



An Roinn Sláinte
Department of Health

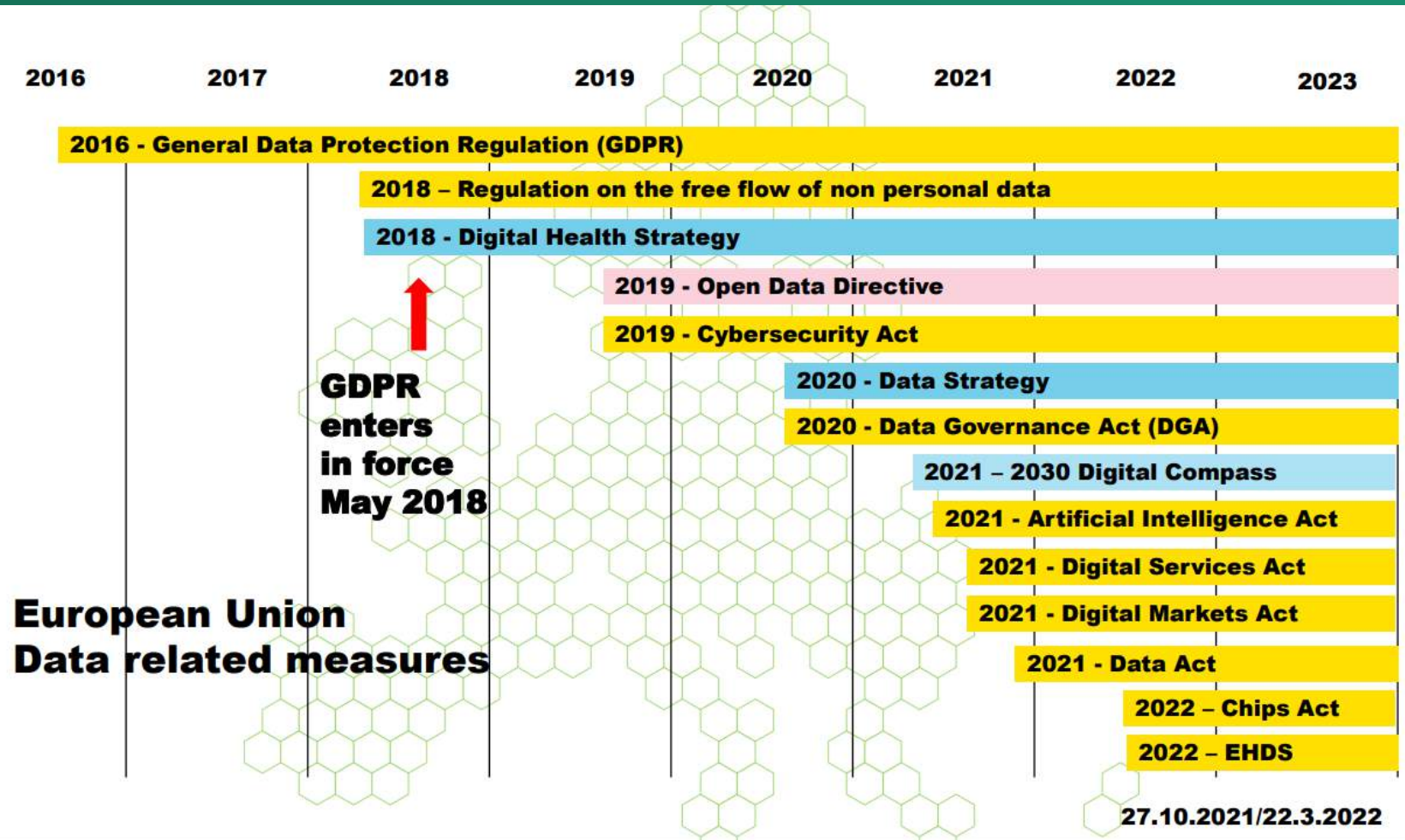
