An Roinn Sláinte
Department of Health

Health Information Policy:
national and EU legislation and preparing for implementation

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1 December 2023 – '*Better Together for Digital'*

To develop an **integrated health information** system to support the development and delivery of integrated care and to ensure **efficient, secure sharing of health information for care and treatment, and for 'relevant' purposes**

Ensuring a **standards-based approach** to health information and the interoperability of health information systems

Strengthening our national **health data collections and infrastructure**

Improving **access, sharing and use of health information** for care and treatment and relevant purposes

Identity management of health information as part of the digitalisation of public services
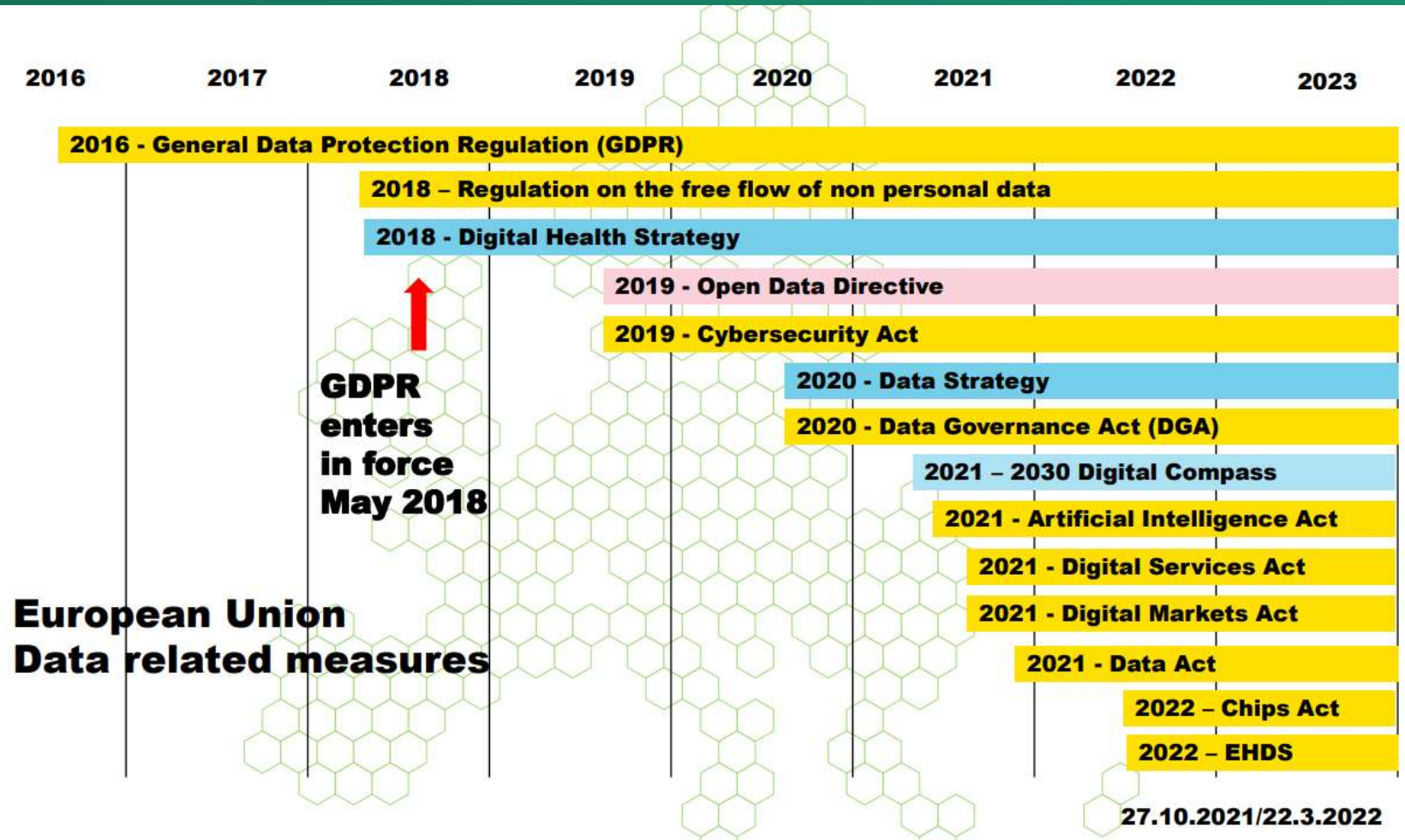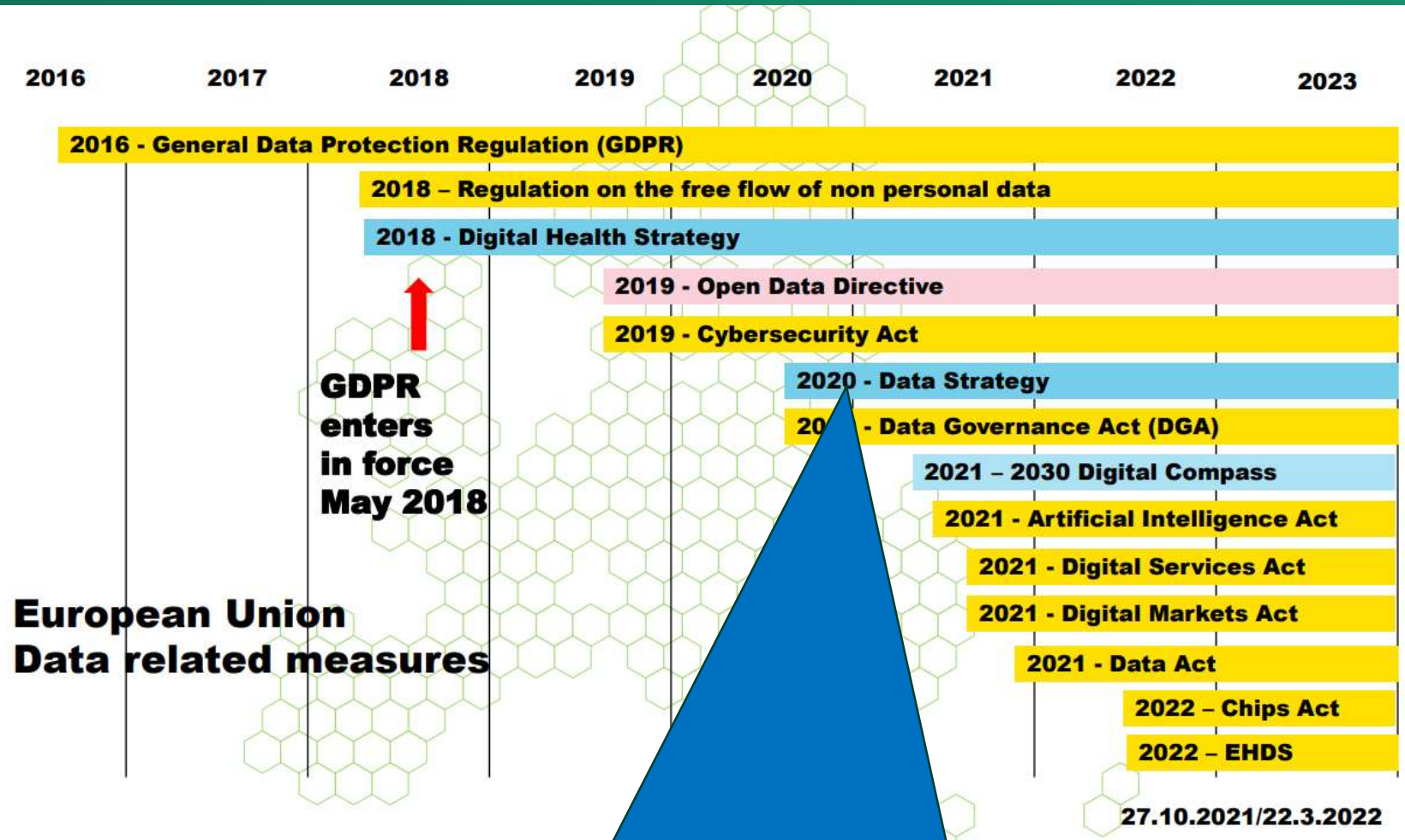
Building **trust** in our national health information system through **engagement**

