

Impact of EHDS

KCE Trials Symposium ◦ 28 November 2024

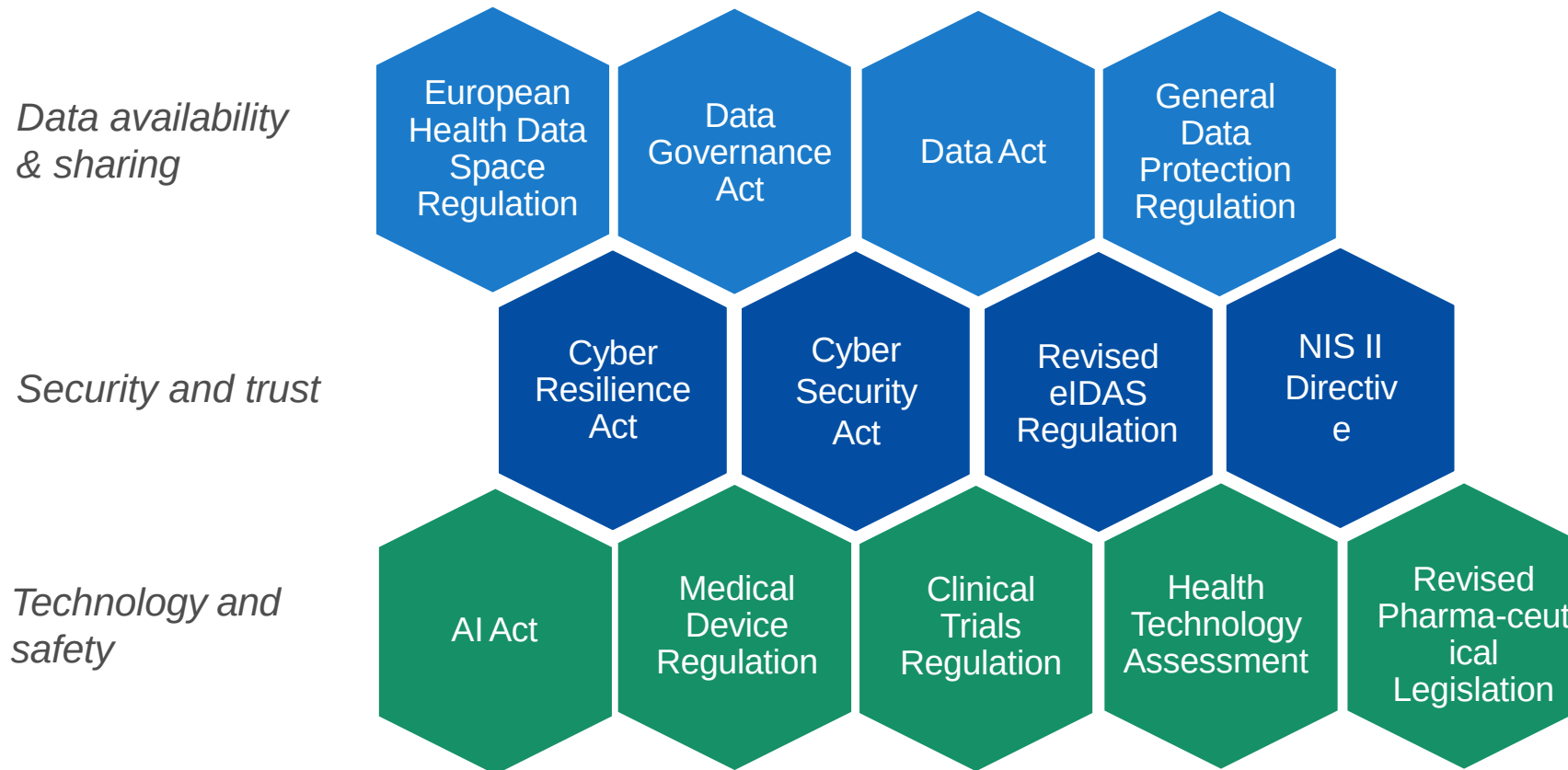
Nick Marly



EU vision and EHDS

In a nutshell

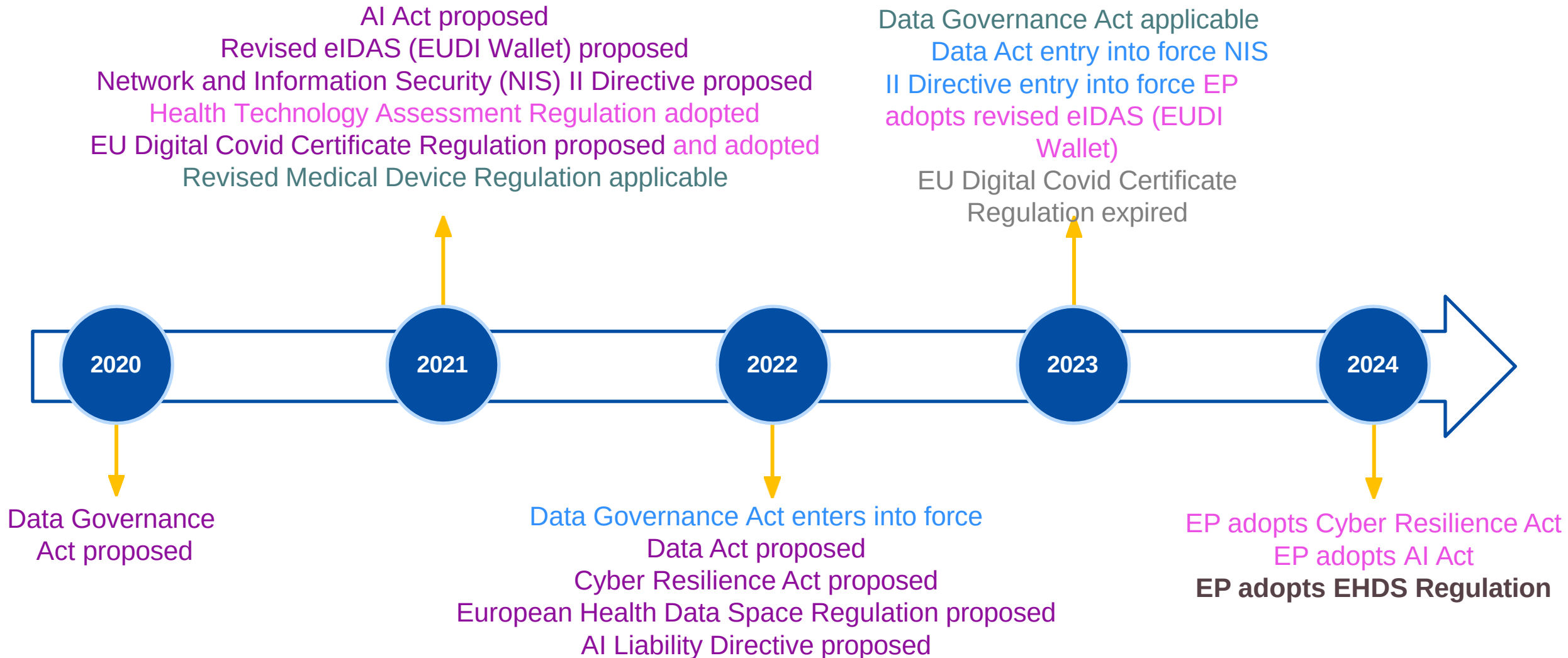
