European Health Data Space

Harnessing the value of health data

27/02/2025

EHDS webinar series

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

European Commission

Agenda

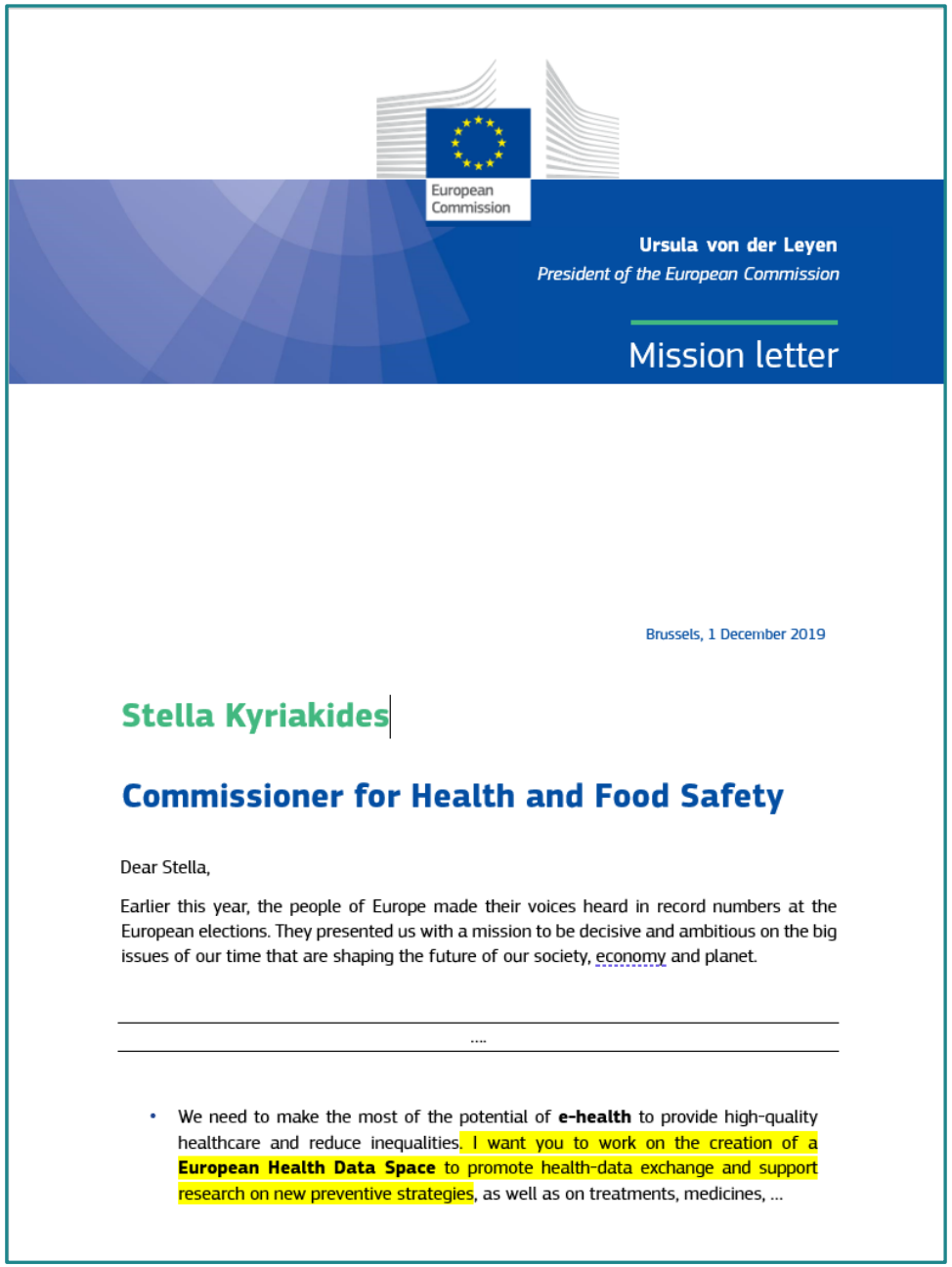
1. EHDS in a nutshell
2. Secondary use
3. What infrastructures will provide support?
4. Transition and next steps
5. Q&A

Target audience: health data holders, health data users, health data access bodies

