



EHDS: latest news and testimony from Finland

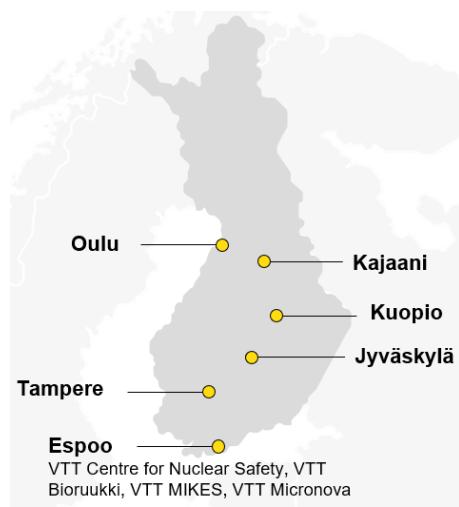
**ENCePP Plenary meeting
1 December 2025**

**Jaakko Lähteenmäki
Principal Scientist,
VTT Technical Research Centre of Finland Ltd**

Outline

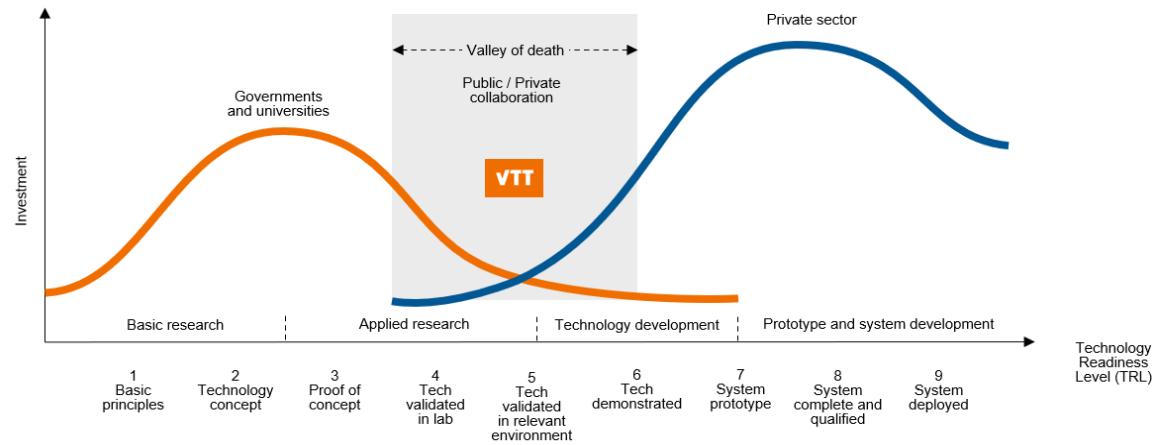
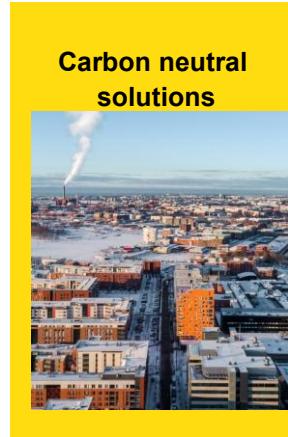
- About VTT
- Finnish healthcare system
- Secondary use of health and social data
- EHDS implementation

VTT is an impartial non-profit **Research and Technology Organisation (RTO)** with the mandate and mission to support economic competitiveness, societal development and innovation



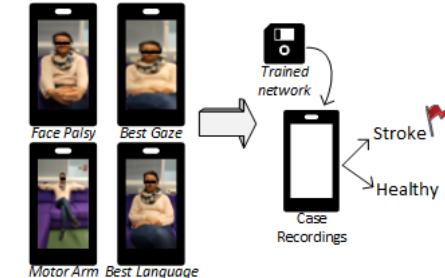
2,390
employees

296 M€
operating income



VTT's motivation to contribute to healthcare regulatory developments

- VTT investigates and develops healthcare innovations
 - Commercialisation is carried out by industrial partners, but regulatory requirements shall be considered at early stage
- Innovations are increasingly based on data and AI
 - Understanding of regulatory frameworks related to accessing and using healthcare data is essential
- Participation in international projects with regulatory impact:
 - **TEHDAS Joint Action** (<https://tehdas.eu/>): European Health Data Space (EHDS) / infrastructure for secondary use of health data
 - **IHI/BRIDGE**: Breakthrough Regulatory Innovation and Development through sandbox Environments