Empowering patients and services providers with greater access to health information

Health Information Policy - aim and objectives

Timeline: European Union — Data related measures

| 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |

- 2016 - General Data Protection Regulation (GDPR)
- 2018 – Regulation on the free flow of non personal data
- 2018 - Digital Health Strategy
- 2019 - Open Data Directive
- 2019 - Cybersecurity Act
- 2020 - Data Strategy
- 20.. - Data Governance Act (DGA)
- 2021 – 2030 Digital Compass
- 2021 - Artificial Intelligence Act
- 2021 - Digital Services Act
- 2021 - Digital Markets Act
- 2021 - Data Act
- 2022 – Chips Act
- 2022 – EHDS

27.10.2021/22.3.2022

GDPR enters in force May 2018

European Union Data related measures

The European Data Strategy (2020)
'Path to Digital Decade 2030' envisages a transformation of society and economy across the EU
European Health Data Space (EHDS) is the first EU sectoral data space regulation

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Health Information Bill
Supporting increased access to **high-quality health datasets** for care and treatment and for secondary use

The European Data Strategy (2020)
'Path to Digital Decade 2030' - transformation of society and economy across the EU
European Health Data Space (EHDS) will be the first EU sectoral data space and regulation with direct effect

Key Provisions in the Health Information Bill

- A legal framework for the development of **digital health records** in Ireland.