Towards a European Health Data Space

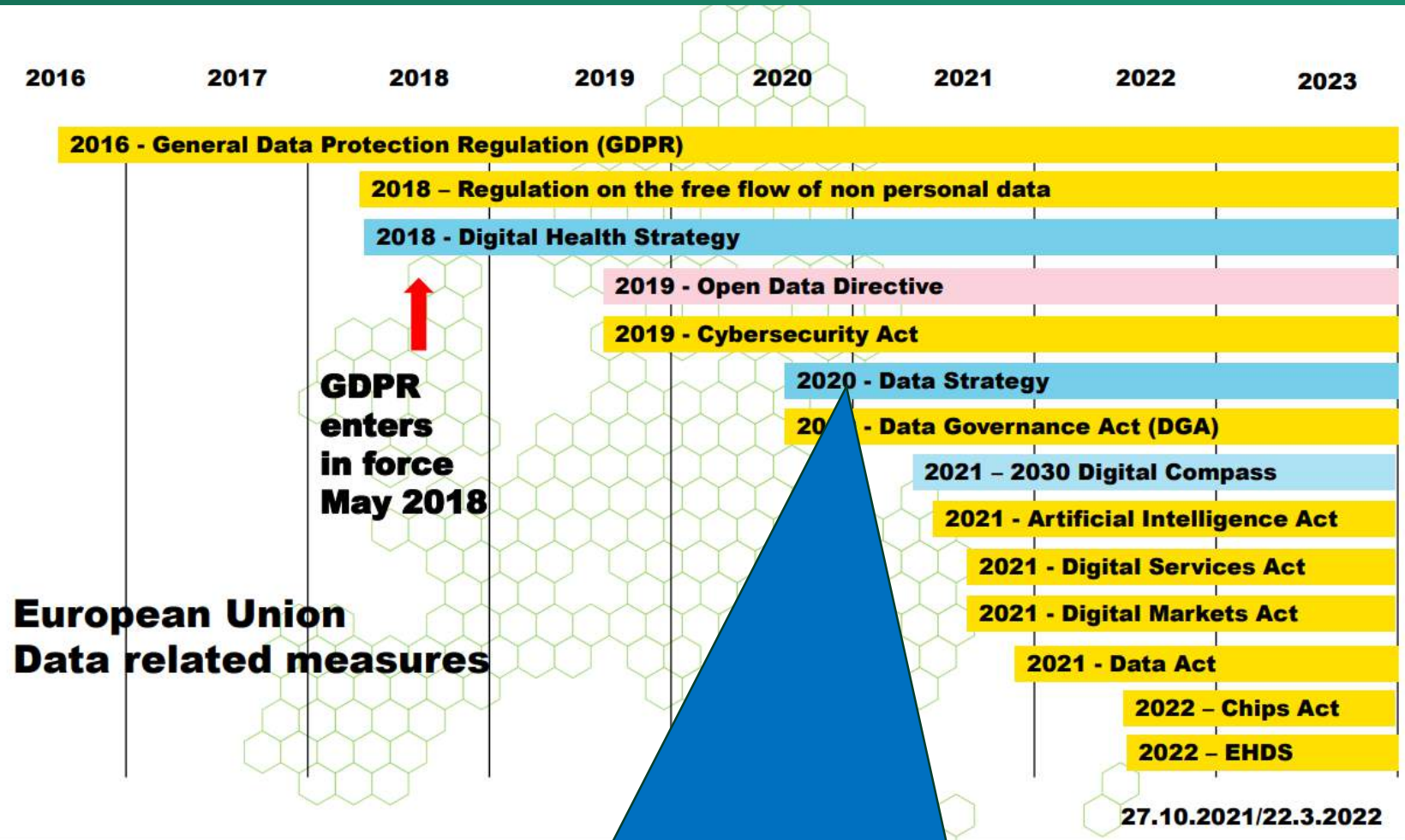
Judith Szlovák

