European Health Data Space

Harnessing the value of health data

06/03/2025

EHDS webinar series

1. Primary Use and Requirements for EHR systems
2. Secondary Use
3. **Implementation and governance – who does what?**

European Commission

Agenda

1. EHDS in a nutshell
2. Tasks in primary use
3. Tasks regarding EHR systems
4. Tasks in secondary use
5. Tasks relating to governance
6. Q&A

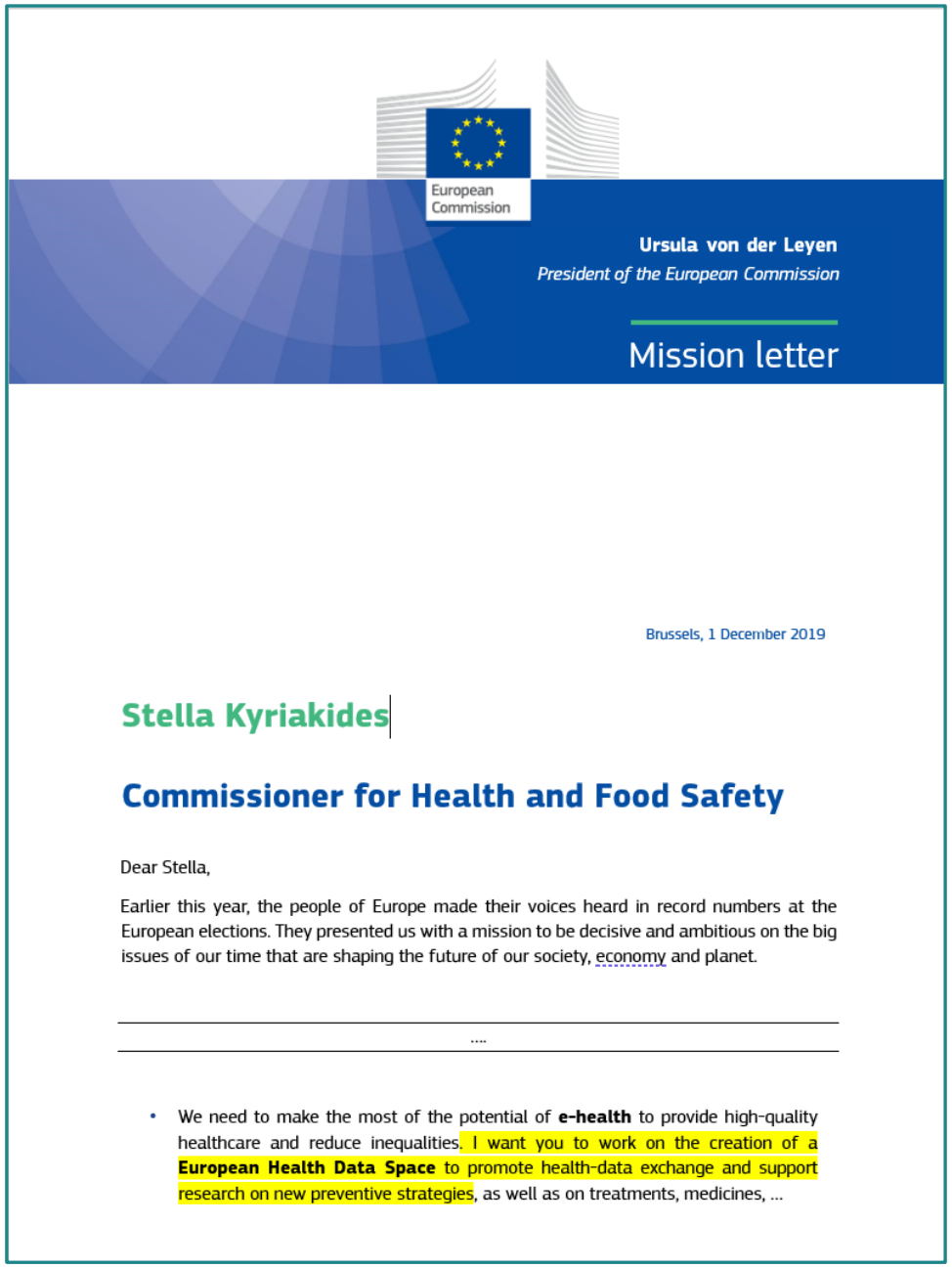
Target audience: digital health authorities, health data access bodies, Member State authorities in general, data holders