Stroke identification based on video

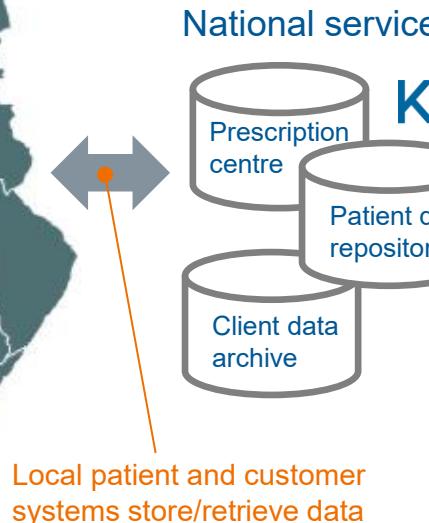


Finnish healthcare and social welfare system overview

- Public healthcare and social welfare services supported by government funds
- Service provision by 21 wellbeing services counties and the city of Helsinki
- Services are also provided by private companies and non-profit organisations



Regional health and social services and pharmacies are connected to national Kanta services



Usage by organizations (2023)

Kanta Services are used by:

- 100% of public healthcare
- 95% of public social services
- 100% of pharmacies
- 72% of private healthcare
- 0.3% of private social services

Usage by citizens

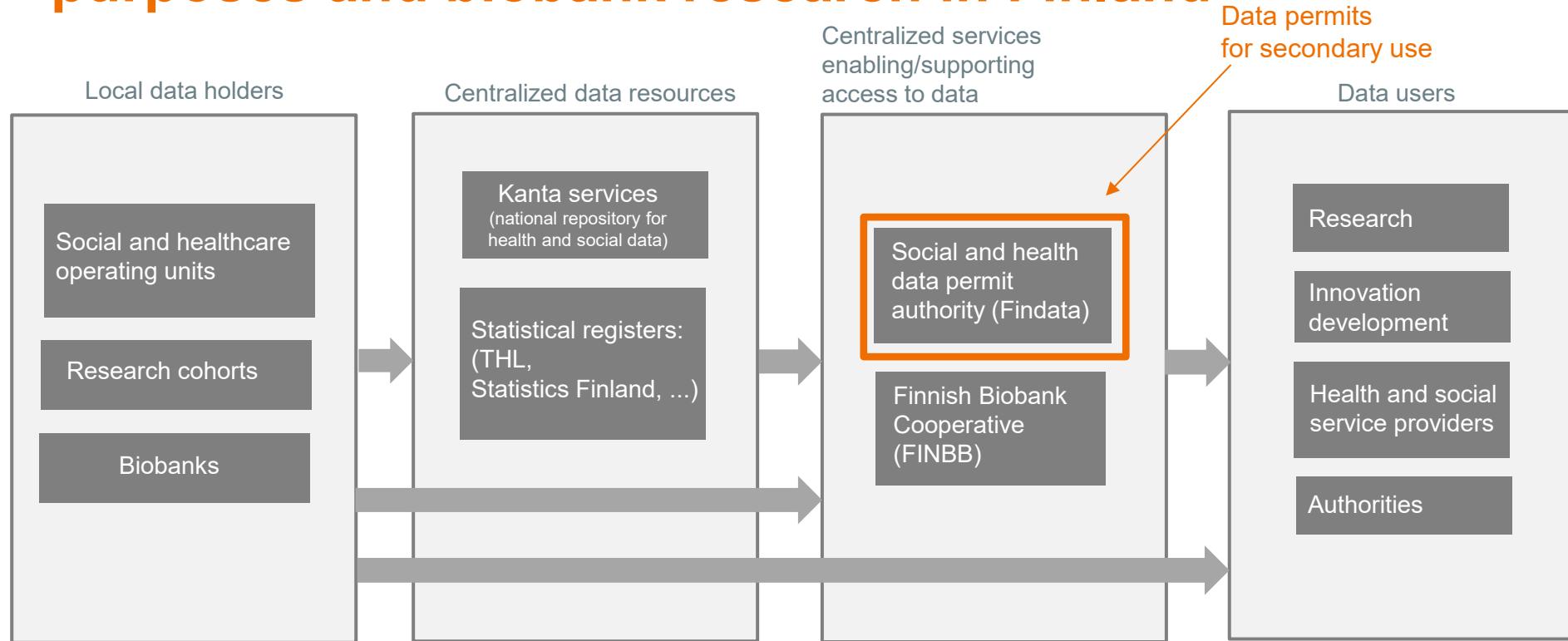
MyKanta users in 2023
3.1 million

MyKanta used
35 million times

Share of MyKanta users by age group



Use of health and social data for secondary purposes and biobank research in Finland



