

EU health data policies

Markus Kalliola

Programme director at The Finnish Innovation Fund Sitra

TEHDAS2 coordinator

markus.kalliola@sitra.fi

@markuskalliola



EHDS final compromise text in a nutshell

1 Chapter 1: General provisions (Art. 1 -2)

2 Chapter 2: Primary use of electronic health data (Art. 3 - 13)

3 Chapter 3: EHR systems and wellness applications (Art. 13a - 32)

4 Chapter 4: Secondary use of electronic health data (Art. 32a - 58)

5 Chapter 5: Additional actions (Art. 59 - 63)

6 Chapter 6: European governance and coordination (Art. 64 - 66)

7-9

**Chapter 7-9: Delegation, Miscellaneous, Deferred application
(Art. 67 - 72)**

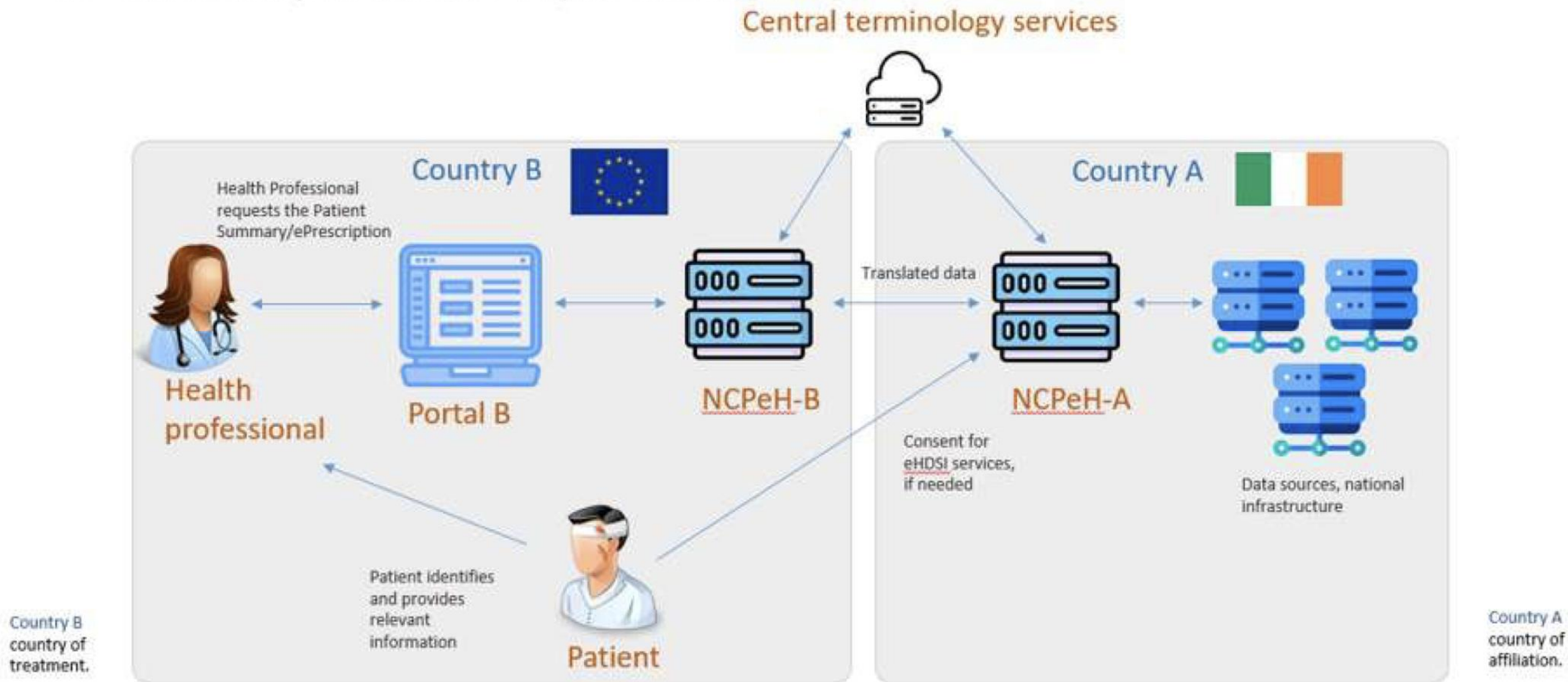


Transition timelines (estimation)