European Commission

1 EHDS in a Nutshell

Why this Regulation (now)?
Three legs of the Regulation

European Commission



European Commission

Ursula von der Leyen
President of the European Commission

Mission letter

Brussels, 1 December 2019

Stella Kyriakides

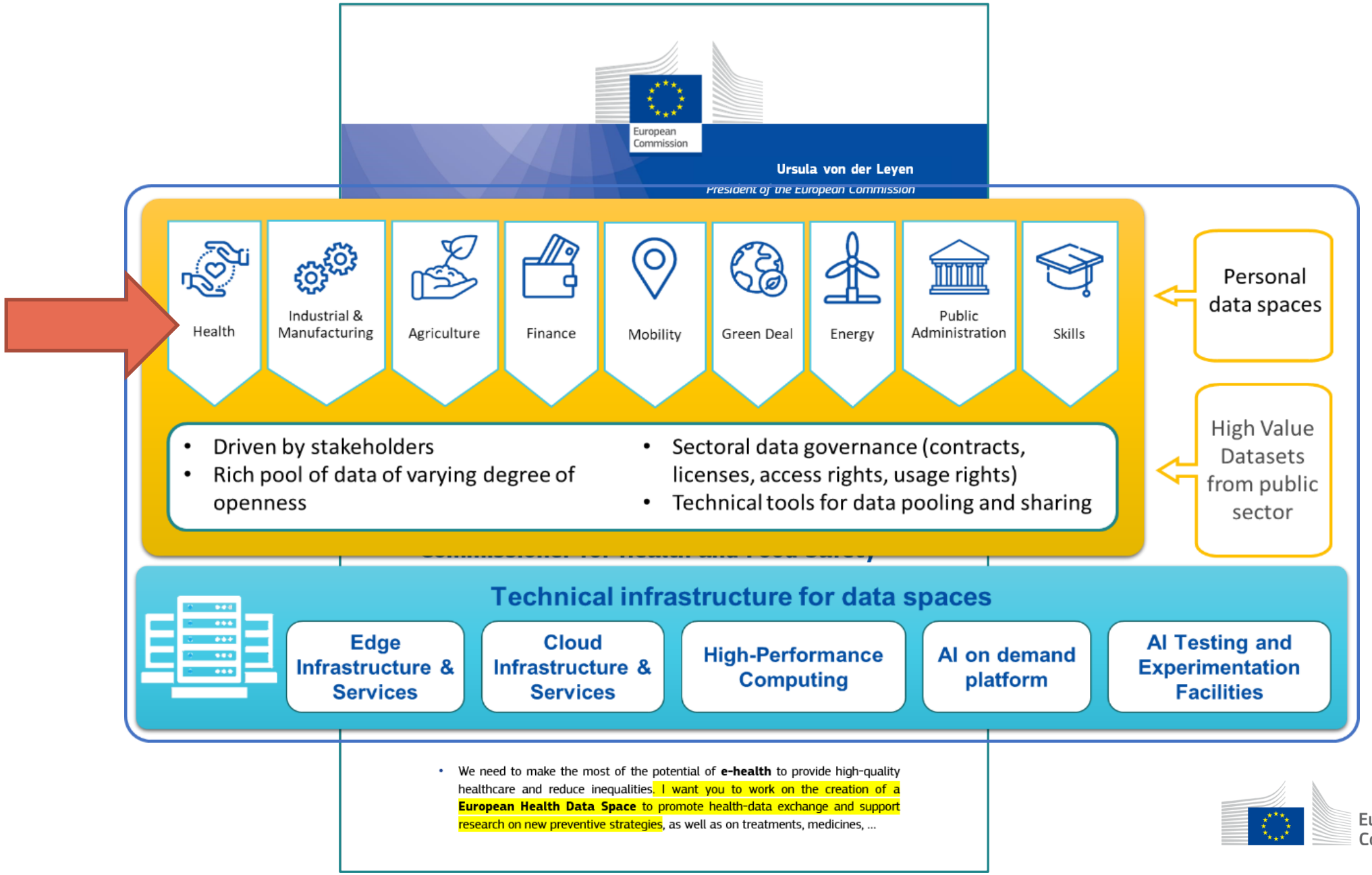
Commissioner for Health and Food Safety

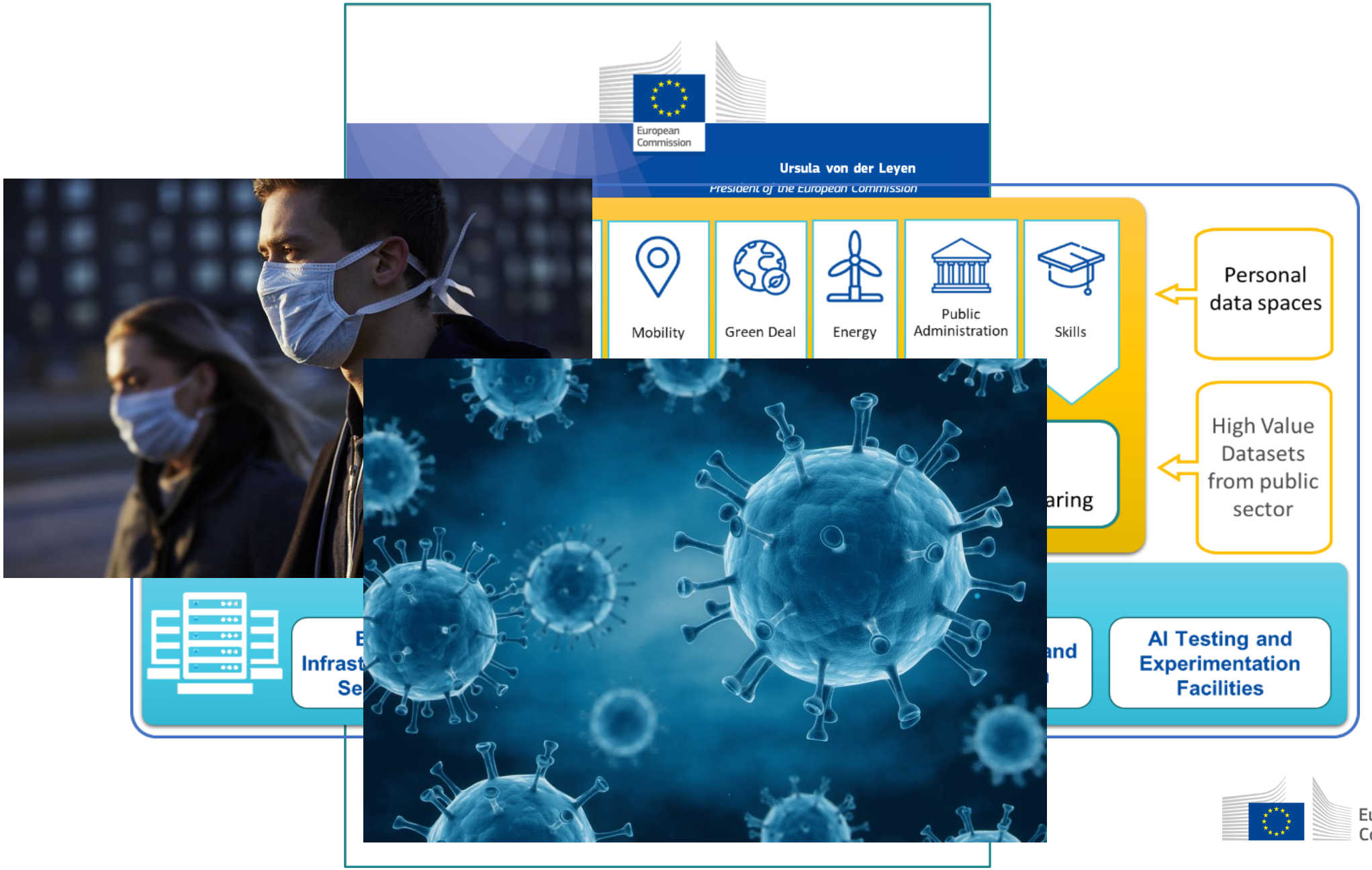
Dear Stella,

Earlier this year, the people of Europe made their voices heard in record numbers at the European elections. They presented us with a mission to be decisive and ambitious on the big issues of our time that are shaping the future of our society, economy and planet.

....

- We need to make the most of the potential of **e-health** to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a **European Health Data Space** to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, ...


European Commission
Ursula von der Leyen
President of the European Commission
Health
Industrial & Manufacturing
Agriculture
Finance
Mobility
Green Deal
Energy
Public Administration
Skills
Personal data spaces
High Value Datasets from public sector
• Driven by stakeholders
• Rich pool of data of varying degree of openness
• Sectoral data governance (contracts, licenses, access rights, usage rights)
• Technical tools for data pooling and sharing
Technical infrastructure for data spaces
Edge Infrastructure & Services
Cloud Infrastructure & Services
High-Performance Computing
AI on demand platform
AI Testing and Experimentation Facilities
• We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, ...



European Commission

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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 – Primary Use

How?

- Strengthening patients' rights on defined categories of their own data;
- 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.

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.