Digital transformation of healthcare: the building blocks



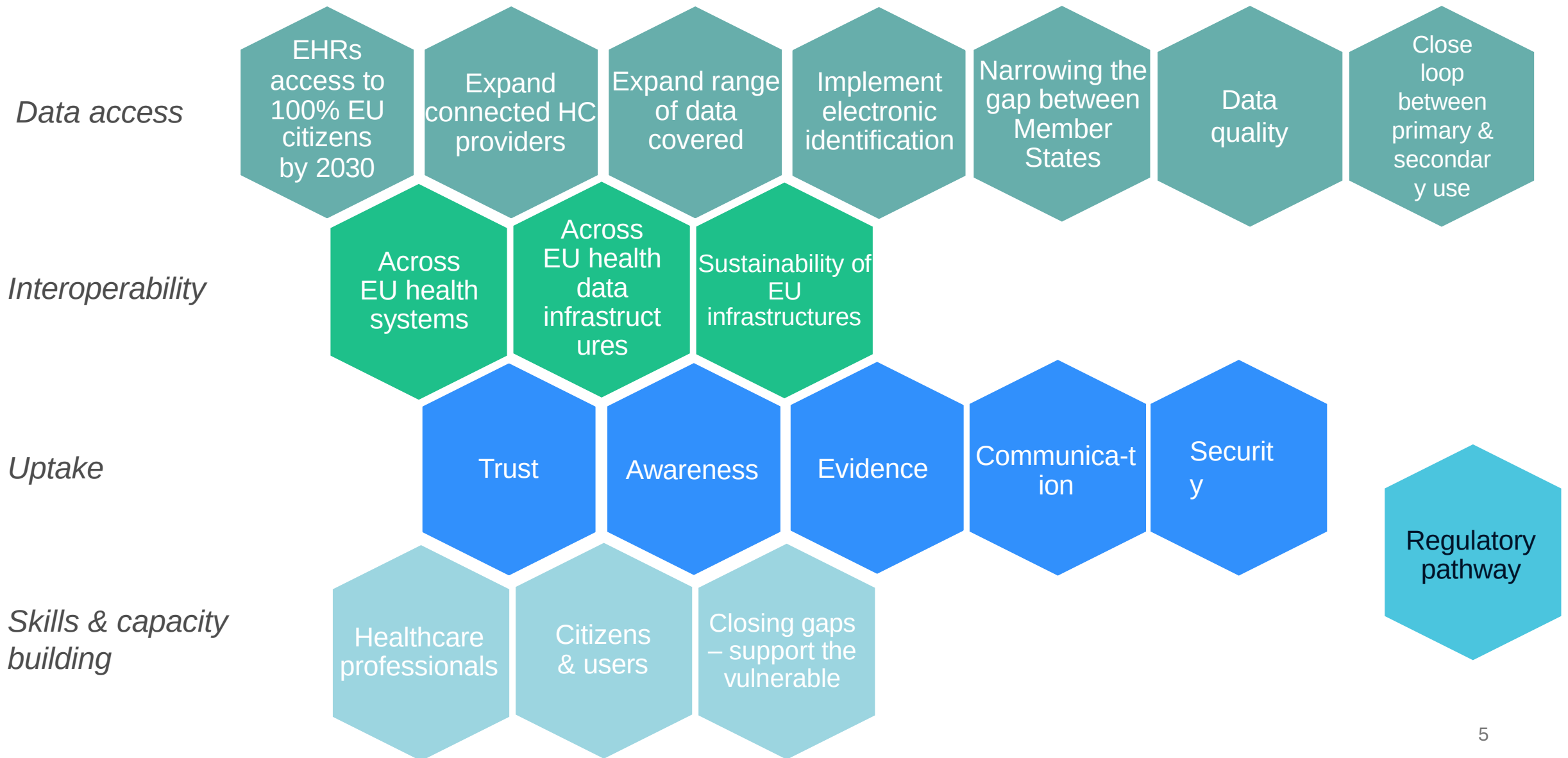
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e-Health target: 100% of EU citizens access to **electronic health records** by 2030