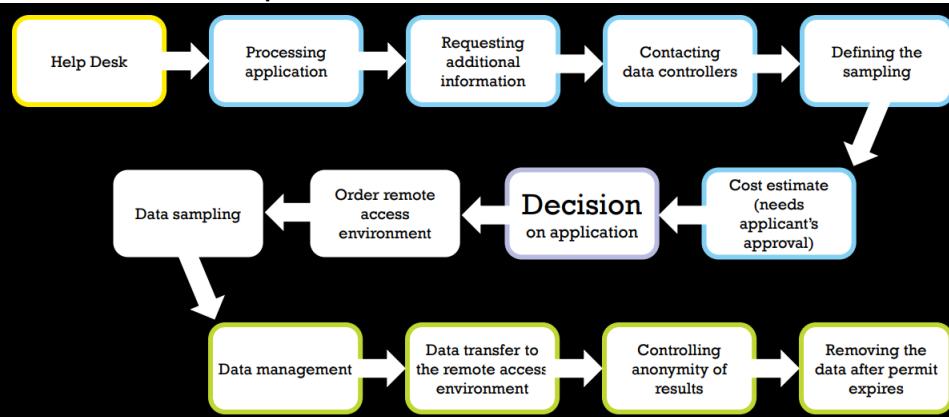
Key national legislation

- Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (“Client Data Act”, 2023)
- Secondary Use of Social and Health Data Act (“Secondary Use Act”, 2019)
- Biobank Act (2012)

FINDATA

<https://findata.fi/en/>

Findata service process



Statistics

	2025 (1-11)	2024
Data permits	112	108
Amendments	179	181
Statistical data requests	21	24

<https://findata.fi/en/permits/issued-permits/>

Digital and Population Data Services Agency

Findata

Data Holders

Finnish Centre for Pensions

Finnish Institute for Health and Welfare (THL)

Finnish Institute of Occupational Health

Finnish Medicines Agency (Fimea)

Kanta services

Ministry of Social Affairs and Health

National Supervisory Authority for Welfare and Health (Valvira)

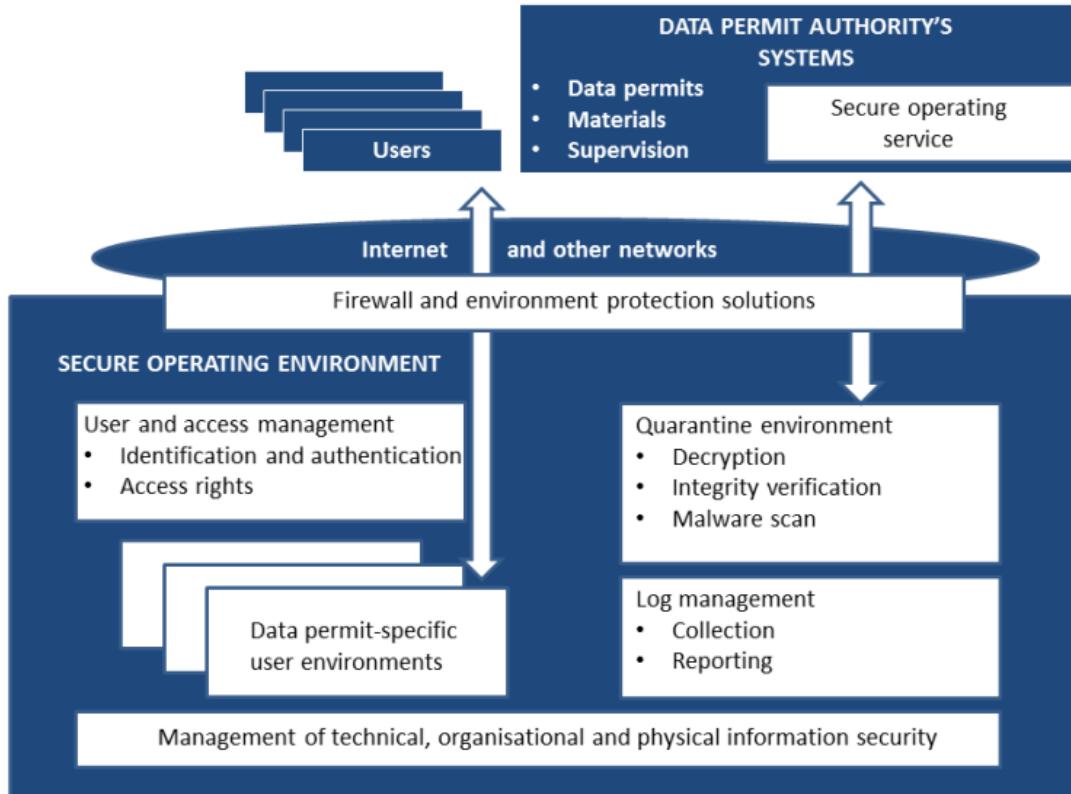
Private Social and Health Service Providers