EHDS in a Nutshell – Secondary Use

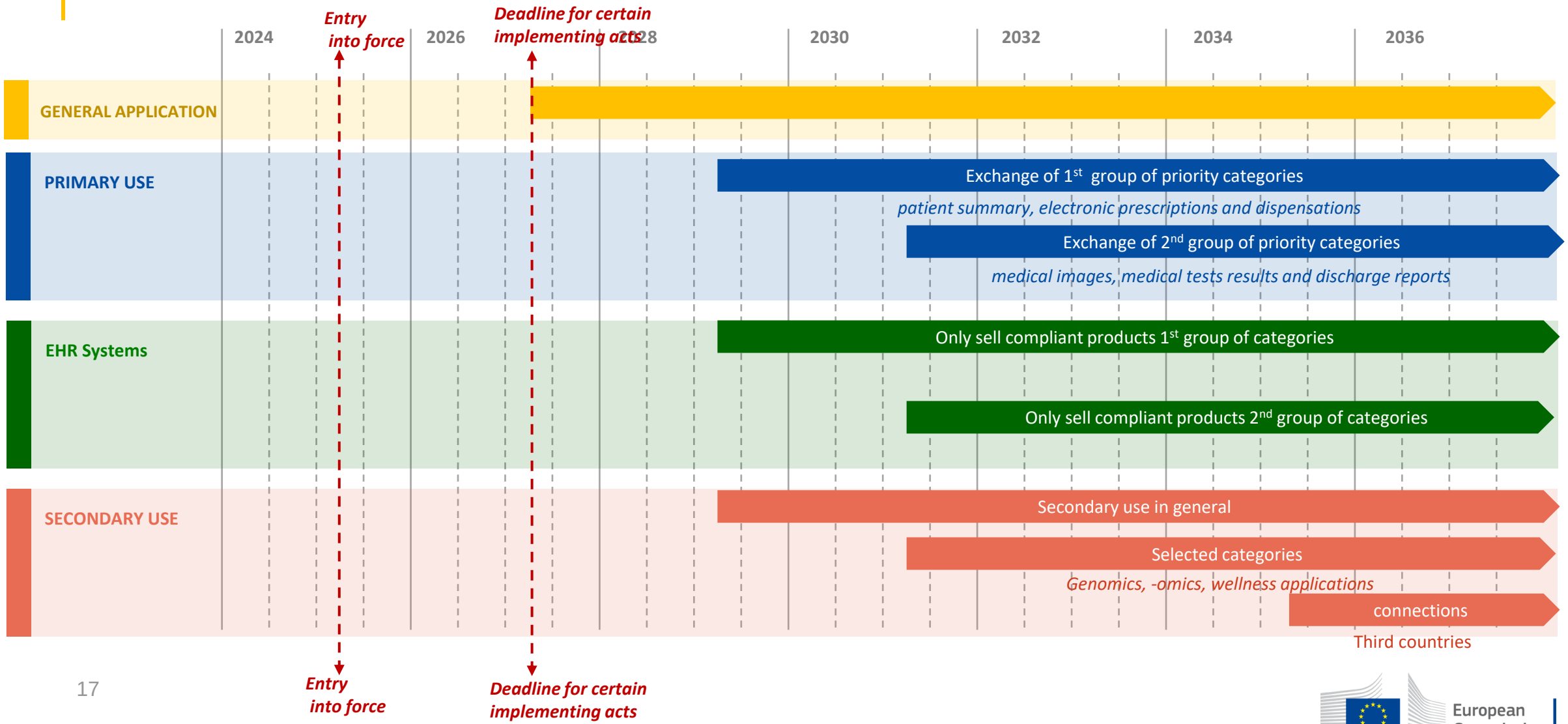
How?

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

Governance – MS and EU level

- MS to set up Digital Health Authorities (primary use) and Health Data Access Bodies (secondary use)
- Coordination on EU level in EHDS Board for exchanging best practices, coming up with guidelines etc.
- COM to provide MyHealth@EU and HealthData@EU infrastructures and certain other services for MS
  - MS Steering groups for guidance

EHDS – Overall timeline for application



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2 Tasks in Primary Use

What organisation and services do MS have to set up?
What infrastructures will MS use?
What do healthcare providers need to do?
What does COM need to do?