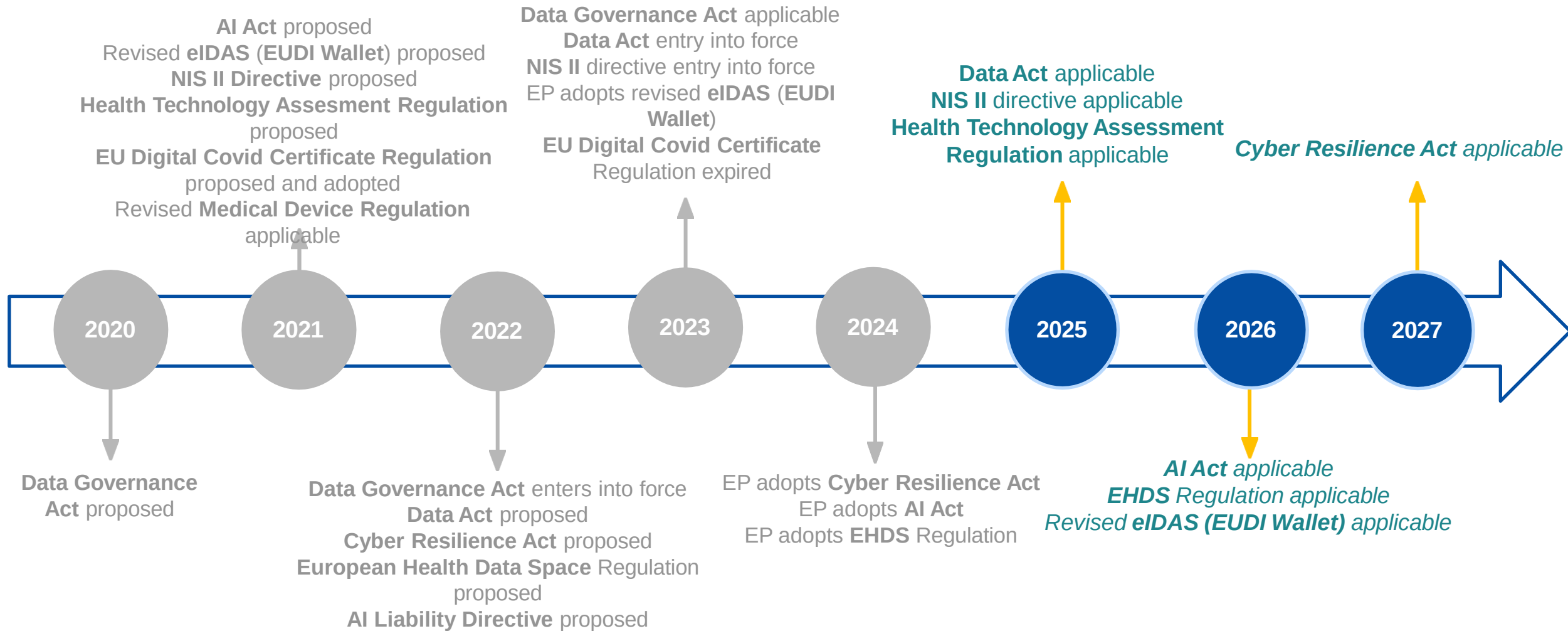
Digital transformation of healthcare: five impactful years



