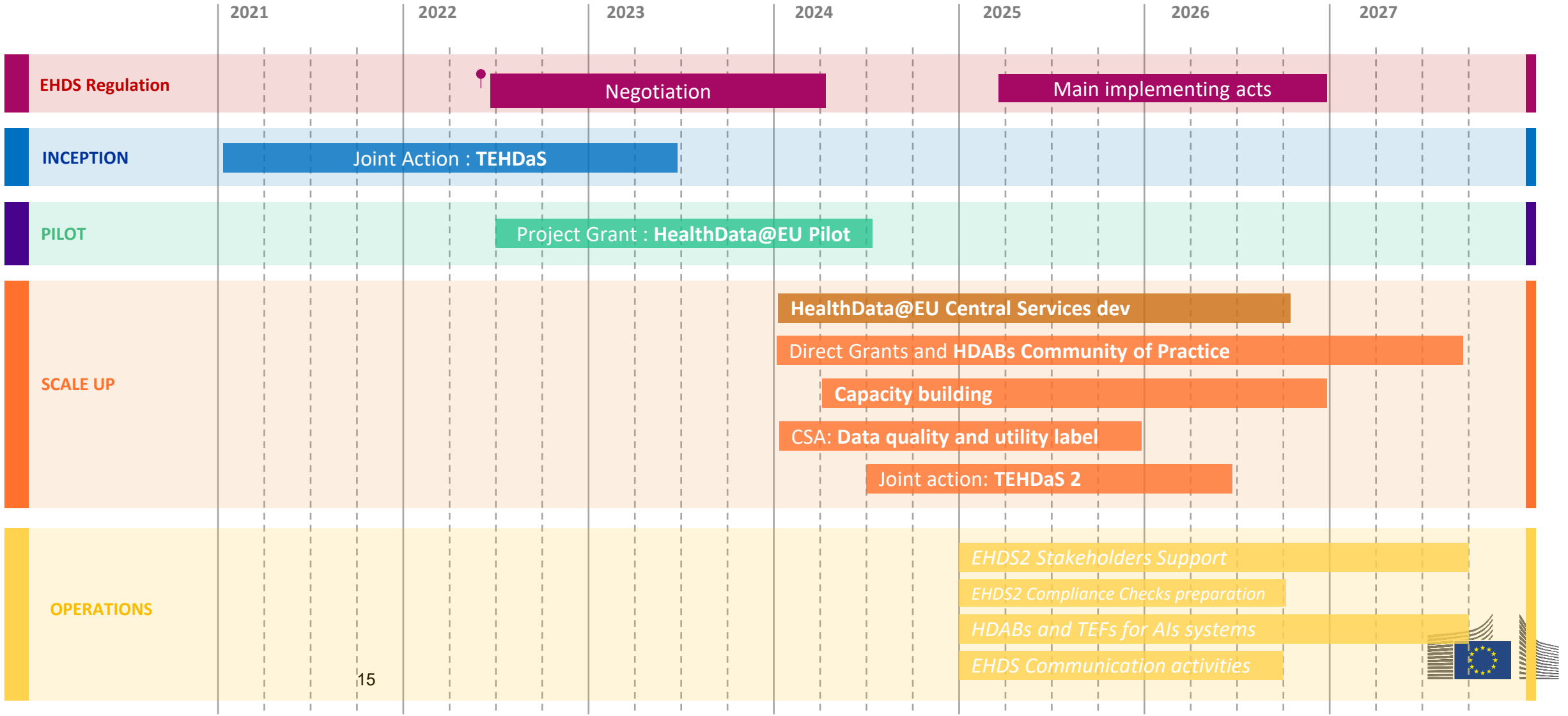
Timelines are indicative.

Overview from primary uses of health data



Overview from secondary uses of health data

Timelines are indicative.



Example: How do things come together in primary uses at EU level?