- A '**duty to share'** health information for care and treatment as well as secondary purposes, spanning public, private and voluntary settings.

- **Patient access** to their digital health records: national patient summary and shared care record.

- Health information to be **collected, shared, linked**, and made available for **policy-making, research, public health, enhanced health service planning and management**.

- A **national health data access body** to connectt with the EHDS infrastructure.

- Emphasis on **strong governance rules** for privacy, security and building public trust.

- A **National Consultative Forum for health information** and **National Health Information Guardian.**

https://www.gov.ie/en/publication/6f6a6-health-information-bill-2023/

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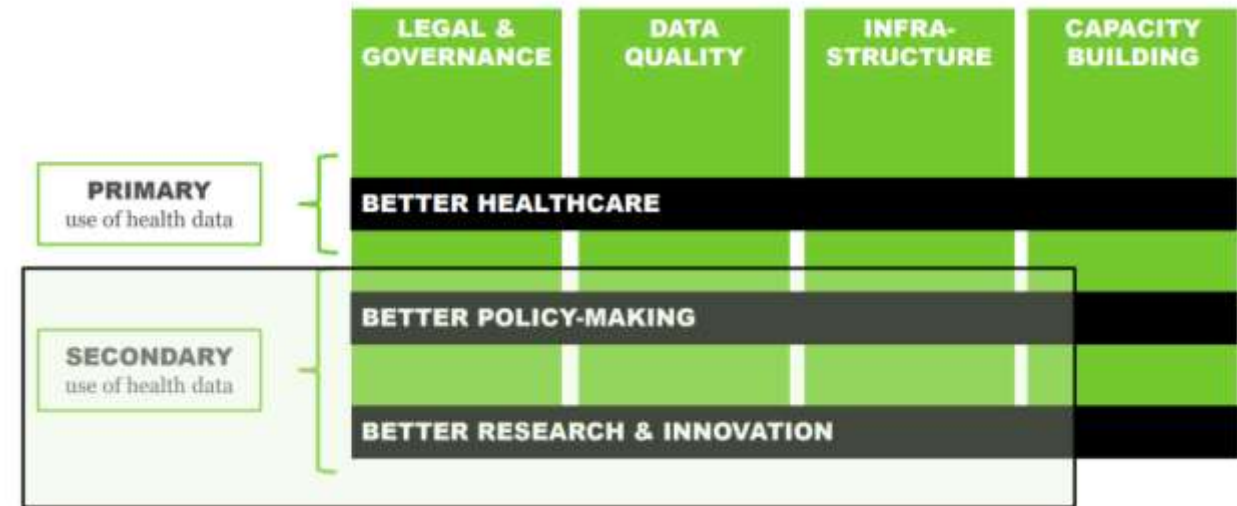# Features of European Health Data Space

To build a common **governance and infrastructure framework** for the movement of electronic health information and **empower individuals** with increased digital access and control of their personal health data

- **MyHealth@EU**
  - standardised and interoperable Electronic Health Records within the EU.

- **HealthData@EU**
  - A consistent, trustworthy and efficient set-up for the use and re-use of health data

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Unlocking data

Patients and health professionals	Secure, digital access to comprehensive up-to-date patient information	More accurate and timely diagnosis and treatment plans	Improve decision making and personalised treatments
Health intelligence	Identify patterns and trends in health status	Access to high-quality data for planning and performance management	
Research and Innovation	Timely access to large-scale datasets for analysis	Develop new treatments, therapies and interventions	

Healthdata@EU pilot infrastructure and use cases

- Demonstrate the feasibility of using the EHDS to carry out infectious disease surveillance, focusing on **antimicrobial resistance** (European Centre for Disease Prevention and Control)

- Foster a better understanding of the **risks of thrombosis in COVID-19 patients** (European Medicines Agency)

- Compare **COVID-19 testing, vaccination and hospitalisation between the general population and vulnerable subpopulations** (Sciensano - Belgium)

- Compare **care pathways for cardiometabolic diseases** in European countries and **build prediction models, using artificial intelligence** (Health Data Hub - France)

- Mobilise and chain **clinical and genomic data** to enhance our understanding of **colorectal cancer** (ELIXIR)

https://ehds2pilot.eu/

Towards implementation of the HIB & European Health Data Space

National Programmes

- National 'Shared Care Record' Programme to access and share **digital health records** and a **National Patient Summary Record**

- **ePharmacy and ePrescription** services

- **National engagement on digital health and social care** (patients and healthcare staff)