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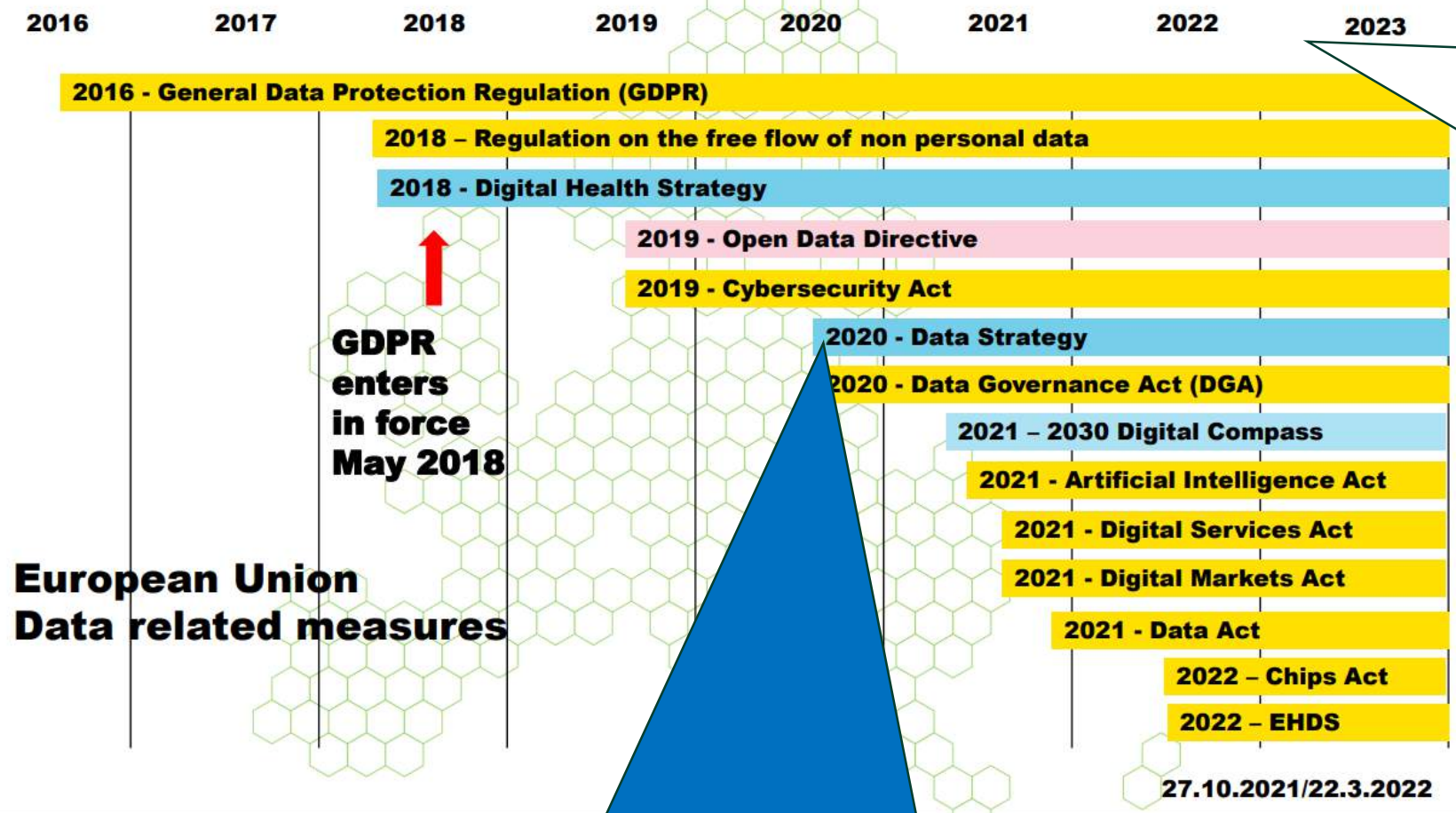
23 November 2023





