

# European Health Data Space

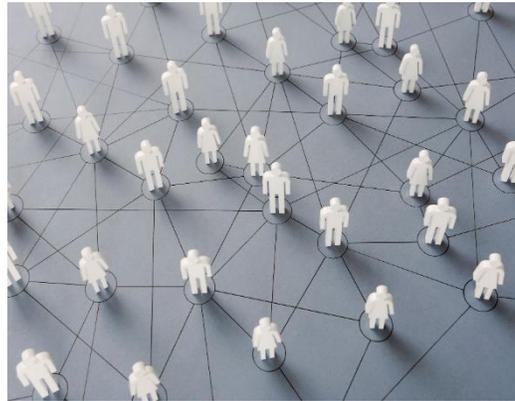
Harnessing the power of health data



# Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

Empower individuals to access and control their personal health data



Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)



# EHDS Regulation in a Nutshell – what is it about?

1. Primary use = use of health 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 health data for research and public interest purposes
  - Making data available for research, policy-making and regulatory activities 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 of health data

## 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.

# Benefits for patients and health professionals

## For patients

- Immediate and free of charge access to their own electronic health data in the priority categories.
- Easy sharing of data with health professionals, including cross-border.
- Possibility to add data, restrict access, see who accessed data, ask for rectification of errors.
- Have access in the European electronic health record exchange format, improving interoperability.
- Easy to use mechanisms for delegated access and appointing proxies
- (dependent on Member State choice): possibility for a full opt-out from exchanges using EHDS infrastructures for primary use.

## For health professionals

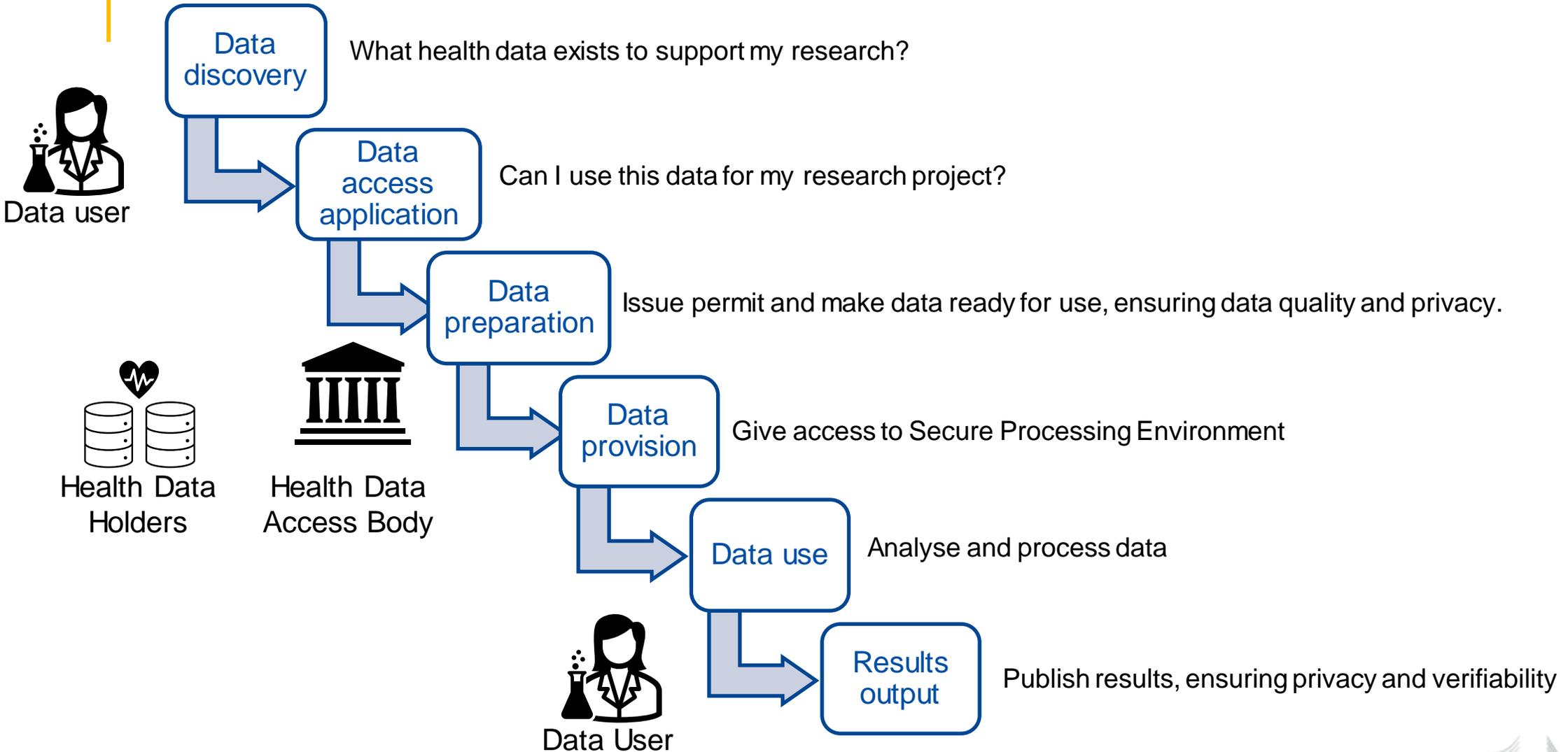
- Easier and quicker access to their patients' data, including cross-border.
- European electronic health record exchange format will facilitate data sharing across systems by increasing interoperability.