Public social welfare and healthcare service organisers

Regional State Administrative Agencies

Social Insurance Institution of Finland (Kela)

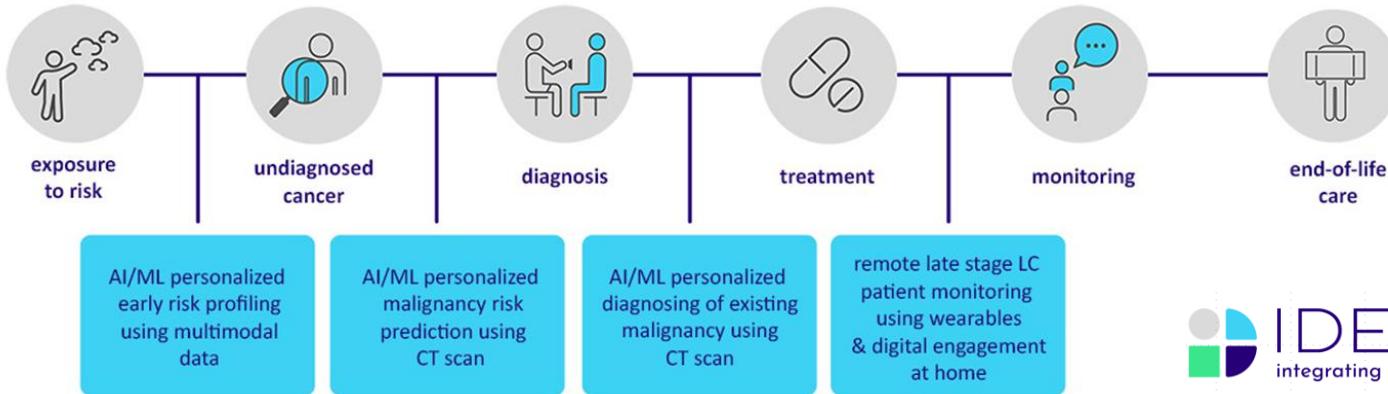
Statistics Finland



- Research data includes all adult Finnish patients with atrial fibrillation and venous thromboembolism who had an anticoagulation drug prescription between 2015-2023 (n = 460 000)
 - Demographics
 - Diagnoses, procedures, hospitalizations and reasons for health care visits
 - Certain bleeding related laboratory tests, medications, risk information and measurements taken
 - Possible date of death
- Data is collected from 5 different registers through Findata process
 - Kela Prescription centre
 - Kela Patient data archive
 - THL AvoHilmo – Primary healthcare
 - THL Hilmo – Specialized healthcare
 - Statistics Finland

VTT research case: AI models for lung cancer

VTT



- IDERHA project aim is **to improve clinical decision-making** and better use of health data
- **AI models for lung cancer screening**, diagnosis, prognosis and home monitoring will be developed
- Finnish health data to be used in validation of the AI models

Data resources (N~190 000, images: N~2000)

- Helsinki University Hospital (HUS) clinical specialised care data (OMOP) and computed tomography images
- THL AvoHilmo – Primary healthcare (OMOP)
- Kela Prescription centre
- Digital and Population Data Services Agency (DVV)
- Statistics Finland

What is working well in secondary use of data in Finland

- Several data holders covered with one data permit application thanks to centralised application process
- Data access can be granted for different types of organisations (including those outside Finland)
- Several (10) secure processing environments (SPE's) are available
- Data catalog for discovering data sets and information at variable level is available

Challenges and pain points

- Major delays occur in collecting data from data holders and preparing data for use
- Especially university hospitals experience the centralised model as complicated and slow → update to national legislation proposed
- SPE's are closed environments. Inputs and outputs to/from SPE's require manual intervention by Findex.
- Federated processing is currently not supported by SPE's

European Health Data Space (EHDS)

- **Objective:** Create a unified framework for using health data across the EU for care, research, innovation, and policy-making.