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Article 20

Establish Digital Health Authority

- What: MS to designate Digital Health Authority
- When: 26/03/2027
- Dependencies: n/a
- Background: evolution of current tasks

Article 15

Defining EEHRxF

- What: COM to lay down specifications for European Electronic Health Record Exchange Format (EEHRxF)
- When: DL for COM 26/03/2027
- Dependencies: n/a
- Background: see Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format

Articles 3 to 12

Ensure setup of access services

- What: Member States to ensure that one or more electronic health data access services (patient-facing) and health professional access services are set up. This includes connecting healthcare providers.
- When: services must be up and running by 26/03/2029 for first group of priority categories, by 26/03/2031 for the second group
- Dependencies: implementing acts for Arts. 4(4), 15 (DL for COM: 26/03/2027), 16(2), 17

Article 13

Registration of electronic health data

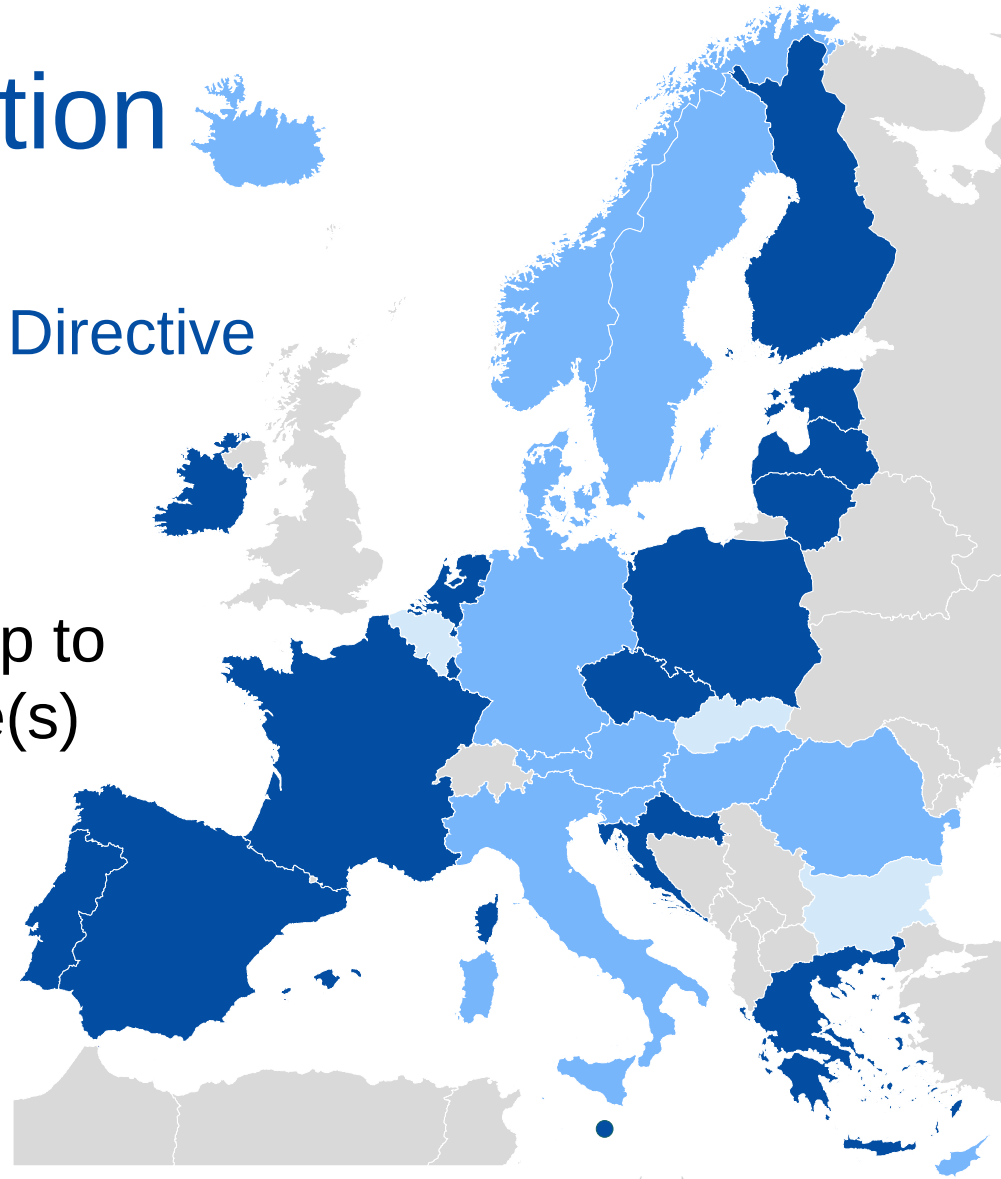
- What: Member States to ensure that priority category data are kept in EEHRxF
- When: by 26/03/2029 for first group of priority categories, by 26/03/2031 for the second group
- Dependencies: implementing act Art. 13(4) (DL)