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

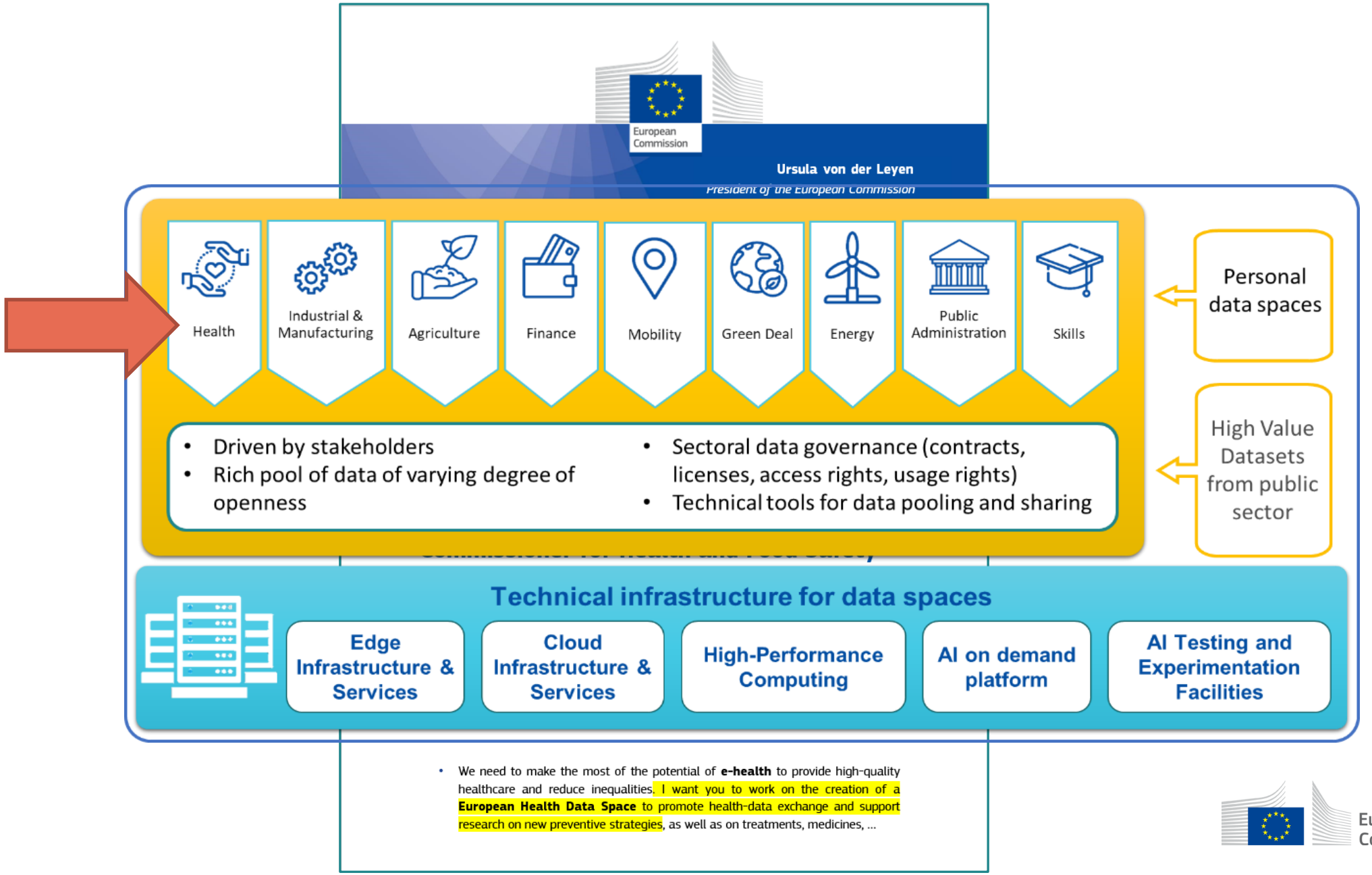
Commissioner for Health and Food Safety

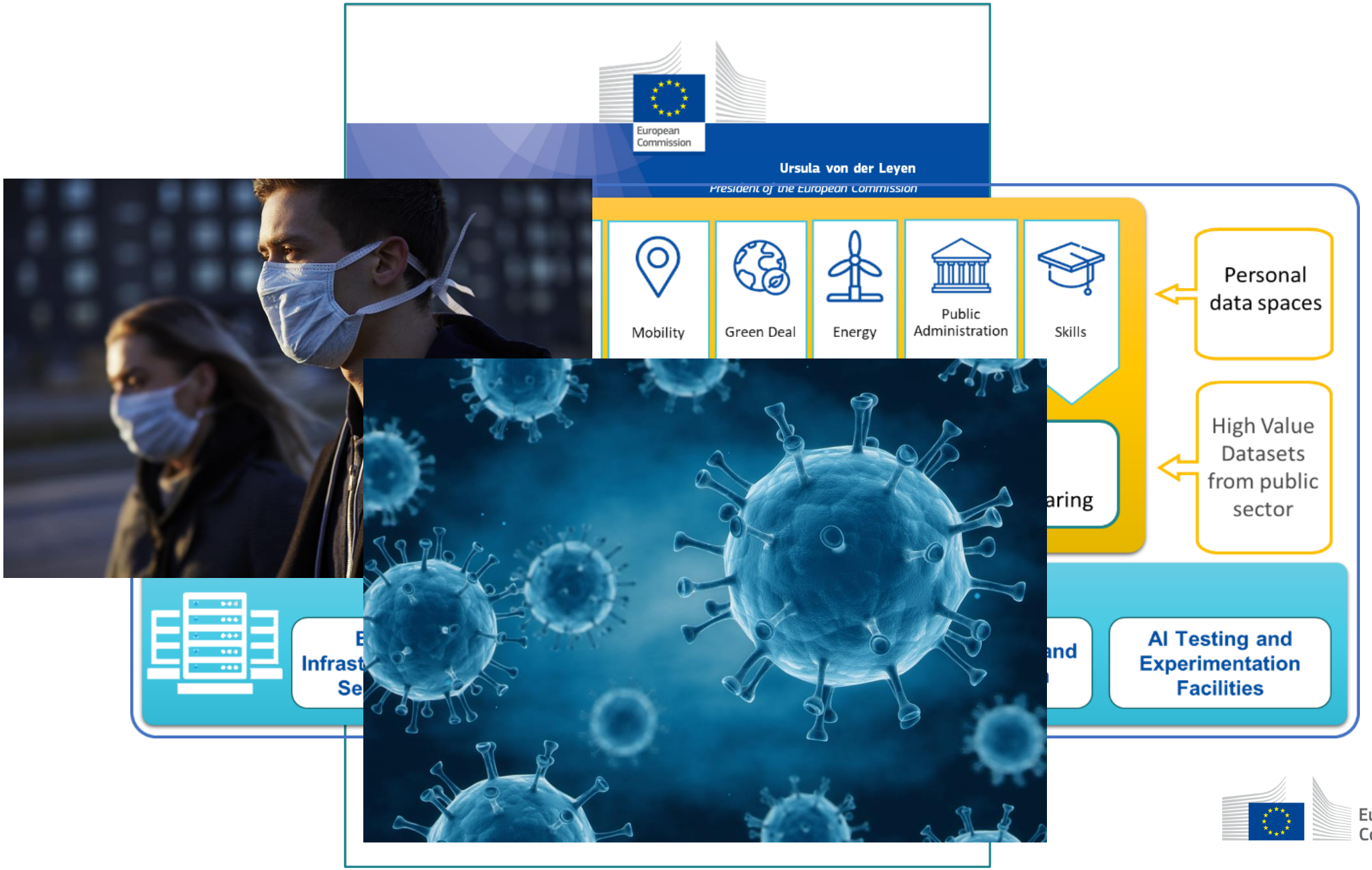
Dear Stella,

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

European Commission

European Commission

European Commission

European Commission

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. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health records systems, supporting both primary and secondary use.

3. 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.

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.

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

How?

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

Benefits of secondary use

For regulators and policymakers

- Easier access to health data for purposes of public health, patient safety, general functioning of healthcare systems...
- Better evidence basis for regulatory activities and policy-making.