# EHDS in a Nutshell – Secondary Use of health data

## How?

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

# User journey



# 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

- Access to more data
- 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

## For industry and innovators

- Easier access to data for research and development
- Harnessing the potential of the data economy in the health sector

# EHDS in a Nutshell – EHR systems

## How?

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

# Benefits of requirements on EHR systems

## For manufacturers

- Easier market access across Member States due to harmonised requirements for interoperability and logging components.
- Increased interoperability reduces switching costs, making market entry easier.

## For patients

- Increased interoperability facilitates data sharing, saving time and money.

## For healthcare providers

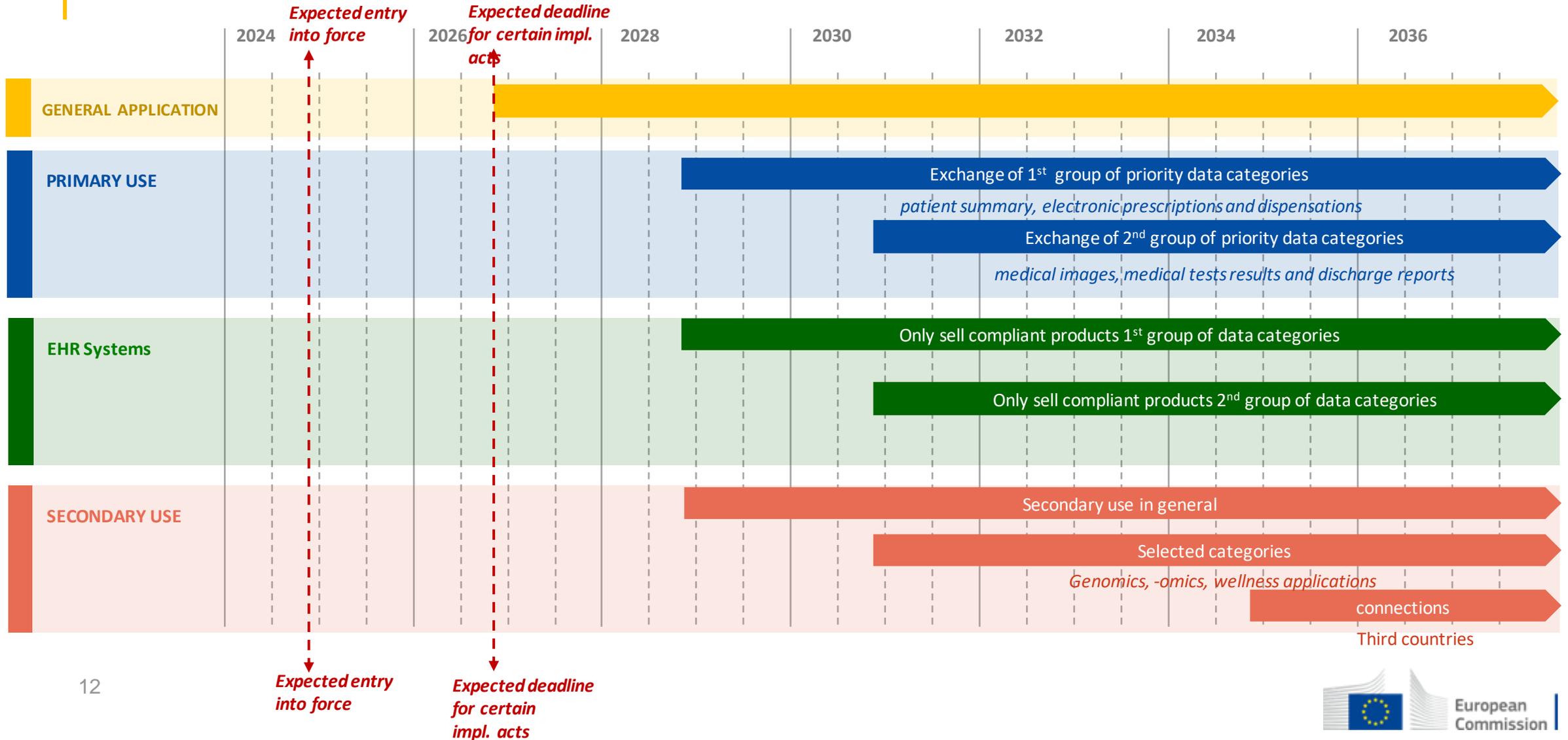
- Can be assured that any EHR system they buy enables them to comply with interoperability requirements.
- Increased interoperability:
  - saves time and money by not uselessly repeating tests;
  - reduces switching costs, decreasing vendor lock-in effects.

# EHDS Implementation: Preparatory work and next steps

EU funded actions to support national implementation efforts and implementation at EU level (generating input for technical specifications, sharing best practices, etc.):

- Direct grants for MS and capacity building support
- [Xt-EHR](#) (Joint Action on primary use)
- TEHDAS2 (Joint Action on secondary use)
- [HealthData@EU Pilot](#) (secondary use)
- [QUANTUM](#) (data quality labelling)
- eHealth Network, EHMSEG, HDAB Community of Practice...

# EHDS – Overall timeline for application



# Thank you