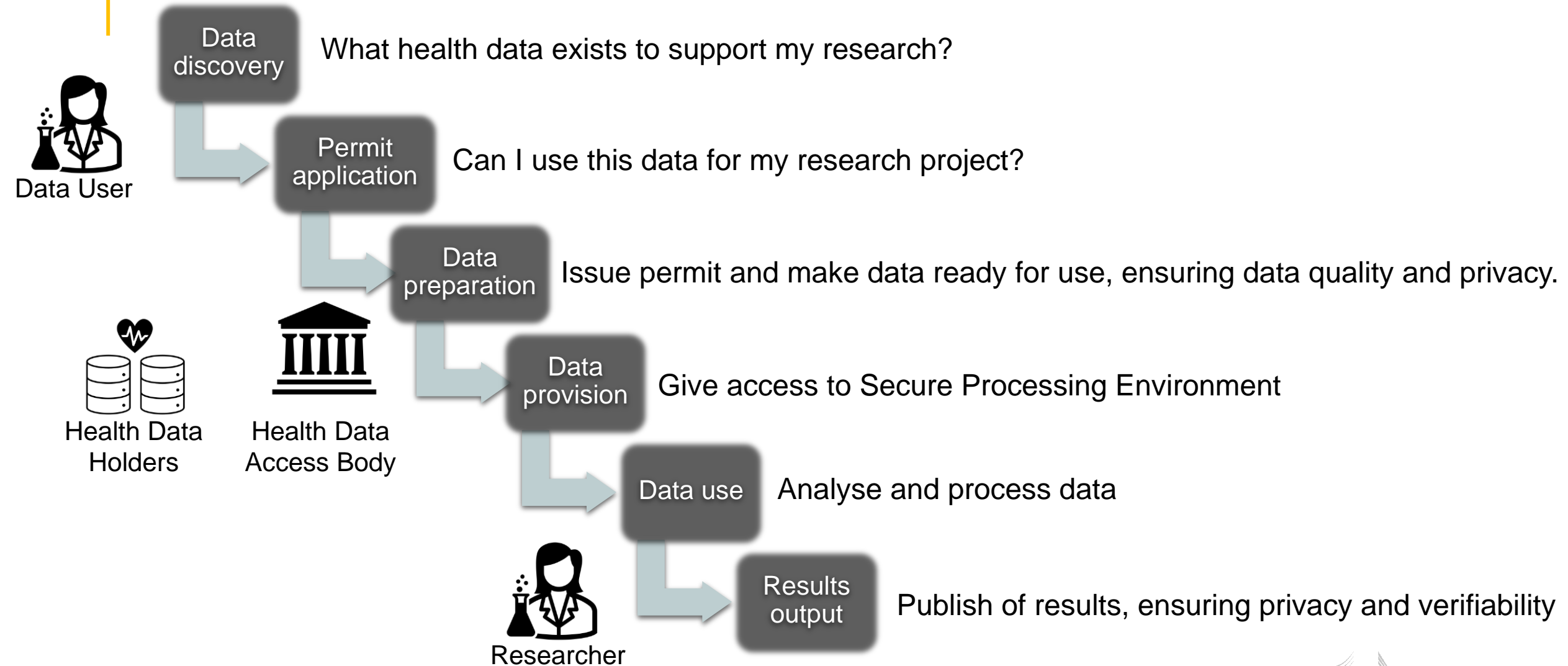
- Entry into force: 11/2024
- Becomes applicable: 11/2026 (2 years)
- **Implementing acts: 11/2026 (2 years)**
- Primary use: 11/2028 (4 years, ep/PS)
- **Secondary use: 11/2028 (4 years)**
- Primary use: 11/2030 (6 years, other data)
- EHR systems: 11/2030 (6 years)
- **Secondary use: 11/2030 (6 years, sensitive data)**
- **Third countries or international organisations: 11/2034 (10 years)**