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



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

EU data strategy and Data Spaces

Rich pool of data
(varying degree
of accessibility)

Free flow of data
across sectors and
countries

Full respect
of GDPR

Horizontal framework
for data governance
and data access

- Technical tools for data pooling and sharing
- Standards & interoperability (technical, semantic)
- Sectoral Data Governance (contracts, licenses, access rights, usage rights)
- IT capacity, including cloud storage, processing and services



Health



Industrial
&
Manufac-
turing



Agriculture



Finance



Mobility



Green
Deal



Energy



Public
Adminis-
tration



Skills

Cross-sectoral Personal Data Space

Services

- Collecting, combining, enriching and refining data into information and insights

Features of European Health Data Space

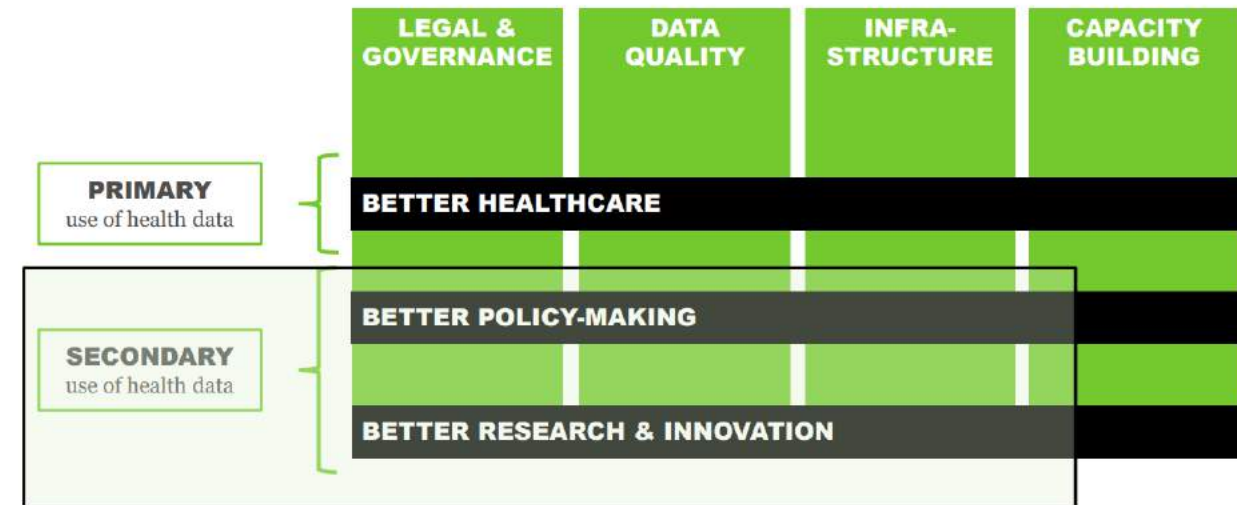
To build a common **governance and infrastructure framework** for the movement of electronic health information and **empower individuals** with increased digital access and control of their personal health data

•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



The European Health Data Space & Open Data

The EHDS Regulation will create a legal framework for standardized access to health data **not currently made available** under Open Data Directive ((EU) 2019/1024).

EHDS listed data categories

- data from EHRs,
- medical devices,
- health-related administrative data,
- clinical trials,
- genetic and genomic data,
- social and environmental determinates of health

EHDS listed purposes include public health, national statistics, educational and training, scientific research.