Article 23

Connect to MyHealth@EU

- What: MS to designate national contact point (NCP) for MyHealth@EU, connect NCP to central services, connect healthcare providers to NCP
- When: 26/03/2029 for first group of priority categories, 26/03/2031 for second group.
- Dependencies: implementing acts for Art. 23(4) and (8) (DL)

Building on existing cooperation



MyHealth@EU under Cross-border Healthcare Directive

- Voluntary system for exchanging patient summaries, prescriptions and dispensations (= first group of priority categories)
- **15 countries** live with at least one service, up to **10 more** expected to go live with first service(s) this year

Evolution of MyHealth@EU for the EHDS

- Voluntary => mandatory
- New services
- New data categories

3 Tasks relating to EHR Systems

Market surveillance
Testing environment

European Commission

Article 43

Designate Market Surveillance Authority

- What: MS to designate Market Surveillance Authorities
- When: 26/03/2027 for designation
- Dependencies: n/a
- Background: COM to provide cooperation tools, e.g. ICSMS

Article 40

Deploy and operate testing environment

- What: MS to deploy and operate testing environments
- When: no defined deadline, but should be up and running before key obligations of Chapter 3 become applicable, so before 26/03/2029
- Dependencies: implementing act for Article 40(4) (DL), development of testing environment by COM
- Background: COM to develop software package for testing environment and make it available to MS

Articles 25 and following

Tasks for manufacturers of EHR systems

- What: only place on the market EHR systems with the two harmonised components that comply with the common specifications under Art. 36, passed the testing environment, are CE-marked and registered in the Art. 49 database
- When: 26/03/2029 for products processing first group of priority categories, 26/03/2031 for second group
- Dependencies: Art. 36 implementing act (DL)
- Background: similar obligations for healthcare providers ‘putting into service’ in-house systems – but 26/03/2031 as target date, for both groups of data categories

Articles 47 to 49

Tasks for manufacturers of wellness apps

- What: when they claim interoperability with EHR systems, label them, comply with Art. 48, register them in the Art. 49 database
- When: 26/03/2029 for apps processing first group of priority categories, 26/03/2031 for second group
- Dependencies: implicitly Art. 36 implementing act (DL)

4 Tasks in secondary use

Health Data Access Bodies
Connection to HealthData@EU

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Establish and designate Health Data Access Body

Article 55 and following

- What: MS to designate one or more HDABs and set up all functions – e.g. application management, transparency portal…
- When: 26/03/2027 for designation, 26/03/2029 for receiving applications
- Dependencies: Art. 70 implementing act (DL) for templates, Art. 73(5) IA (DL) for SPE specs
- Background: UHDAS to be set up by 26/03/2029 as well

Article 75

Connecting to HealthData@EU

- What: MS to connect their NCPs to HealthData@EU – federating catalogues, forwarding applications.
- When: 26/03/2029 for most Art. 51 categories, 26/03/2031 for last ones
- Dependencies: IA for 75(12) (DL)

Building secure processing environments (SPEs)

Article 73

- What: HDABs need to ensure that they can provide a SPE to make data available in.
- When: 26/03/2029 for most Art. 51 categories, 26/03/2031 for last ones
- Dependencies: IA for Art. 73(5) (DL)
- Background: additionally, COM can provide SPE for cross-border cases – see Art. 75(9)

Article 60

Tasks for holders

- What: provide dataset descriptions to HDAB, be ready to provide data pursuant to permit/request.
- When: 26/03/2029 for most of Art. 51 categories, 26/03/2031 for the remaining ones
- Dependencies: implementing act for Art. 77(4) (DL)

Tasks for users

- What: can apply for permits/requests
- When: 26/03/2029 for most of Art. 51 categories, 26/03/2031 for the remaining ones
- Dependencies: none for the users

4 Tasks relating to governance

EHDS Board
Steering Groups

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Transition from eHealth Network to new governance mechanisms

Articles 92 to 95, 105

- In short: EHDS Board succeeds eHealth Network (plus extension to secondary use)
- Starts to apply 26/03/2027
- Expectation:
  - gradual replacement over time, finalised by repeal of Art. 14 CBHCD 26/03/2031.
  - eHN subgroups to be succeeded EHDS Board subgroups
- Parallel existence for some time: MS can use existing voluntary eHN cooperation as staging ground for getting ready for EHDS.

Articles 92, 94

Governance (1) : EHDS board

Objectives

- Facilitate cooperation and exchange of information between MS and Commission.
- Competence for both primary and secondary use of electronic health data.

Composition

2 representatives per MS : one for primary use, one for secondary use.

Each MS has 1 vote.