Primary use of health data – myhealth@eu

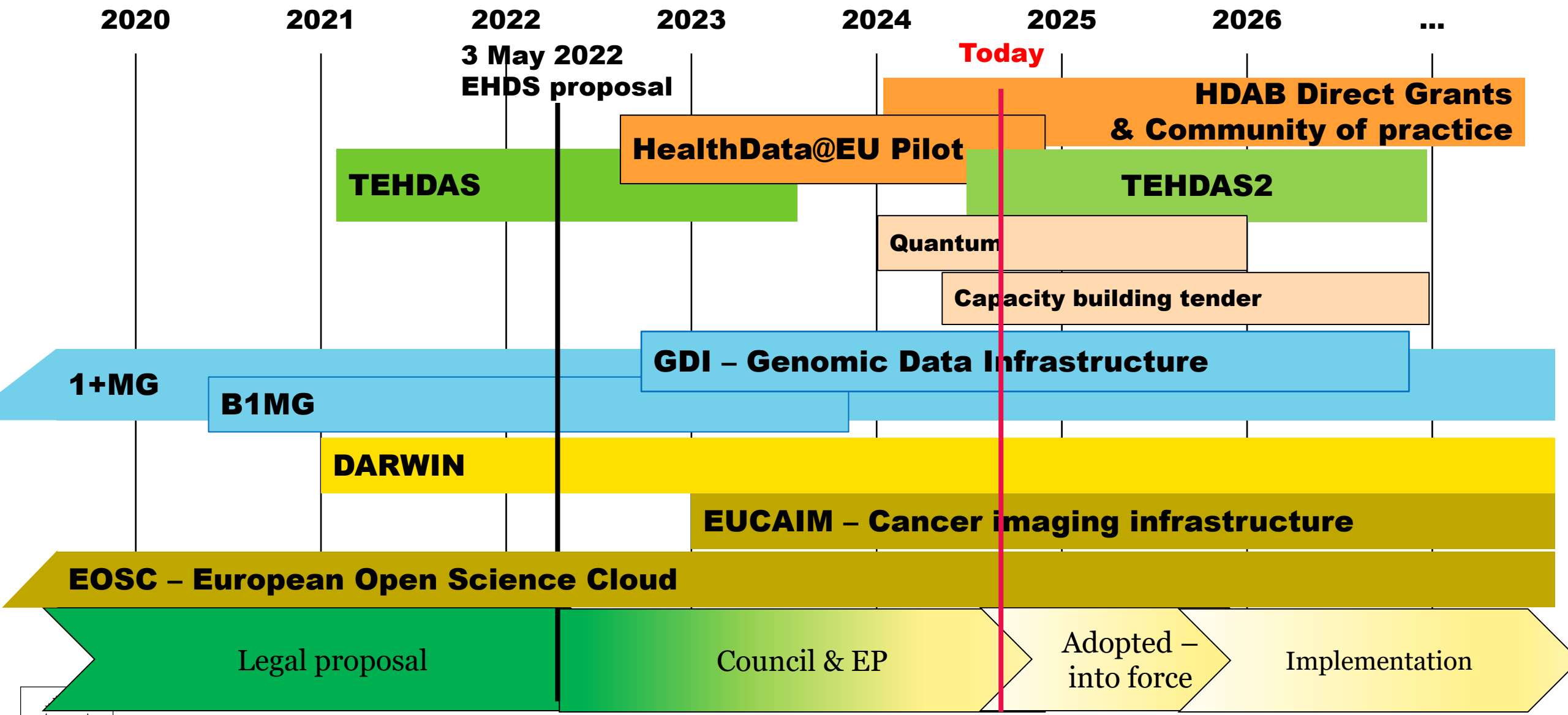
The current MyHealth@EU Infrastructure



Overview of a generic data access approval process



Major initiatives and projects related to EHDS2



What else impacts health data use in the coming years?