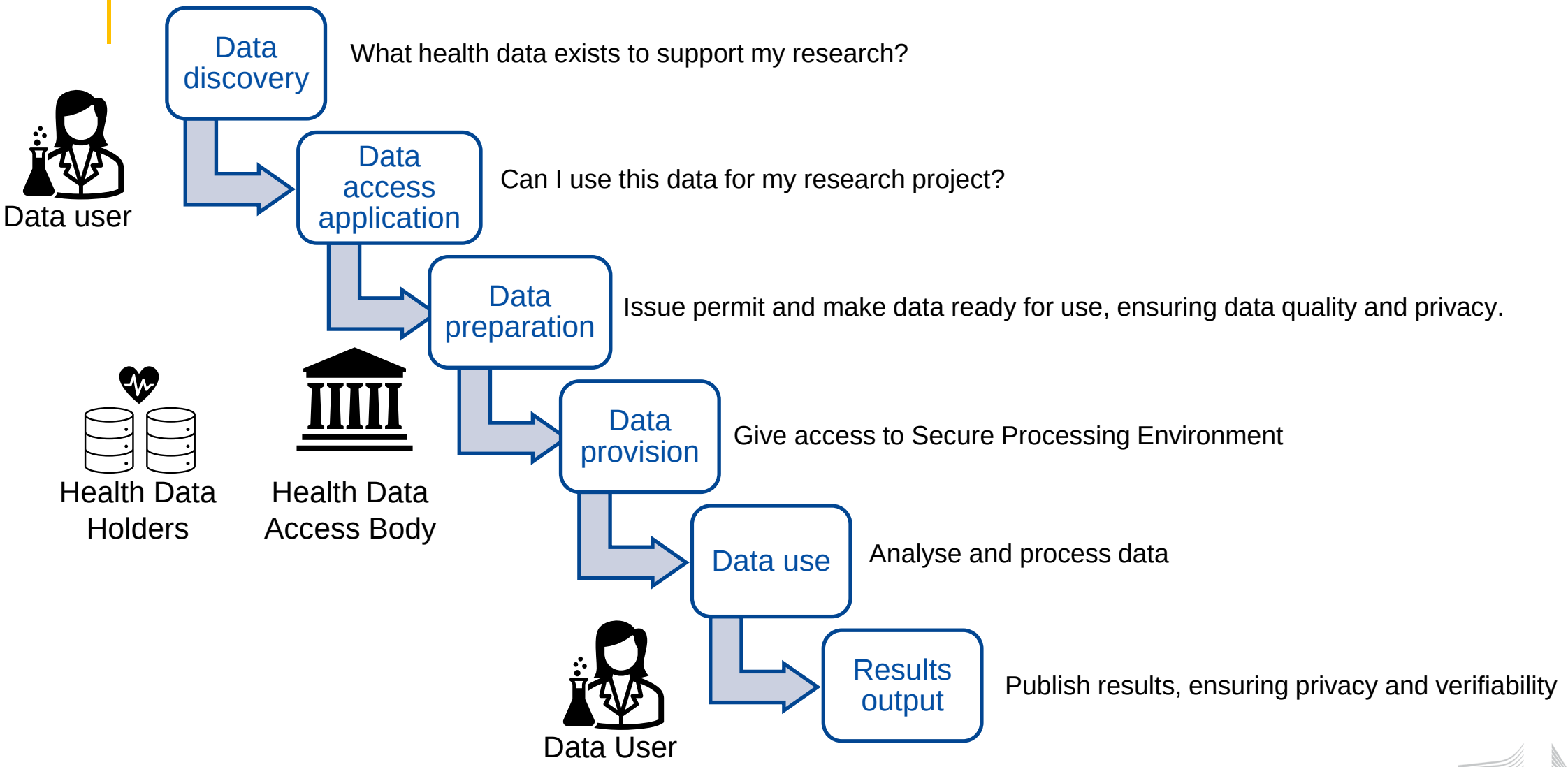
For patients

- In the long run: research leading to new and better treatments
- Transparency of data use

For researchers, including in industry

- Easier access to data for research and development;
- Knowing which health data of which quality are available where;
- Easier and more cost-efficient access to data;
- Easier merging of data, including cross-border .

User journey



Article 2(2)(u)

Health 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**;

+

Having the right or obligation to process personal data as controller or the ability to make non-personal data available.

established in the EU

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 health data intermediation entities to fulfill these duties.

Notification to the Commission of any relevant national legislation.