Decision-making by consensus or, failing that, by a 2/3 majority of MS.

The members act in the public interest and independently.

Functioning

Co-chairing by a representative of COM and one MS.

Adoption of procedural rules and a code of conduct proposed by COM. Secretariat provided by COM.

Invites supervisory authorities, market surveillance authorities, EDPB, EMA, ECDC, ENISA as relevant.

Possible sub-groups for specific subjects with representation of digital health authorities and health data access bodies.

Article 95

Governance (2) : Steering groups for infrastructures

Objectives

- Guiding the development and operation of MyHealth@EU and HealthData@EU cross border infrastructures.

Composition

1 representative per MS each.

Each MS has 1 vote.

Decision-making by consensus or, failing that, by a 2/3 majority of MS.

Functioning

Elect their own chairs

Adopt their own rules of procedures, can create subgroups.

Secretariat provided by COM

Possibility to invite observers to exchange on subjects of interest (other authorized participants, representatives of patients, health professionals, and industry).

Article 93

Governance (3) : Stakeholder Forum

Objective

- Platform for the exchange of information and cooperation with stakeholders.

Composition

Representatives of patients' organisations, health professionals, industry, consumer organisations, scientific researchers and academia

Appointed by COM following public call for interest and a transparent selection procedure

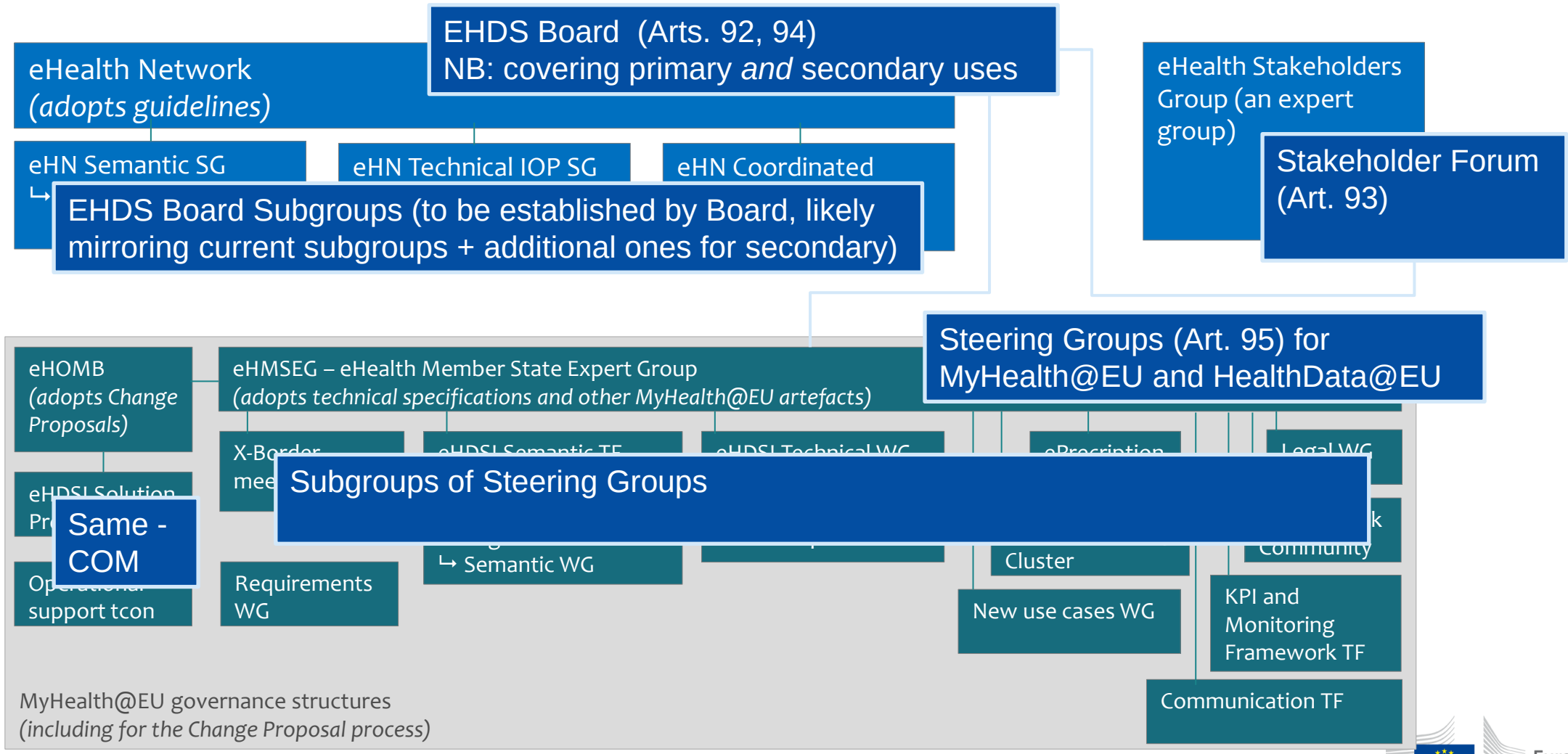
Functioning

Chaired by COM

Adopts its own rules of procedures, can create subgroups.