MyHealth@EU platform

- Cross-border infrastructure with EU **interoperability and security** requirements

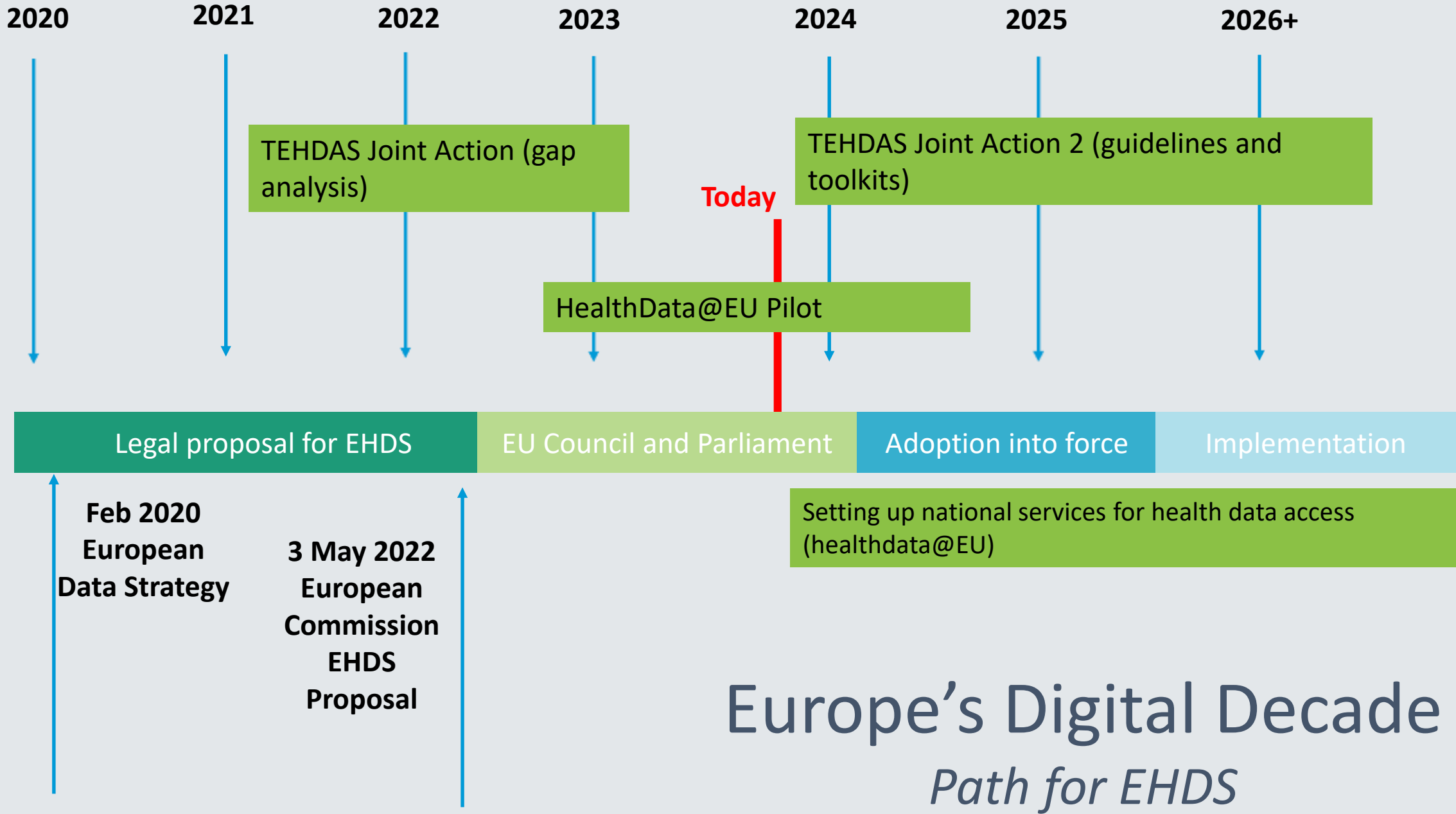- EU4Health investment for **technical developments and testing**

HealthData@EU infrastructure and services

- EU4Health Joint Actions for national gap analysis and data quality and utility labelling of national datasets

- EU4Health investment in **setting up services for health data access.**

2020 **2021** **2022** **2023** **2024** **2025** **2026+**

TEHDAS Joint Action (gap analysis)

TEHDAS Joint Action 2 (guidelines and toolkits)

Today

HealthData@EU Pilot

Legal proposal for EHDS | EU Council and Parliament | Adoption into force | Implementation

Setting up national services for health data access (healthdata@EU)

Feb 2020 European Data Strategy

3 May 2022 European Commission EHDS Proposal

Europe's Digital Decade
Path for EHDS