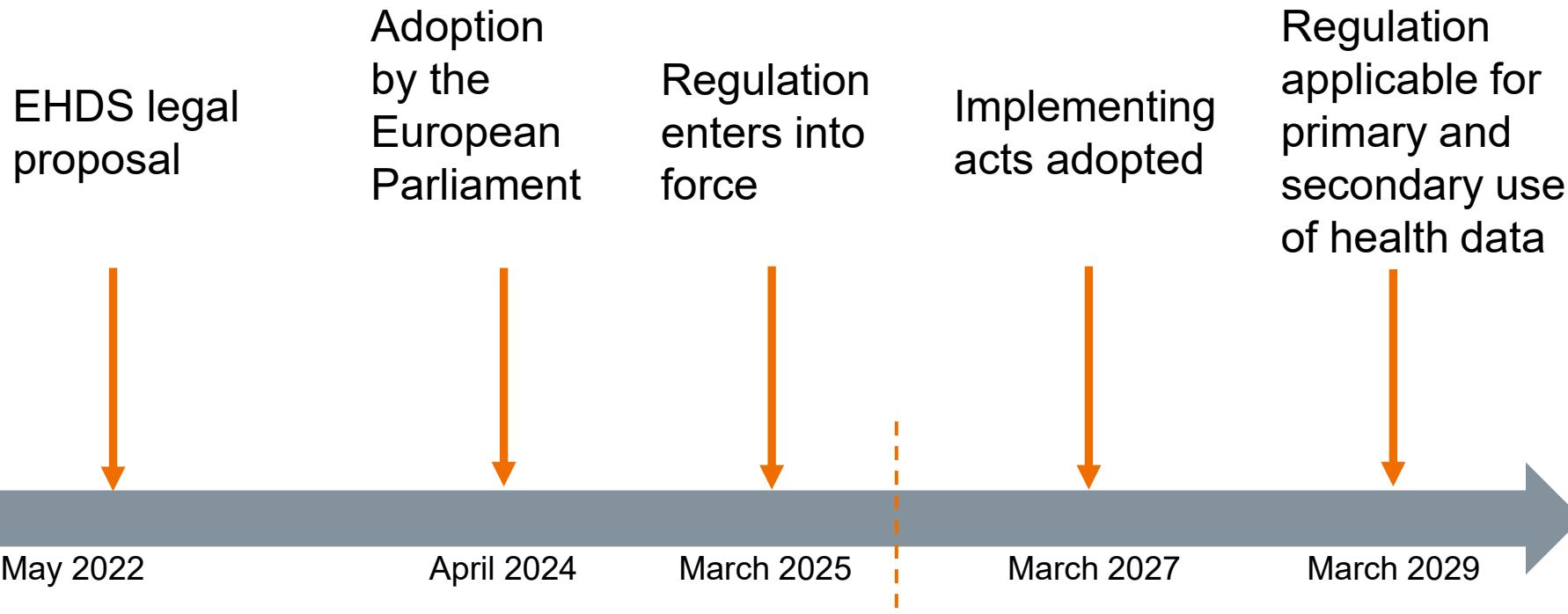


- **Primary purpose:** data usage for providing health and social services for the customer



- **Secondary purpose:** data usage for other purposes than the primary purpose, for example: research, statistics or knowledge-based management