Secretariat provided by COM

Comparison to eHealth Network, subgroups, current MyHealth@EU governance



4 Transition & Conclusion

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

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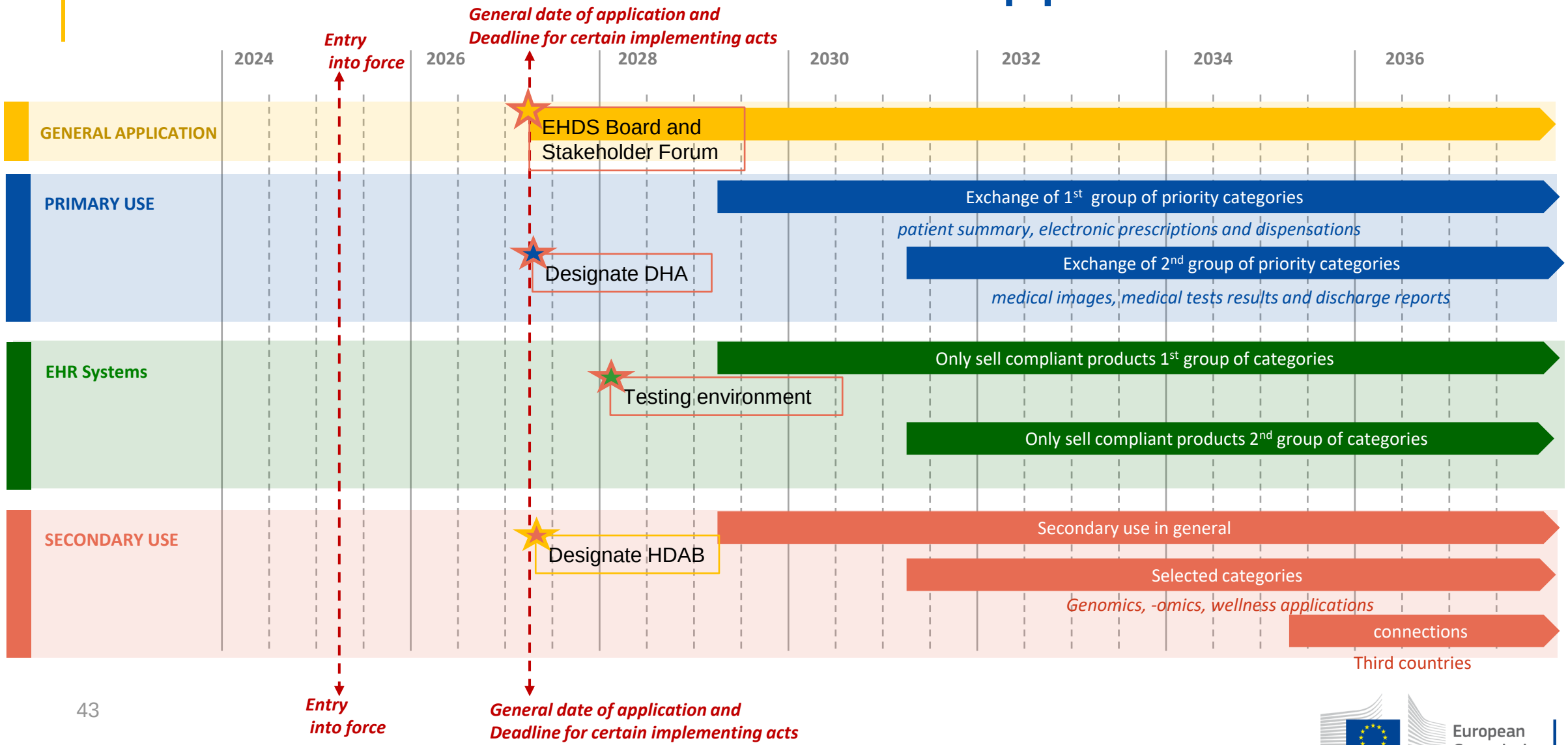
EHDS – Overall timeline for application



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Thank you!
Questions? Answers!

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