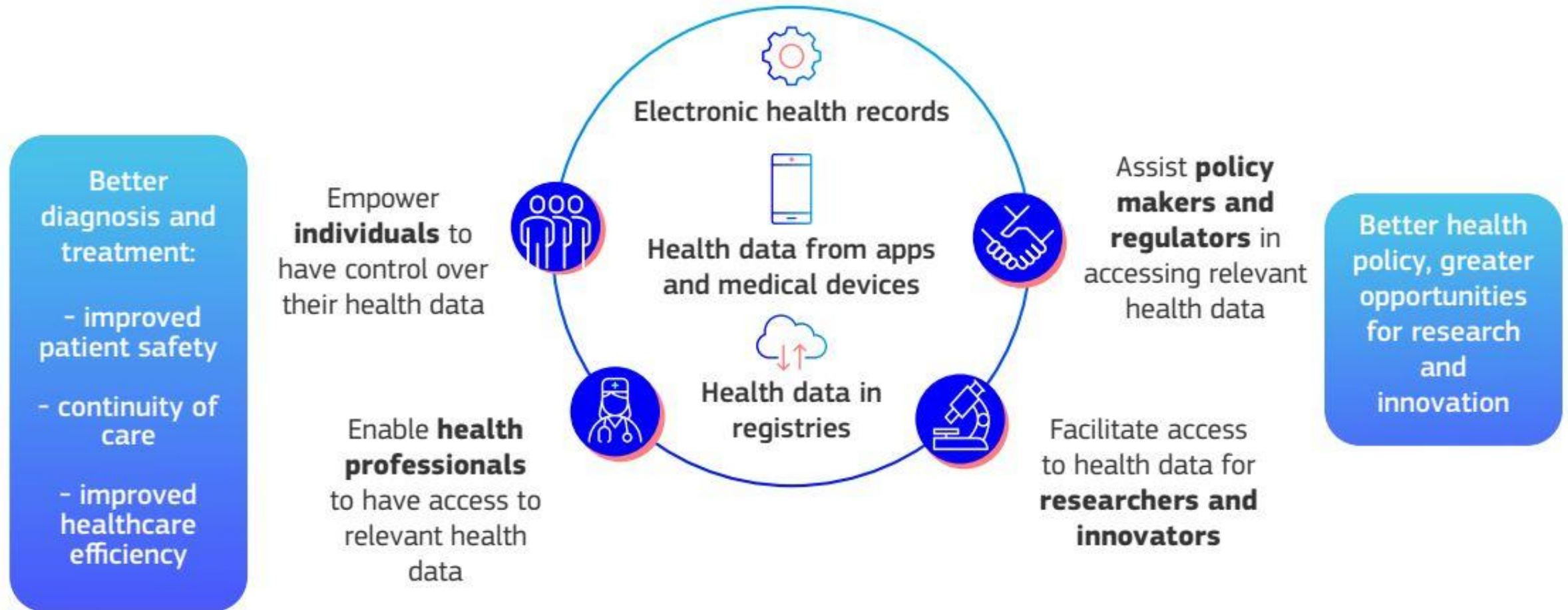
Advancing towards patient-centred & personalised healthcare



