How to leverage European Health Data Space(EHDS) and other regulatory initiatives to build computable phenotype and common outcome library?

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EU Regulatory Framework and Implementation Agenda

- **European Health Data Space (EHDS),** which aims to facilitate the secure exchange of health data across Member States, enhancing research and healthcare delivery.
- **AI Act,** which establishes comprehensive rules and guidelines for the development and deployment of AI systems, with specific provisions for healthcare applications.
- **Medical Device Regulation (MDR),** which sets stringent standards for the safety and performance of medical devices, including those incorporating AI and other digital technologies.
- **Implementation Challenges,** which concern especially the diverse readiness levels among EU Member States, stakeholders, interplay between different regulatory frameworks and the challenges in harmonizing digital health strategies.
- **Other initiatives,** which highlight successful implementations and ongoing projects in EU and Member States.

Is the EHDS as a new map for redefining health data management?

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European Health Data Space 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

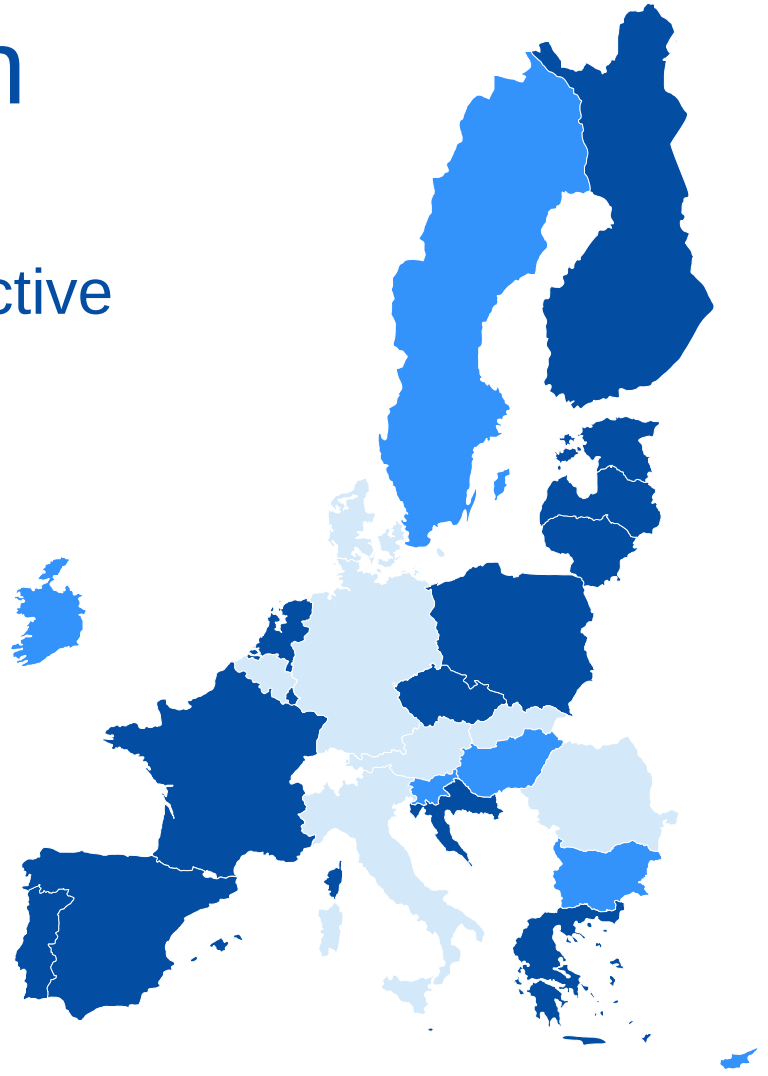
How?

- 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.

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)
- **14 MS** live with at least one service, **6 more** scheduled to go live with first service(s) this year



Evolution of MyHealth@EU for the EHDS

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

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
- Data catalogues of available datasets
- Permits for data use, common safeguards

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**;

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established in the EU

Having the right or obligation to process

or the ability to make these data available.

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 intermediary entities to fulfill these duties.

Notification to the Commission of any relevant national legislation.

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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

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.