The European Health Data Space & Open Data

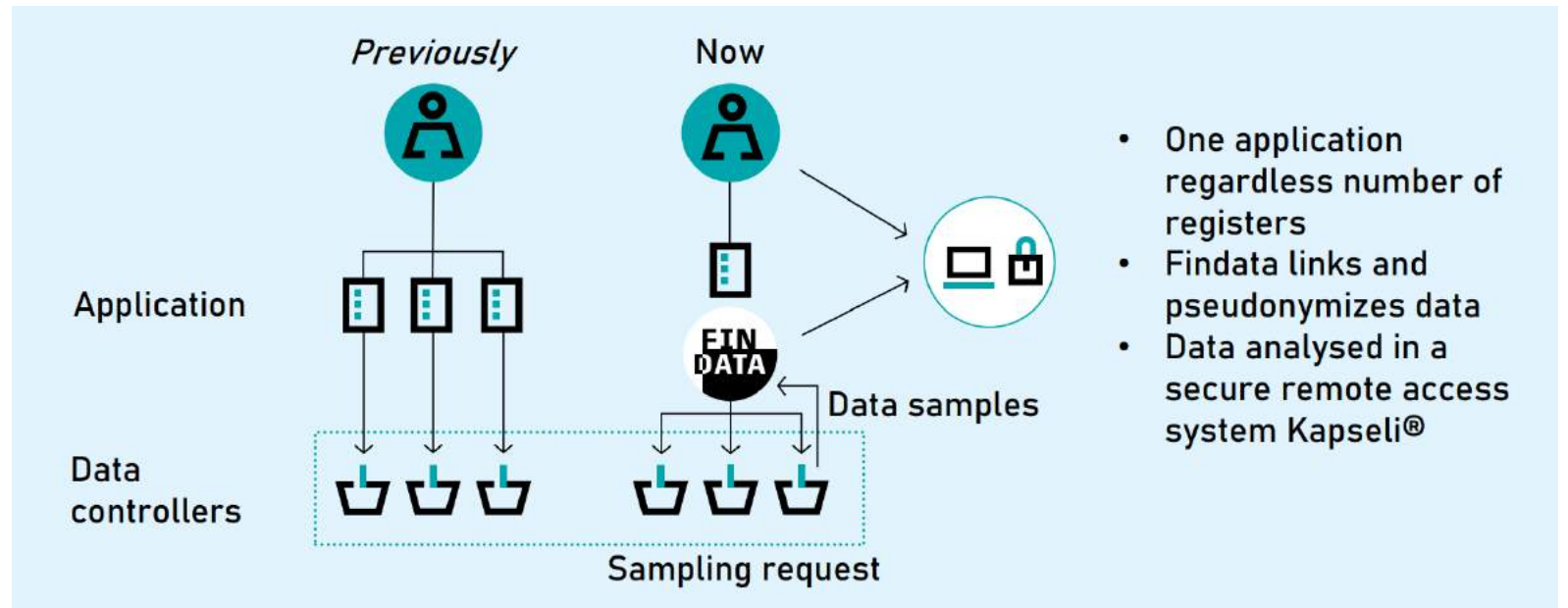
Accessing Healthdata@EU

- EHDS is **built on FAIR principles** (findable, accessible, interoperable and reusable)
- **Single application point** via a health data access body (for multi-country requests)
- Descriptions available in **metadata catalogues** across the EU to enhance data discovery
- **Clear governance structures** for decision making on access to data
- **Publication** of decisions, results and release of enriched datasets