Ensuring timely and effective implementation



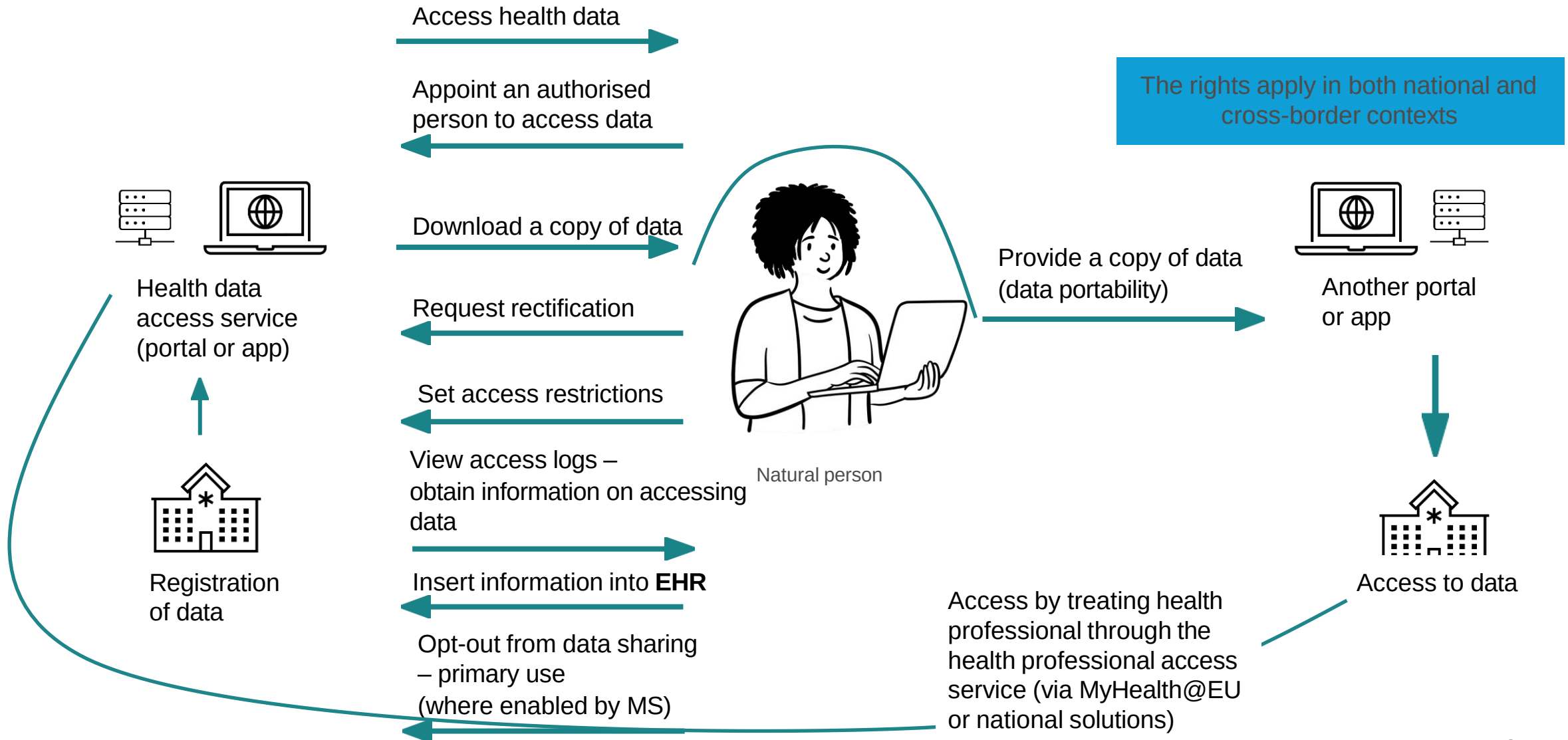
EHDS in a nutshell – what is it about?



Primary Use

Within the EHDS

Rights of natural persons in primary use



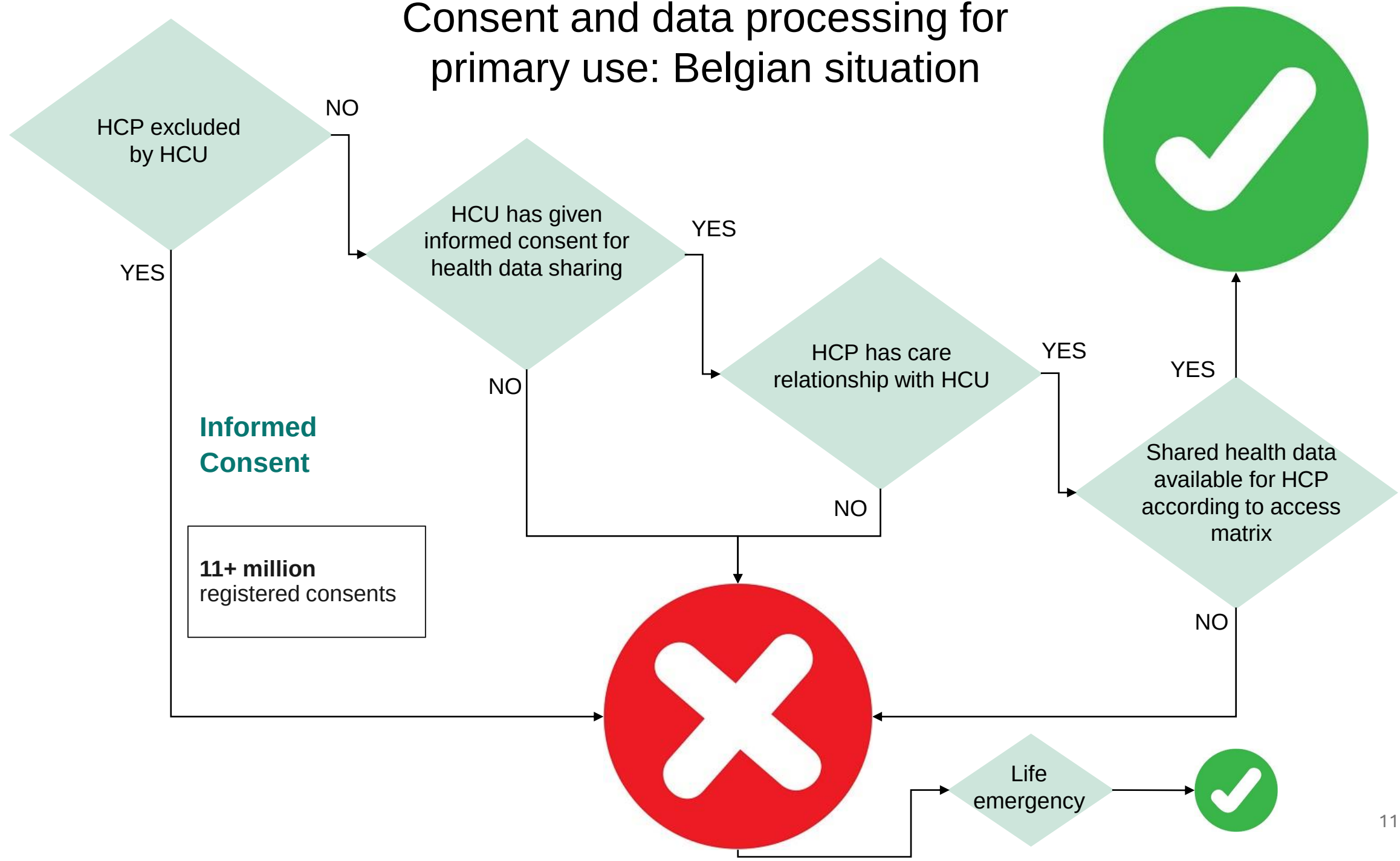
Consent and data processing for primary use