European Commission

Article 1(6) to (9)

Scope exclusions and non-exclusivity

- Does not affect reporting obligations => e.g. pharmacovigilance and notifiable disease reporting stay the same;
- Does not affect other further processing laid down by Union or MS law;
- Does not affect other frameworks for secondary use => they can continue to exist;
- Cannot be used for law-enforcement purposes.

Article 51

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

European Commission

Health Data Access Bodies (HDABs) and Union Health Data Access Service

Articles 55 to 59

- HDABs as orchestrators:
  - Publish dataset catalogues
  - Assess and decide on applications;
  - Liaise with health data holders;
  - Ensure data gets made available;
  - Provide public transparency.
- Member States can designate one or more HDABs.
- Union Health Data Access Service to be set up as functional equivalent to HDABs for data held by EUIBs.

Articles 60(3), 77 to 79

Dataset catalogues and quality labels

Dataset descriptions and dataset catalogues

- Data holders will have to provide basic descriptions of their datasets to HDABs => detailed elements to be set out in implementing act;
- HDABs publish catalogues;
- HealthData@EU federates national catalogues.

Data quality and utility label

- More detailed description of datasets, including ‘levels’ of label => detailed elements to be set out in implementing act;
- Mandatory if data collection received public funding => NB: funding *for collection* specifically, not for activities that result in incidental collection.
- Otherwise voluntary

Articles 68, 69

Application procedures

A streamlined procedure across EU

Single application form

Single permit template

Fees based on the complexity and duration of data access.

Data Access Application

For processing personal electronic health data.

Includes **detailed application requirements** such as applicant details, data description, intended use, ethical assessments (where required by MS law), and security measures.

Data can be accessed in **pseudonymised format** unless **anonymised data** suffice for the purpose.

If accepted, the applicant receives a **data permit.**

= direct access to data under stricter conditions.

Data permits are generally granted for up to 10 years with possible extensions.

Data Request

For obtaining answers in **anonymised statistical format** only.

Less stringent application focused on identity, intended use, and safeguards without direct access to personal data.

= only **statistical outputs from anonymised data**, suitable for broader or public interest inquiries without personal data access.

Articles 53, 54

Allowed and prohibited purposes

- **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;

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.*

- vocational or higher **education or teaching activities** in health or care sectors;
- **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.

- Taking 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.

Articles 52, 66, 71, 73

Safeguards

Secure Processing Environment (SPE)

SPE setup to restrict data access to **authorised users.**

State-of-the-art measures to prevent unauthorised data modification, access, or removal.

Logging and monitoring of activities within the SPE for compliance and audit purposes.

Download of personal data strictly prohibited.

Additional Safeguards

Legal and organisational measures to **protect intellectual property and trade secrets**.

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 Minimisation and Purpose Limitation

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

Pseudonymised data provided unless anonymised data suffices, with strict controls on de-identification.

Article 71

Opt-out

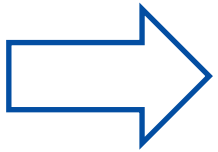
Natural persons have the right to opt-out from the secondary use of their health data

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*



What did the legislators leave open?

Where and **how** to exercise it not defined in detail => flexibility for MS

Basic requirement is "***on/off switch***"