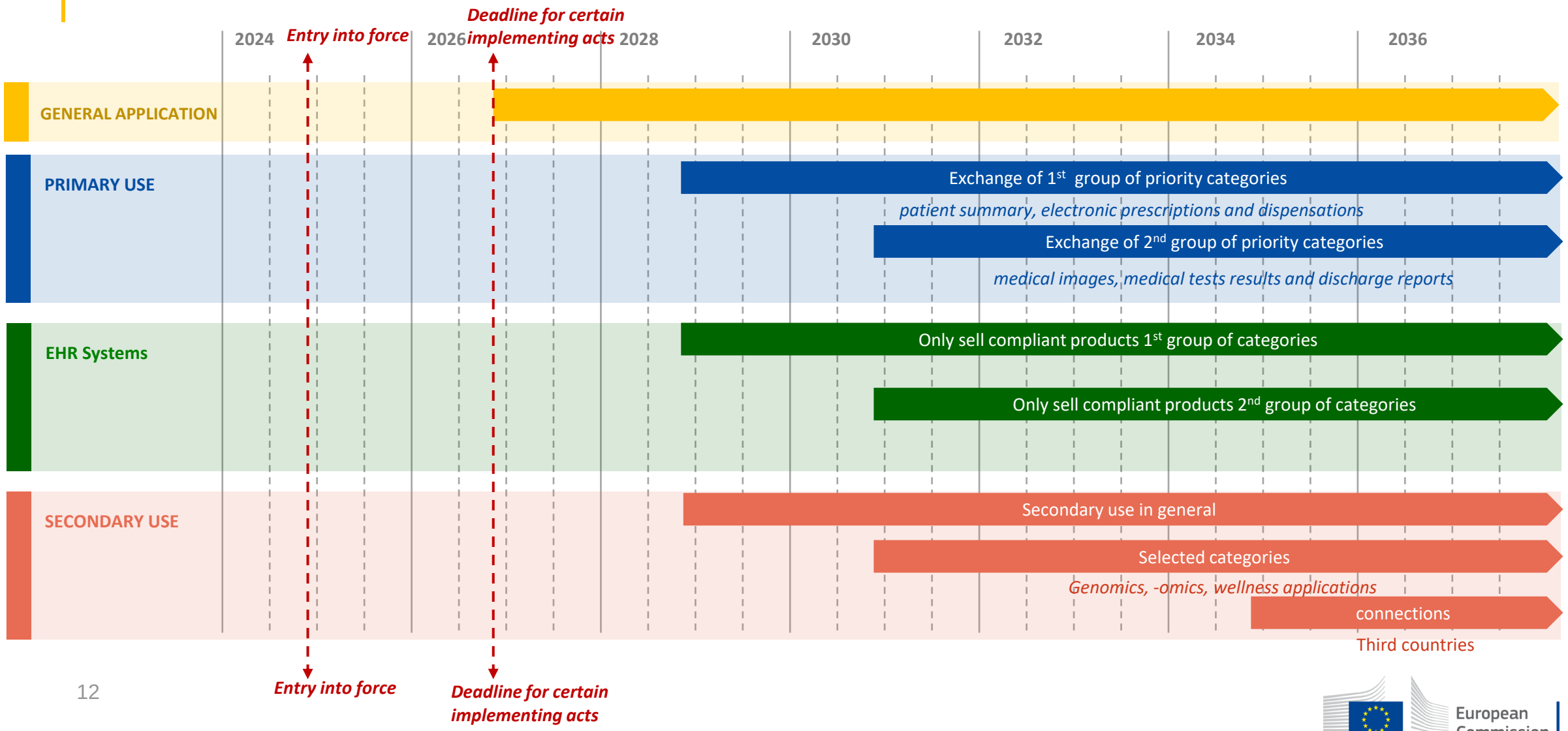
Key areas of interplay AI Act with EHDS

Key objectives:

Avoid duplication and leveraging on EHDS for compliance with data quality requirements of the AI Act

- **High-risk AI systems claiming interoperability with EHRs**: compliance with interoperability requirements of EHDS
- **Compatibility of common specifications for EHRs** with requirements for high-risk AI systems under AI Act
- For high-risk AI systems claiming interoperability with EHRs**, registration under AI Act** but with mentioning of interoperability aspects
- **Data quality and utility label** as a leverage for compliance with AI Act requirements
- **No labelling of wellness apps if those are high-risk AI systems**: avoid double labelling

EHDS – Overall timeline for application



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Preparatory work and next steps