- EHDS establishes health data exchange for primary use **as a matter of important public interest**.
 - **Explicit consent may not be required** for the processing of health data for direct care purposes.

However:

- Patients retain the right to object to certain data sharing.
- Member states **may** implement an **opt-out** for sharing of data for primary use.
 - If an opt-out is implemented, it must be harmonized for internal and cross-border and harmonized with an EU standard.

Consent and data processing for primary use: Belgian situation



Secondary Use

Within the EHDS

Data access and use

Conditions for secondary use:

- **Article 33 EHDS: *Categories of data***
 - Member States **may** implement an **opt-in** for a limited number of data categories: genetic and genomic data, molecular data, biobank data, data from wellness Apps.
- **Article 34 EHDS: *Categories of purposes***
 - Member States **must** implement an **opt-out for all categories of purposes**
 - Member States **may** introduce **restrictions** on the opt-out for reasons of public interest/health, policy making, statistics and scientific research requested by public sector bodies and Union institutions or mandated by EU or national law
 - However: without prejudice within a Member State for access to electronic health data under existing national or EU law.

Data access and use

- **Article 34 EHDS: Permitted categories of purposes => Purposes for secondary use of data**
 - Protection against cross-border threats to health, public health surveillance high quality and safety of healthcare, patient safety
 - Policy making and regulatory activities
 - Statistics
 - Higher education
 - Scientific research – health technology assessment – developing and innovation + training, testing and evaluating of algorithms (AI + MD)
 - Improvement of healthcare (delivery of care, treatment optimization)

Data access and use

- **Article 35 EHDS: Prohibited categories of purposes**
 - Taking decisions **detrimental to a natural person or a group of natural persons** based on their electronic health data;
 - In relation to job offers or offering less favourable terms in the provision of goods or services, including to exclude them from the benefit of an insurance or credit contract or to modify their contributions and insurance premiums or conditions of loans, or the effect of **discriminating on the basis of the health data** obtained;
 - **Advertising** or marketing activities;
 - Developing products or services **that may harm individuals, public health or societies at large**, including, but not limited to illicit drugs, alcoholic beverages, tobacco and nicotine products, weaponry or products or services which are designed or modified in such a way that they create addiction or that they contravene public order or cause a risk for human health;
 - Activities **in conflict with ethical provisions** pursuant to national law.

EHDS – HDAB Roles & Responsibilities

- EHDS
 - Primary Use for persons and health care professionals & Cross-border
 - EHR Systems & wellness applications
 - Secondary Use, real world data
 - Governance, Capacity, ...
- EHDS Secondary Use – Health Data Access Bodies:
 - **Facilitating** - FAIR Data (findable, accessible, interoperable, reusable)
 - **Authorisation/Permit**
 - **Processing** (secure processing environments)
- EHDS Secondary Use – Other:
 - Trusted Data Provider
 - Intermediation Entity (IE)
 - Coordinating HDAB

Data access and use

EHDS Article 45: Data Access Application

- A **natural person or legal person** may submit a data access application for purposes to in Art. 34 (i.e. purposes for which electronic health data can be processed for secondary use) to the health data access body.