Mechanism to make data available

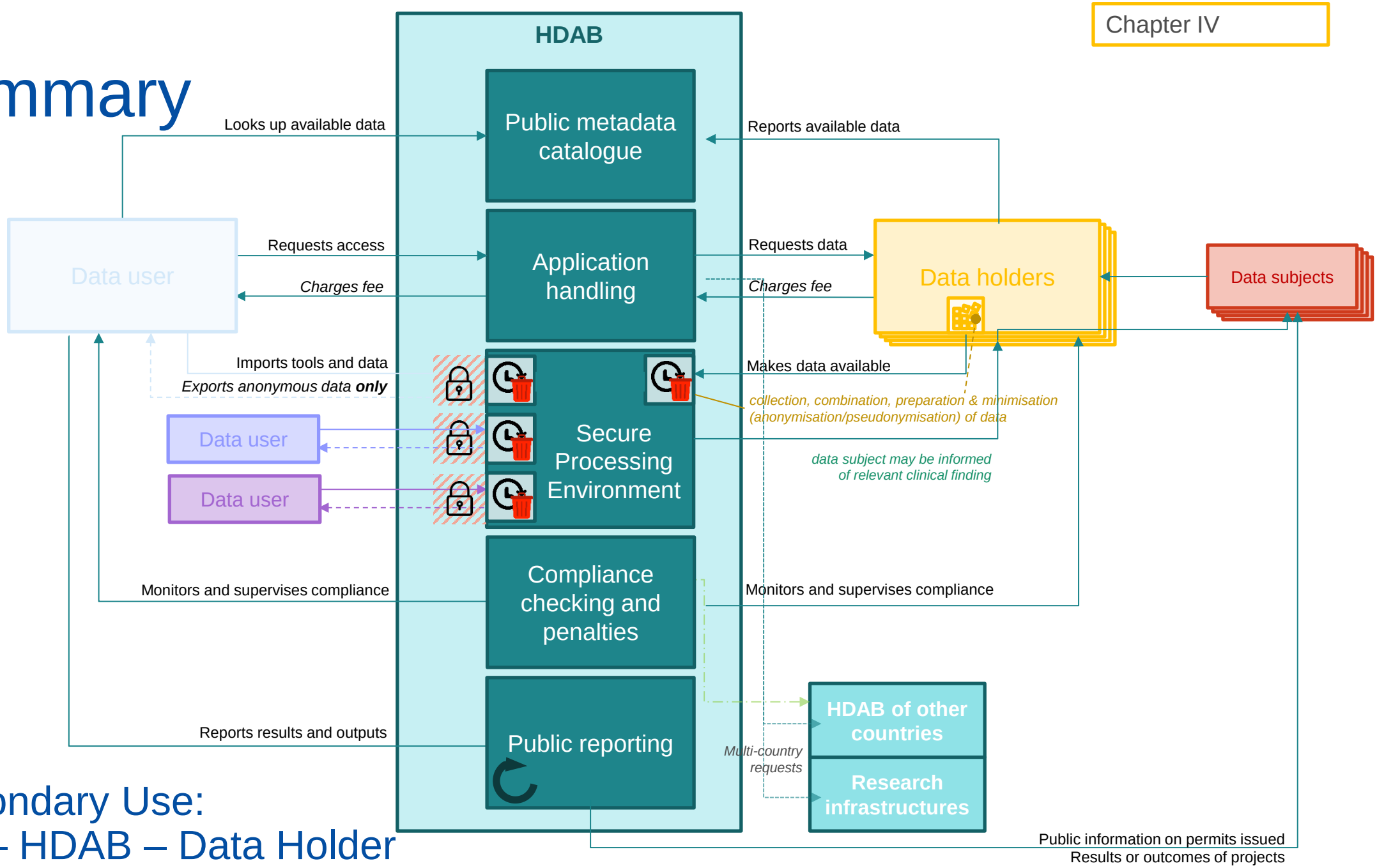
In practice only available for **public sector data users**

Article 62

Fees: **who** pays for **what** and **when**?

- General principles
  - Up to cost recovery : fee structure to be spelled out in IAs;
  - Discounts for certain health data user categories;
  - Non-discriminatory .
- Part for HDABs, part for health data holders
  - Entire amount paid to HDAB;
  - Part for holders or SPE providers passed through.
- When: not explicitly defined, however possibility for user to drop out after estimate of holder part implies two steps:
  - **Payment upon application**: costs for HDAB assessment
  - Upon estimate: part for holder + further costs for HDAB : **payment with permit**

Summary



EHDS Secondary Use:
Data User – HDAB – Data Holder

3 What infrastructures will provide support?

HealthData@EU

European Commission

Articles 75

Infrastructures – HealthData@EU

What does HD@EU actually do?

- Connecting contact points to the central platform
- Federating data catalogues
- Receiving and dispatching applications
- (COM can provide SPE in certain conditions)