MyHealth@EU under the Cross-border healthcare directive 2011/24/EU

European Health Data Space Regulation

eHealth Network/eHMSEG


eHealth Network guidelines

eHealth Network

GUIDELINE

on

the electronic exchange of health data under Cross-Border Directive 2011/24/EU

ePrescription and eDispensation of Authorised Medicinal Products

Release 3.1

eHealth Network guidelines

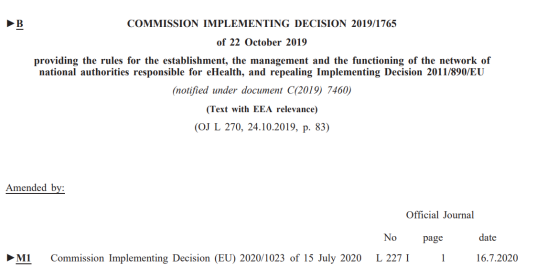
eHealth Network

Guideline on

the electronic exchange of health data under Cross-Border Directive 2011/24/EU

Patient Summary

Guidelines


►B COMMISSION IMPLEMENTING DECISION 2019/1765

of 22 October 2019

providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU

(notified under document C(2019) 7460)

(Text with EEA relevance)

(OJ L 270, 24.10.2019, p. 83)

Amended by:

		Official Journal No	page	date
►M1	Commission Implementing Decision (EU) 2020/1023 of 15 July 2020	L 227 I	1	16.7.2020

eHealth Network (art. 14) implementing act

Article 15 EEHRxF

Article 15

European electronic health record exchange format

1. By … [two years from the date of entry into force of this Regulation], the Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 14(1), setting out the European electronic health record exchange format. Such format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. Such format shall support transmission of structured and unstructured health data and shall include the following elements:

Article 23 MyHealth@EU

And other articles: 7, 16, 17, 24

SECTION 3

CROSS-BORDER INFRASTRUCTURE FOR PRIMARY USE OF PERSONAL ELECTRONIC HEALTH DATA

Article 23

MyHealth@EU

1. The Commission shall establish a central interoperability platform for digital health ('MyHealth@EU') to provide services to support and facilitate the exchange of personal electronic health data between the national contact points for digital health of the Member States.

Steering Group for MyHealth@EU

Zooming in: 3 pillars of EEHRxF

Harmonised datasets

- *Containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data*

Coding systems and values

- *To be used in datasets containing electronic health data*

Technical interoperability specifications

- *For the exchange of electronic health data, including its content representation, standards and profiles*

Current state of play

- The Xt-EHR joint action is making their recommendations for the European Electronic Health Record Exchange Format (EEHRxF) for all 3 pillars.

- The JA is conducting targeted consultations, interested parties should sign up on their website. The JA deliverables are entering the consultation phase soon.

- The best time for the industry and implementers of the Format to give inputs is during the joint action consultation phase.

Fundamental principles for EEHRxF

- It is essential that the standards used in the EHDS implementation are **freely accessible**.
- Key implementation resources like validators and guides **must remain open-source** and **accessible to the community to support widespread adoption and compliance** and ensure **transparency and openness**.
- We invite Standard Development Organisations, Member States, and stakeholders to engage with the Commission on ensuring open access to standards and key resources.

Importance of the EEHRxF

art 7
- fulfilling the rights of national persons
- especially in regard to their right to data portability