EHDS Article 47: Health Data Request

- **The applicant** may submit **a health data request** for the purposes referred to in Article 34 **with the aim of obtaining an answer only in anonymised statistical format**.
- A health data access body shall **not** provide an answer to a **health** data request in **any other** format and the **health** data user shall have no access to the electronic health data used to provide this answer.

Data access and use

EHDS Article 46: Data Permits

- Authorise and issue data permits pursuant (if the application fulfils one of the purposes listed)
- Define technical and organisational measures to protect the rights of natural persons pursuant to the data permit
- Monitor and supervise compliance with the requirements laid down in this Regulation by health data users and health data holders
- Create transparency on data permits, make public
- Maintain a management system to record and process data access applications, data requests, the decision, ...

Data access and use

EHDS Article 33a: Intellectual property rights and trade secrets

- a) Health Data Holders (**HDH**) **must inform HDAB** of any electronic health data containing content or information protected by IP or trade secrets + justification + available when description of data sets is made;
- b) HDAB shall take all specific **appropriate and proportionate measures**, including legal, organisational, and technical ones, necessary to preserve the protection of IP rights, trade secrets and/or the regulatory data protection right;
- c) HDAB may formulate **conditions to get access** to this data including contractual arrangements;
- d) If risk of infringement is too high, **HDAB should refuse access** to Health Data User (HDU). HDAB should inform HDU of this decision;
- e) HDH ad HDU can **log a complaint**;

Rare Diseases

Use Case

Real World Data / Real World Evidence

RWD Types

- Clinical data: EHR, Radiology, Lab results
- Medication: prescribed, OTC
- Claims data: insurance, medical claims
- Molecular Profiling: genomic and genetic testing data
- Family History: health conditions, lifestyle
- Mobile Health: wearables, telemonitoring
- Environmental: pollution, dust, climate
- Patient Reported: PROM / PREM
- Social Media
- Literature

Benefits

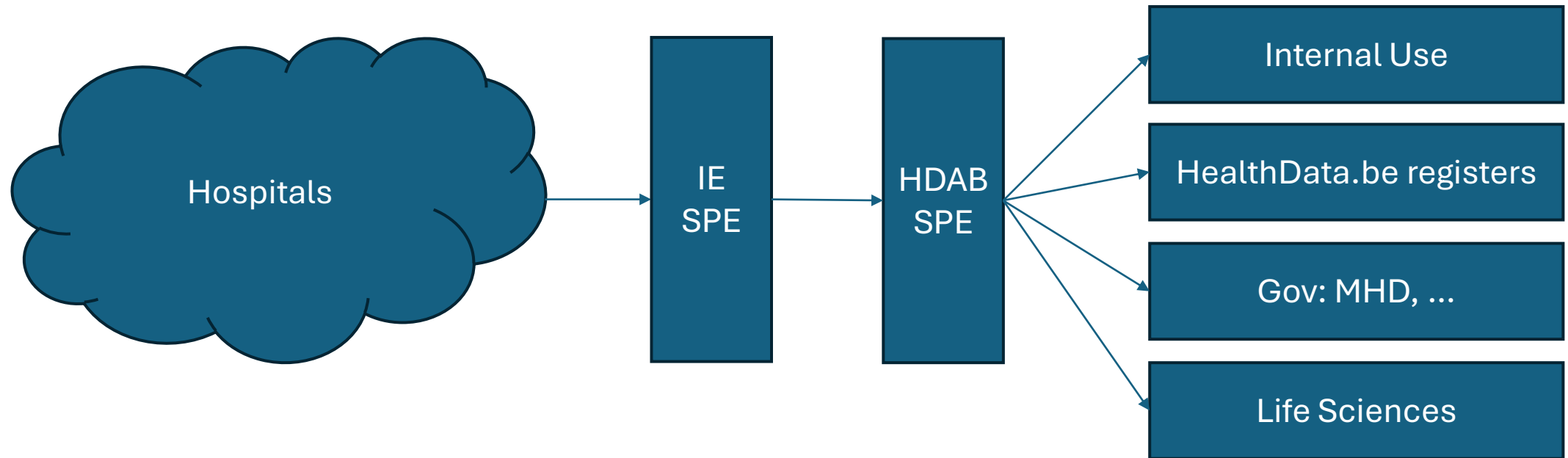
- Product & Therapy Development
- Improved Patient Outcomes
- Cost and Time Efficiency
- Health Economic Evaluation
- Population Health Management and Prevention

Rare Diseases data availability

- Ensuring **incentives for quality registration** and extraction of data.
- Making **structured data** from EHR systems available for secondary use also from unstructured data (NLP, ...).
- Structuring and **coding** these data based on SNOMED CT.
- **Identification** of rare disease cases, coding with ORPHAcode (AI support).
- Setting up or joining a **Data Network** (distributed, centralised / OMOP CDM or FHIR based) and enabling the usage of this data via SPE HDAB.
- Make **data from the first line and from the person** concerned available, by among others integrate decisions support in EHR-systems.
- **Link** with other data: claims data, environmental, ...
- Ensure **cross-border** data for bigger populations (via EHDS, research networks, ...).