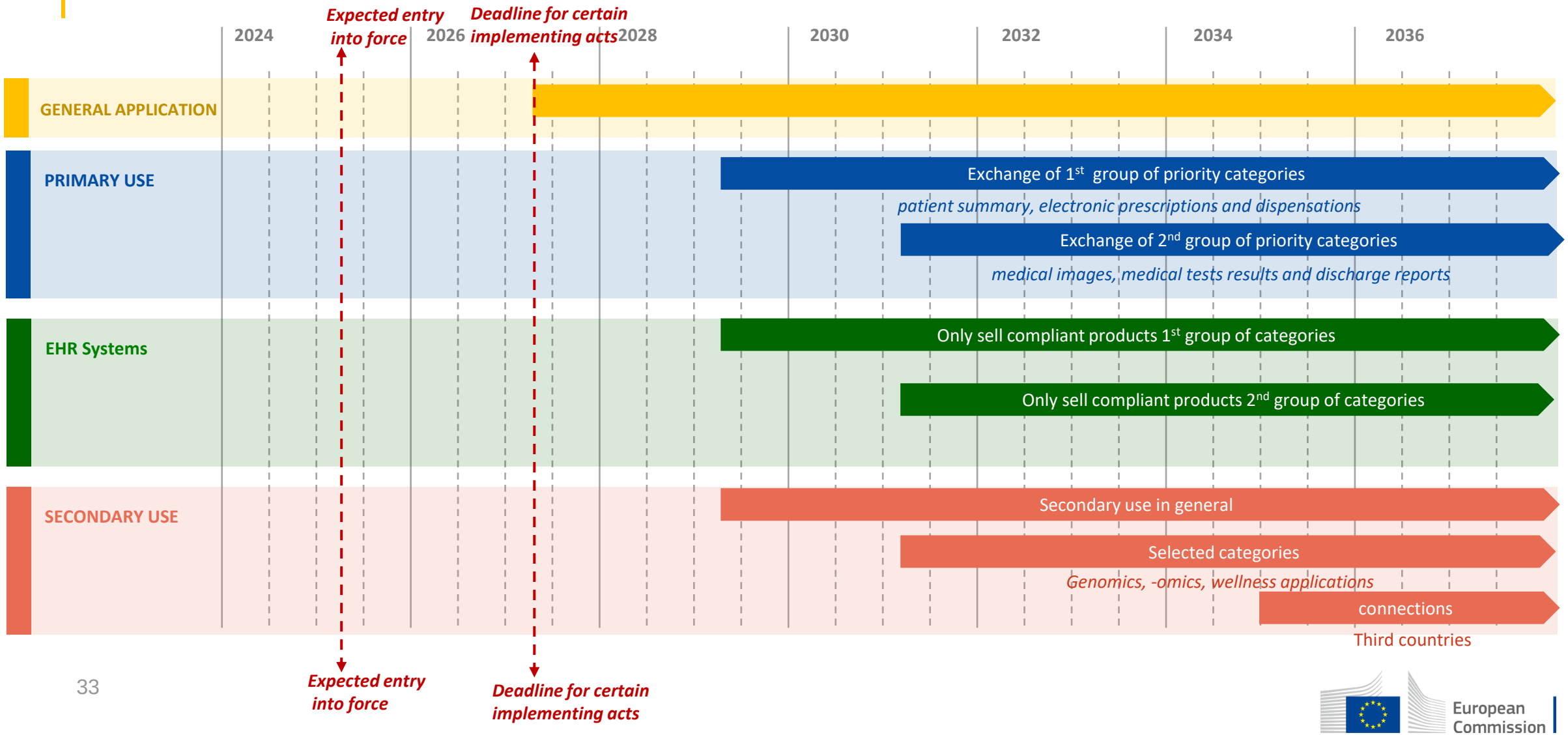
➢ *Quite different data handling from MyHealth@EU*

4 Transition & next steps

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

European Commission

EHDS – Overall timeline for application



European Commission

What will happen when?

- For health data holders:
  - Early 2029: provide dataset descriptions for most categories and be ready to make those data available;
  - Early 2031: provide dataset descriptions for remaining categories and be ready to make those data available
- For health data users:
  - Early 2029: can submit applications for most data categories
  - Early 2031: can submit applications for remaining data categories

What will happen when?

- For Member States:
  - Early 2029: have HDABs set up and ready to receive applications for most of Art. 51 data categories;
  - Early 2031: extension to remaining categories.
- For Commission/EU institutions:
  - Same timeline as for the other actors.

Preparatory work and next steps

Joint actions, projects etc. to generate input for technical specifications, sharing best practices, etc.:

- Xt-EHR (primary use)
- TEHDAS2 (secondary use)
- HealthData@EU Pilot (secondary use)
- QUANTUM (data quality labelling)
- Direct grants for MS and capacity building support
- eHealth Network, EHMSEG, Community of practice…

Thank you!
Questions? Answers!

European Commission