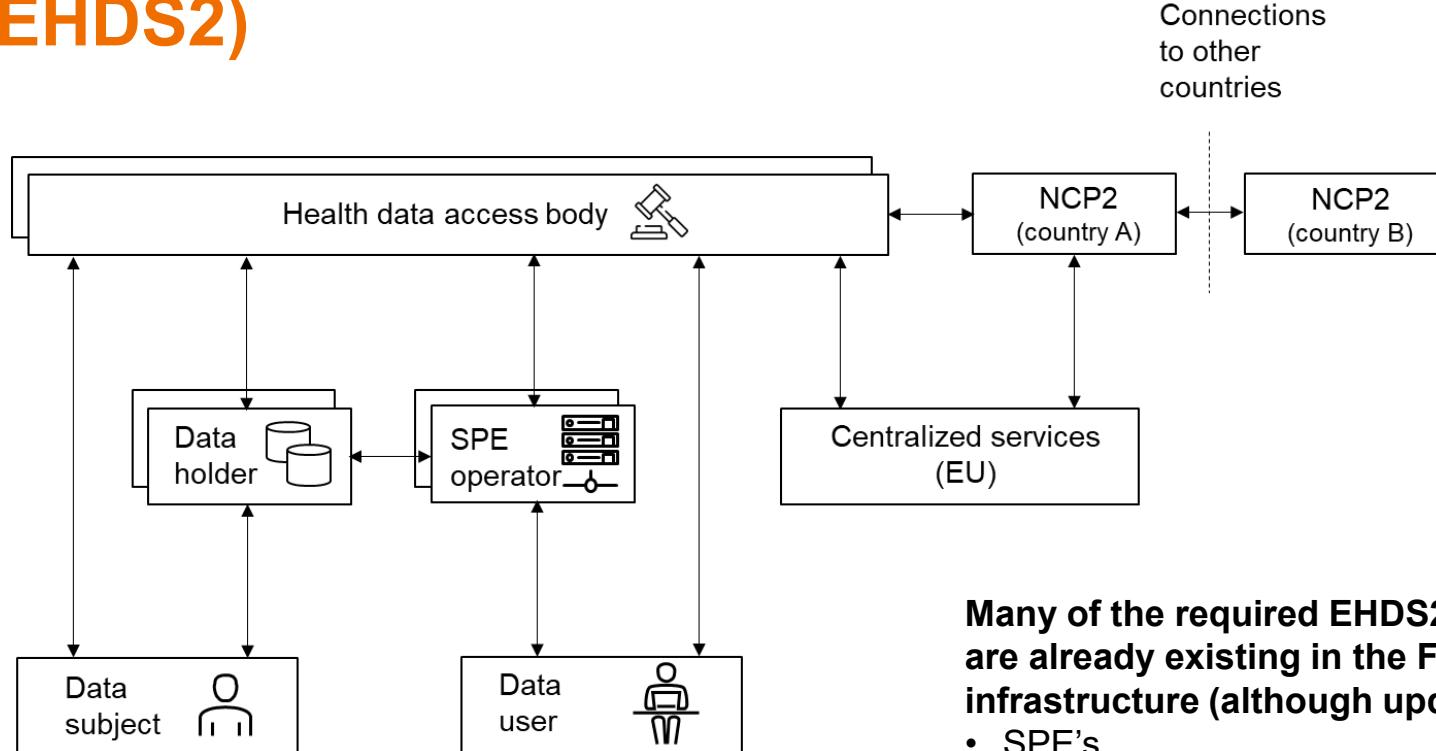
EHDS Timeline



EHDS – Impact on secondary use of health data

- Secure access for research & innovation:
 - Authorized researchers and innovators can use anonymized or pseudonymized health data across the EU
- Standardized data access framework:
 - Common rules and permits issued by national Health Data Access Bodies.
 - Ensures interoperability and consistency across member states.
- Enhanced data availability:
 - Easier access to large, diverse datasets for public health, AI development, and policy evaluation
- Privacy & security safeguards:
 - Strong data protection, consent management, and auditing requirements.
- Promotes evidence-based policy and innovation:
 - Supports faster insights for health interventions, research breakthroughs, and service optimization.

EHDS architecture for secondary use (EHDS2)



Many of the required EHDS2 components are already existing in the Finnish data infrastructure (although updates needed):

- SPE's
- data discovery services
- data user guidance functions
- data application process
- data curation and preprocessing

EHDS implementation in Finland

- National steering group established for coordinating national EHDS implementation
 - subgroups for primary use and secondary use
- On-going EU-funded activities for EHDS2:
 - Strengthening Finnish Health Data ICT for Secondary Use (**FinHITS**)
<https://findata.fi/en/finhits/>
 - Value from Nordic Health Data (**VALO**)
<https://www.sitra.fi/en/projects/valo-value-from-nordic-health-data/>
 - Second Joint Action Towards the European Health Data Space (**TEHDAS2**),
<https://tehdas.eu/>