Data Network Hospitals

- IE = Intermediation Entity, cannot be HDAB
- SPE = Secure Processing Environment



EHDS Solidarity

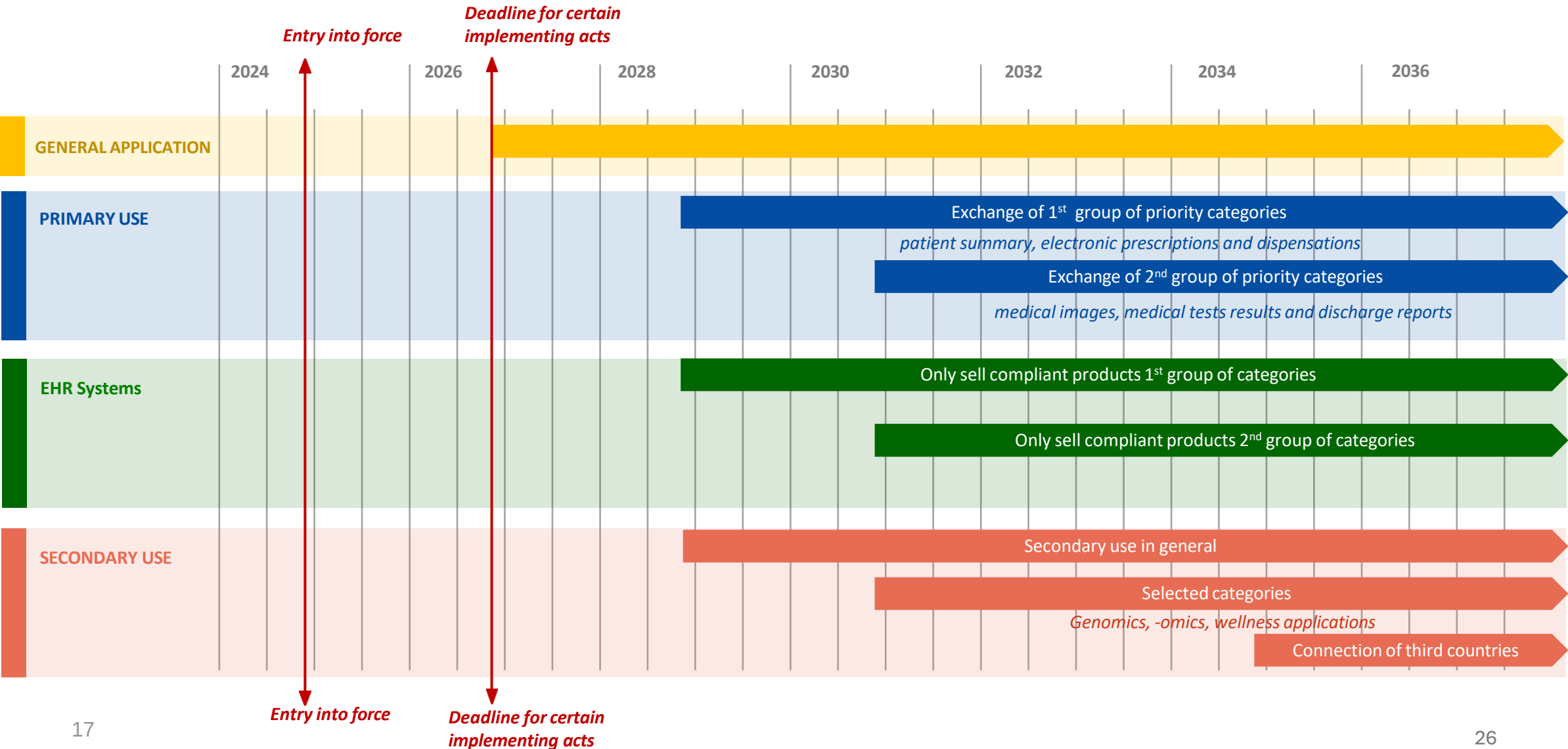
EU Timeline

Age of Data Solidarity / what's in it for me



- Literacy and Inclusion
- Return on Individual Investment
- Personal medicine/treatment
- Decision support, PHM dashboards
- Data Solidarity
- Transparency about goals
- Responsibility of all stakeholders

EHDS – Overall timeline for application





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Thanks to (knowledge & slide reuse):

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