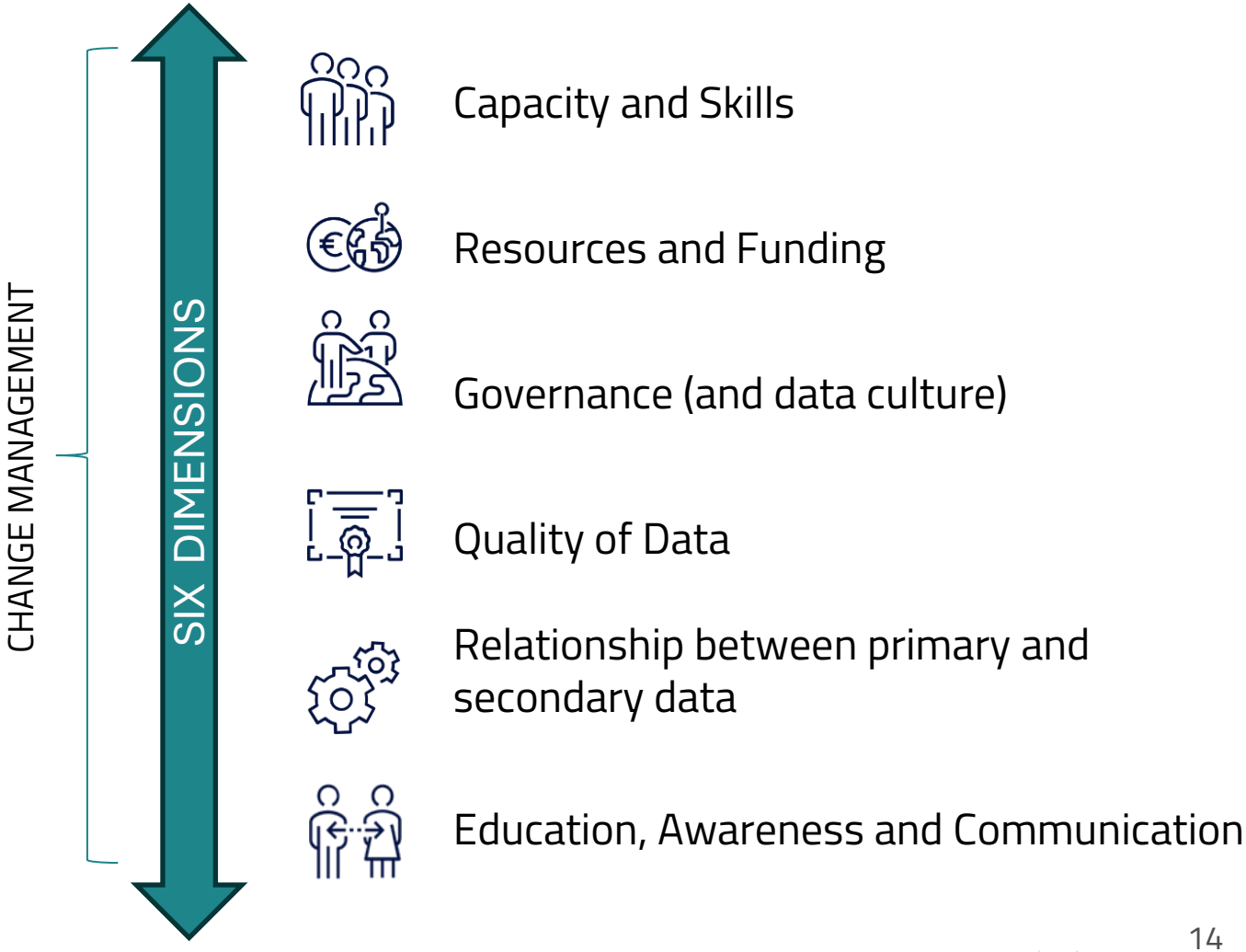
Joint actions, projects etc. to generate input for technical specifications, sharing best practices, etc.:

- 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, Community of practice…

EIT Health Think Thank report on EHDS implementation

Findings and Solutions

Over 120 findings and solutions collected from policy makers, health data access bodies, digital and medical devices industry, health institutions, higher education providers , healthcare providers patient organisations



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Other EU initiatives

- ***The European Cancer Imaging Initiative***

The European Cancer Imaging Initiative, a key part of Europe's Beating Cancer Plan (EBCP), aims to leverage AI imaging to enhance cancer care. By integrating digital technologies like AI and High-Performance Computing (HPC), the initiative seeks to improve clinical decision-making, diagnostics, and treatments.

- ***ELIXIR: Streamlining Life Science Research in Europe***

Founded in 2014, ELIXIR is a pan-European infrastructure organization that brings together life science resources from across Europe, enhancing data accessibility, analysis, and sharing among researchers. This effort supports deeper insights into biological processes.

- ***The EU's 1+Million Genomes***

2018 Member States' Declaration signed by 27 countries by now. The EU's '1+ Million Genomes' (1+MG) initiative aims to provide secure access to genomics and clinical data across Europe to support research, health policy, and personalized healthcare, improving disease prevention.

- ***EBRAINS***

EBRAINS is a comprehensive research infrastructure dedicated to brain-related research, emphasizing interoperability and high-quality data. It offers FAIR brain data sets, a multilevel brain atlas, AI-based analytical tools, and access to high-performance computing resources, robotics, and neuromorphic platforms. EBRAINS operates through a pan-European network across 11 countries.

- ***European Reference Networks:*** *Share.Care.Cure.*

European Commission established, according to the EU directive on patient' rights for cross-border health care, 24 European Reference Networks (ERNs). These are virtual networks comprising healthcare providers from across Europe, aimed at fostering clinical and scientific cooperation for complex or rare diseases. ERNs concentrate specialized treatment, knowledge, and resources. ERNs can also establish RD registries.

- ***TEF-Health – Advancing AI and Robotics in EU Healthcare***

The EU is determined to lead in AI excellence, especially in healthcare, where AI and robotics have the transformative potential. TEF-Health aims to ensure that these technologies are safe and effective. Launched in January 2023, it involves 51 partners from nine countries. It focuses on validating AI and robotics in real-world healthcare scenarios and developing regulatory standards.