- AI act
 - Came into force 1 August 2024
 - Becomes applicable in 6 – 36 months
 - Different risk categories, but health AI as high risk
 - New requirements for risk management, data governance, technical documentation, transparency, human oversight:
 - Penalties EUR 35 million or 7% of global turnover.
- NIS2 (Network and Information security Directive)
 - Becomes applicable 18 October 2024
 - Risk management, corporate accountability, reporting obligations, business continuity
 - EC president Ms. Von der Leyen announced July 2024 that the new EC will publish a cyber security action plan for hospitals after 100 days in office -> Q1 2025
- Others:
 - New pharma regulation (not yet adopted), EU beating cancer plan etc.



Sitra's role?

What is a joint action?



Joint Action Towards the European Health Data Space – TEHDAS

Joint Action

Supports the Member States and the Commission
Develops and promotes concepts for sharing of data in
secondary use

Participants

Nominated authorities from 25 European countries

Duration

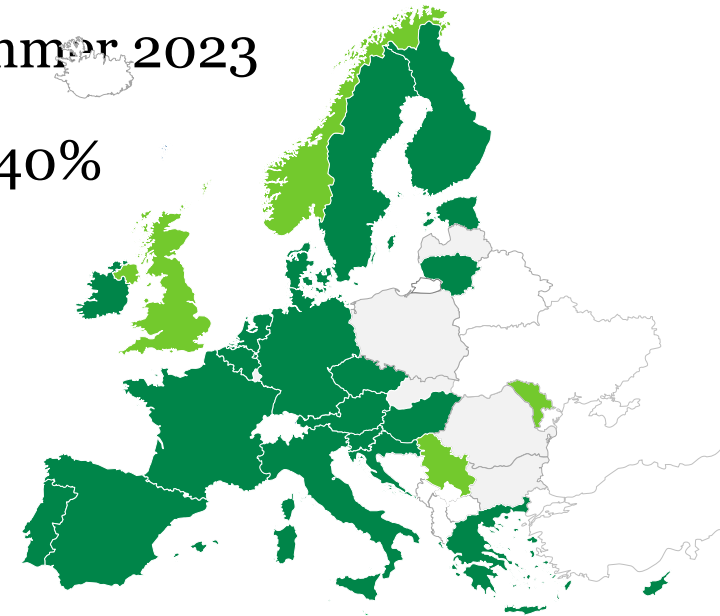
30 months from February 2021 – Summer 2023

Co-funding

€4 million - EU 60%, Member States 40%

Project coordinator

Sitra, Finnish Innovation Fund



The needs, expectations and views of stakeholders on economic sustainability



Options for governance models for data-sharing at EU level, in particular networking for secondary use



Definitions, good practices and use cases of GDPR-compliant data altruism

Secondary use of health data



Availability of comparable high-quality health data for research and innovation



Citizen perception of health data and data-sharing practices



Shared European data infrastructures across the EU (cf. eHDSI)

Joint Action Towards the European Health Data Space ~TEHDAS2

Grant code	DI-g-23-79	
Procedure type	Direct grant (joint action) to Member States	
Partners	Authorities from 30 Member States	
Total Budget	EUR 6 M (80% EU Support)	
EU/MS Contribution	EUR 4,8M + EUR 1,2M	
Start of the project	1 May	
Duration	32 Months	
Coordination	The Finnish Innovation Fund Sitra	
Contract management	HaDEA	

Expected impact

1. increased preparedness for the implementation of the proposed EHDS;
2. better coordination of Member States' joint efforts towards the secondary use of health data;
3. reduced fragmentation on policies and practices for secondary use of health data

Tangible results in the form of guidelines and technical specifications



Effective coordination, clear communication and monitoring of the joint action



Facilitate the discovery and comparability of datasets for secondary use purposes



Harmonised implementation of EHDS



Advance both common understanding about and operationalization of access to health data



Engage with various stakeholders to facilitate relevance of results. Guidelines for outside EU collaboration.



Produce clear and implementable technical specifications



Facilitate the substantive engagement of citizens within the European Health Data Space (EHDS)



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