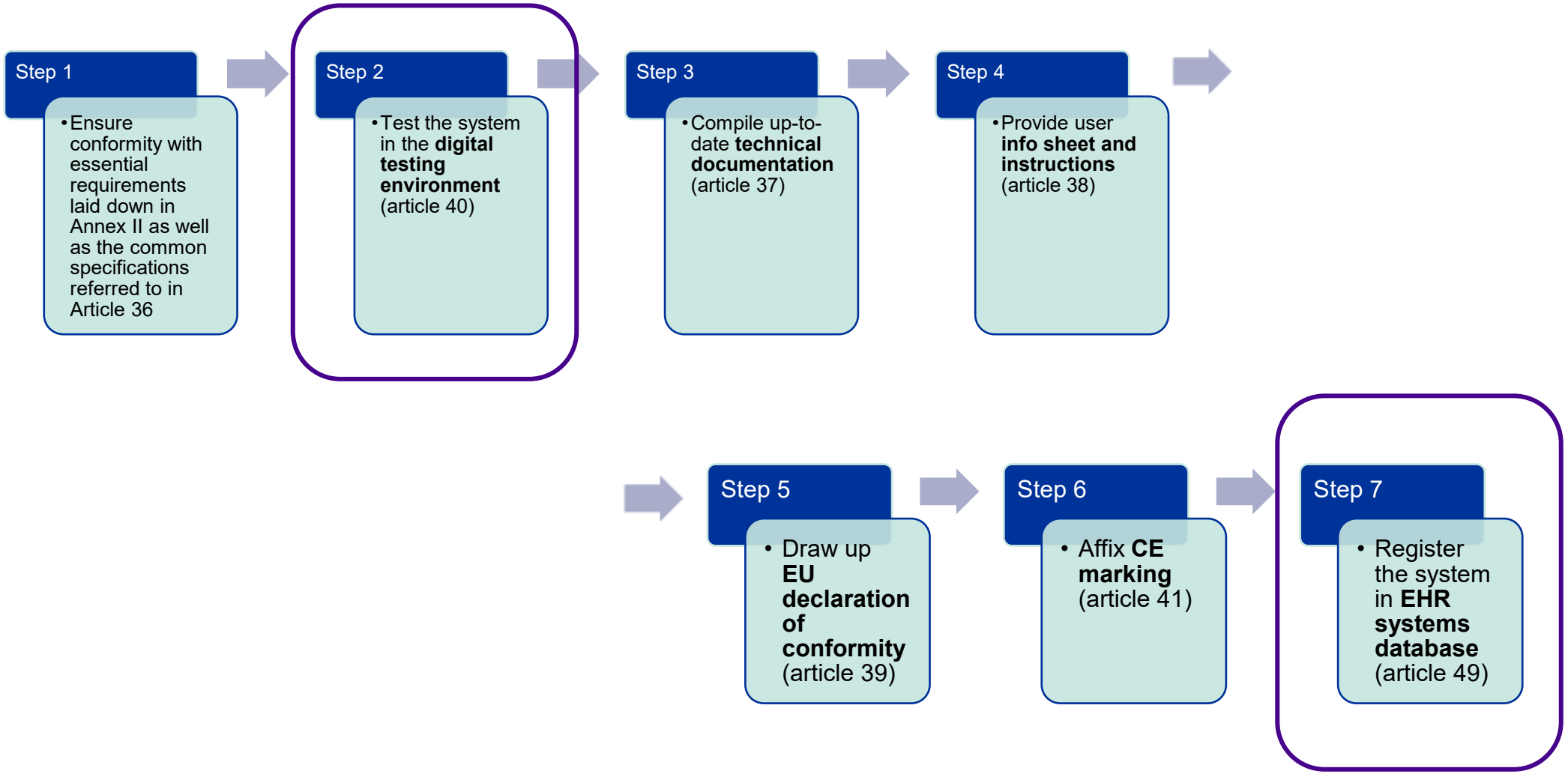
art 23
- each NCP shall enable the exchange of data in priority data categories in the EEHRxF

art 30
- manufacturers shall ensure that the EHRs are in conformity with essential requirements and common specifications
- Including the interoperability component (Annex II)

EEHRxF Support Centre (EU4Health Work Programme 2024)

- **DI-p-24-72** *Support centre for the European Electronic Health Record exchange Format (EEHRxF) and for the interoperability and security of electronic health record systems*
  1. supporting the creation, stimulation and moderation of an EEHRxF community of practice
  2. consolidating requirements and specifications
  3. conducting analysis and monitoring work as well as support actions
  4. providing and maintaining tools and resources online
  5. support implementers and other relevant stakeholders on the adoption EEHRxF and best practices
- **Budget:** EUR 4.5 million
- Implemented by EC - HaDEA
- **More information in the WP 2024:** EU Funding & Tenders Portal

Certification of EHR systems (simplified)



DTE relase 1 planned in July

Webinar invite will follow!

Key Features:

- User Authentication so users can log in using their EU login credentials, ensuring secure and clear authentication.
- User Authorization to join the community.
- Test interface easy to navigate.
- Validators of MyHealth@EU CDA constraint files.
- Test report generated after tests execution.

In release 1 the validators are CDA constraint files, is there an official decision on technology?
No. As scope of harmonised interoperability components is not yet confirmed, these validators are implemented in the EU DTE to test validation features.

Thank you