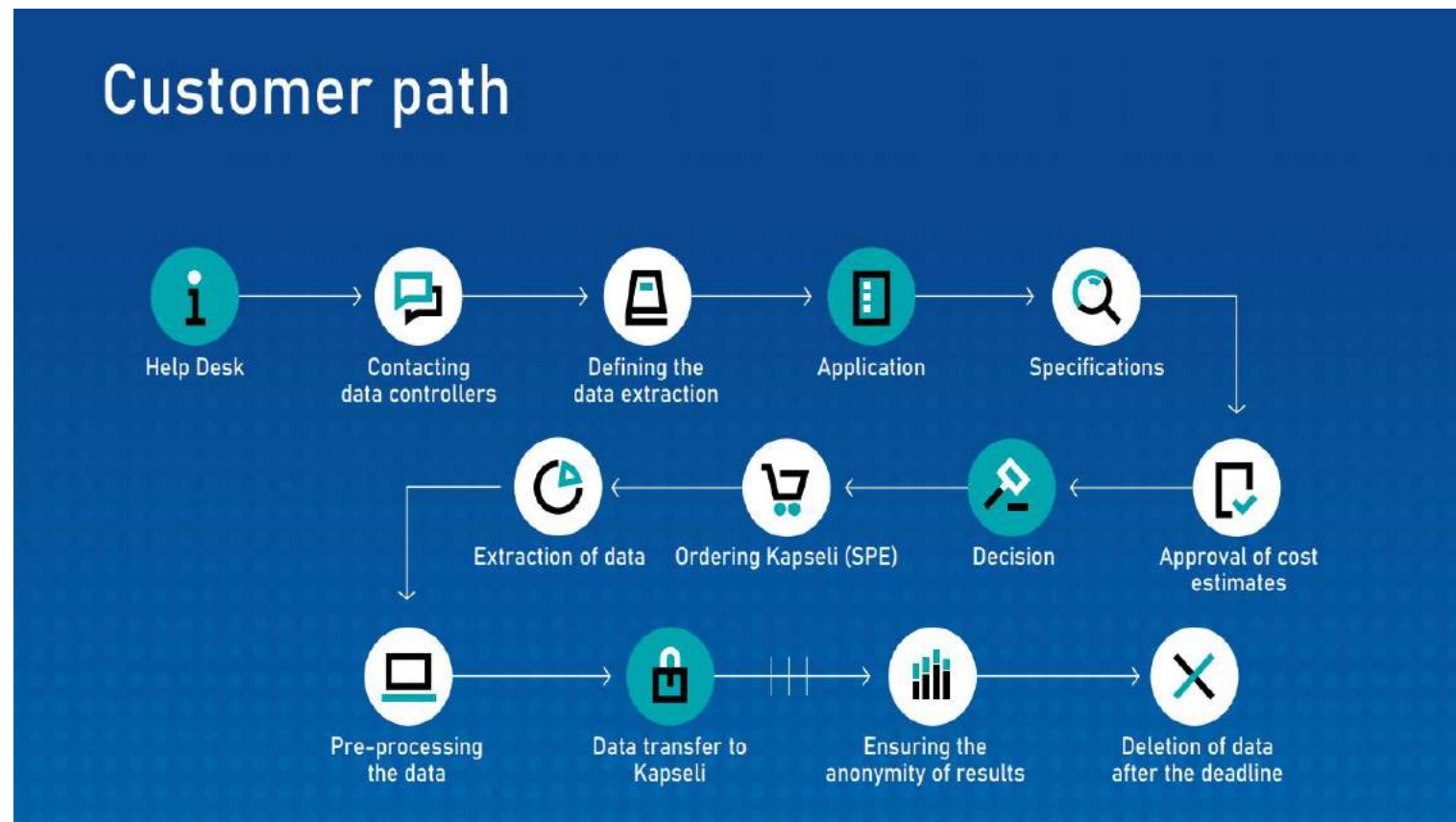
EU agencies, bodies and data infrastructures may be connected '**authorised participants**' in the **EHDS**



So, what will change? *Lessons from Finland*

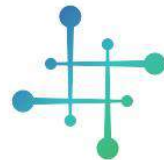


*How will this happen?
Lessons from Finland*



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)



EHDS
HealthData@EU Pilot

<https://ehds2pilot.eu/>

Towards implementation of the European Health Data Space



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National infrastructure and services

- **EU4Health Joint Actions** for national gap analysis and data quality and utility labelling of national datasets
- **Health data access body and services** (national and EU funded)



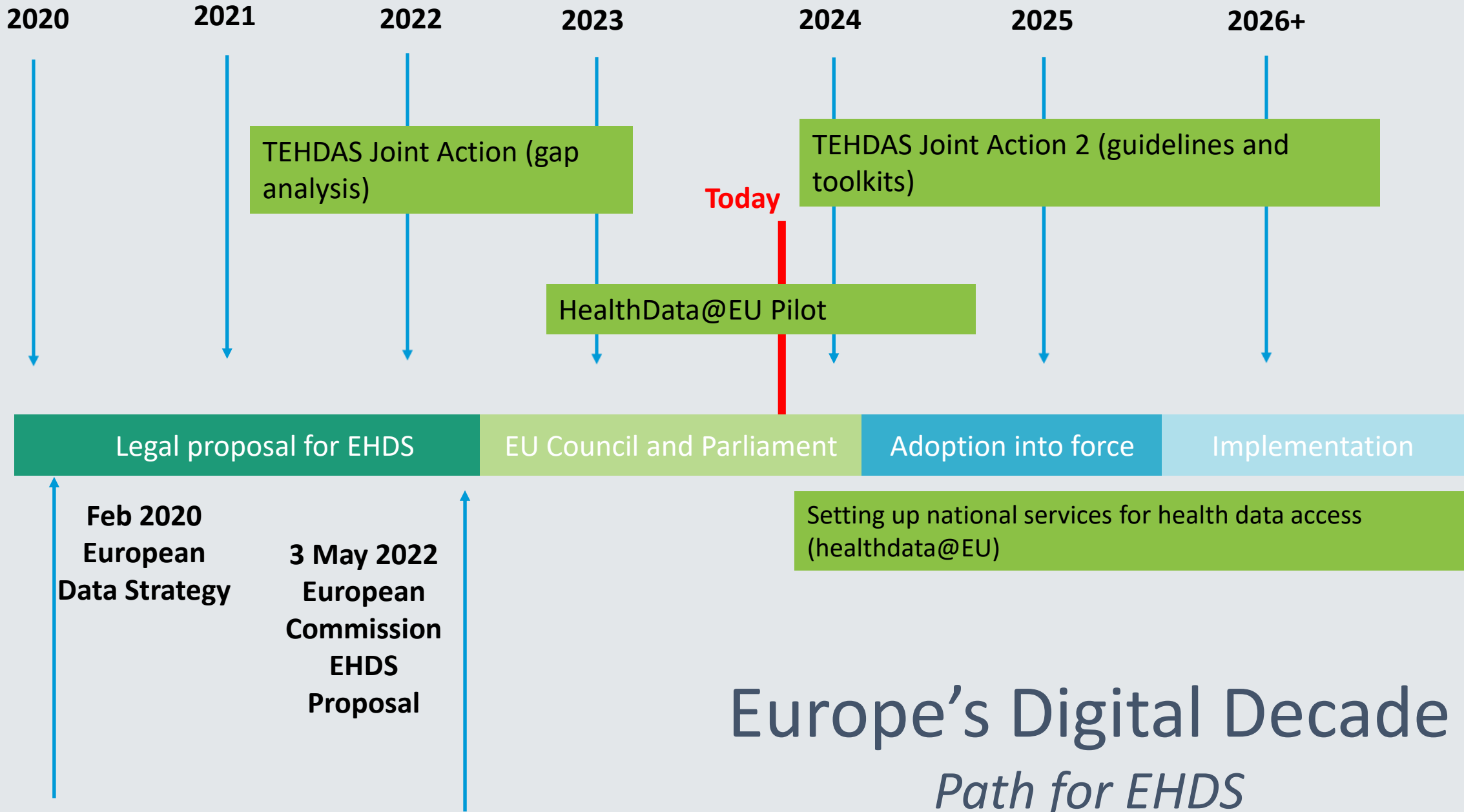
EU4health



Health Information Bill (2023) 'duty to share'

- **'Digital first'** principle
- Health information to be collected, uniquely identified and linked for **care and treatment** and **reused** for policy-making, research, public health, enhanced health service planning and management from **public, private and voluntary health settings.**







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Thank You