Ongoing work to align Finnish infrastructure with EHDS2 (FinHITS)*

- Data Access Applications Management System (DAAMS)
- Data set catalogue
- Secure processing environment (SPE)
- Connectivity with HealthData@EU infrastructure
- Health data quality enhancements

* <https://findata.fi/en/finhits/results/>

Guidelines and specifications to support EHDS implementing acts - TEHDAS2

VTT

TEHDAS 2

29 European countries

6.0 M€

EU4Health Programme

5/2024 – 12/2026

Finnish Innovation Fund Sitra

Guidelines and technical specifications for EHDS2 implementation

<https://tehdas.eu/>

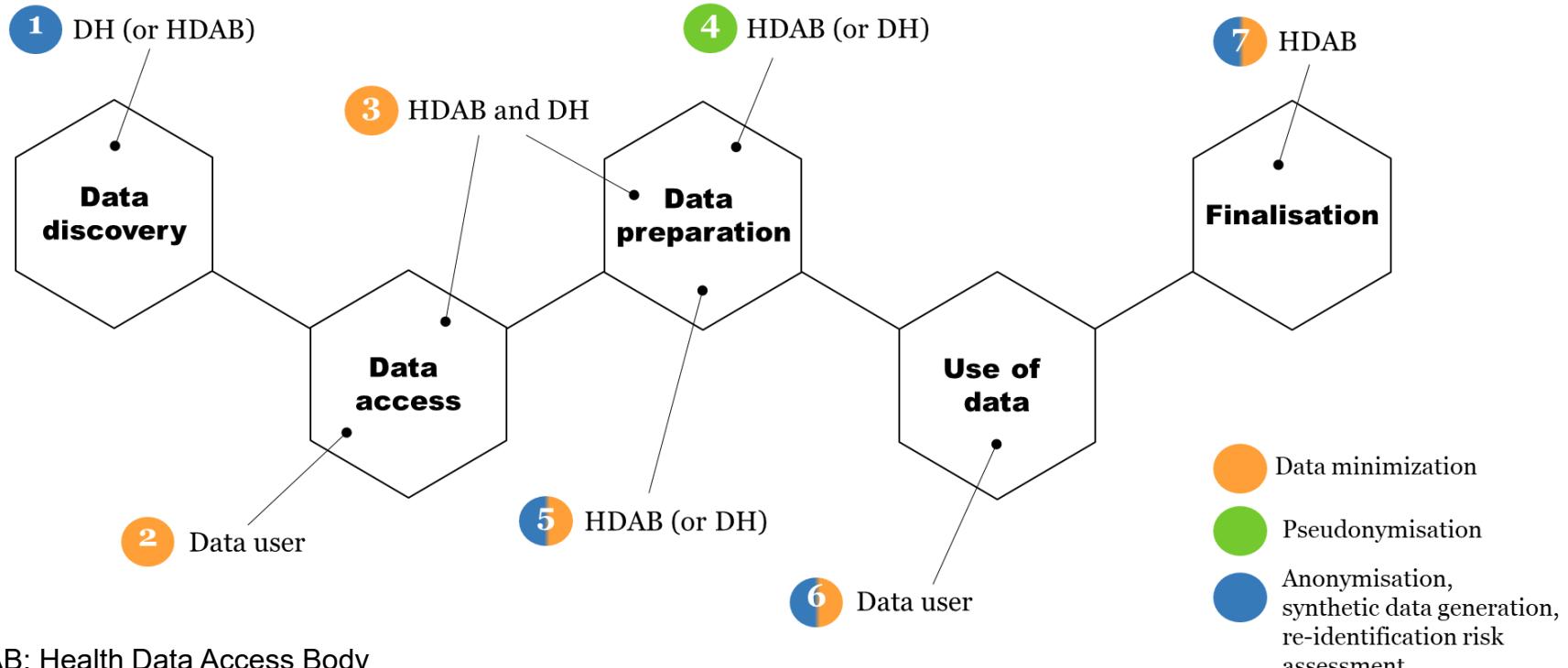


Areas contributed by VTT*:

- Data protection along user journey
- Common IT infrastructure
- Secure processing environment requirements

* Public consultation documents: 7,8 and 9
<https://tehdas.eu/public-consultations/>

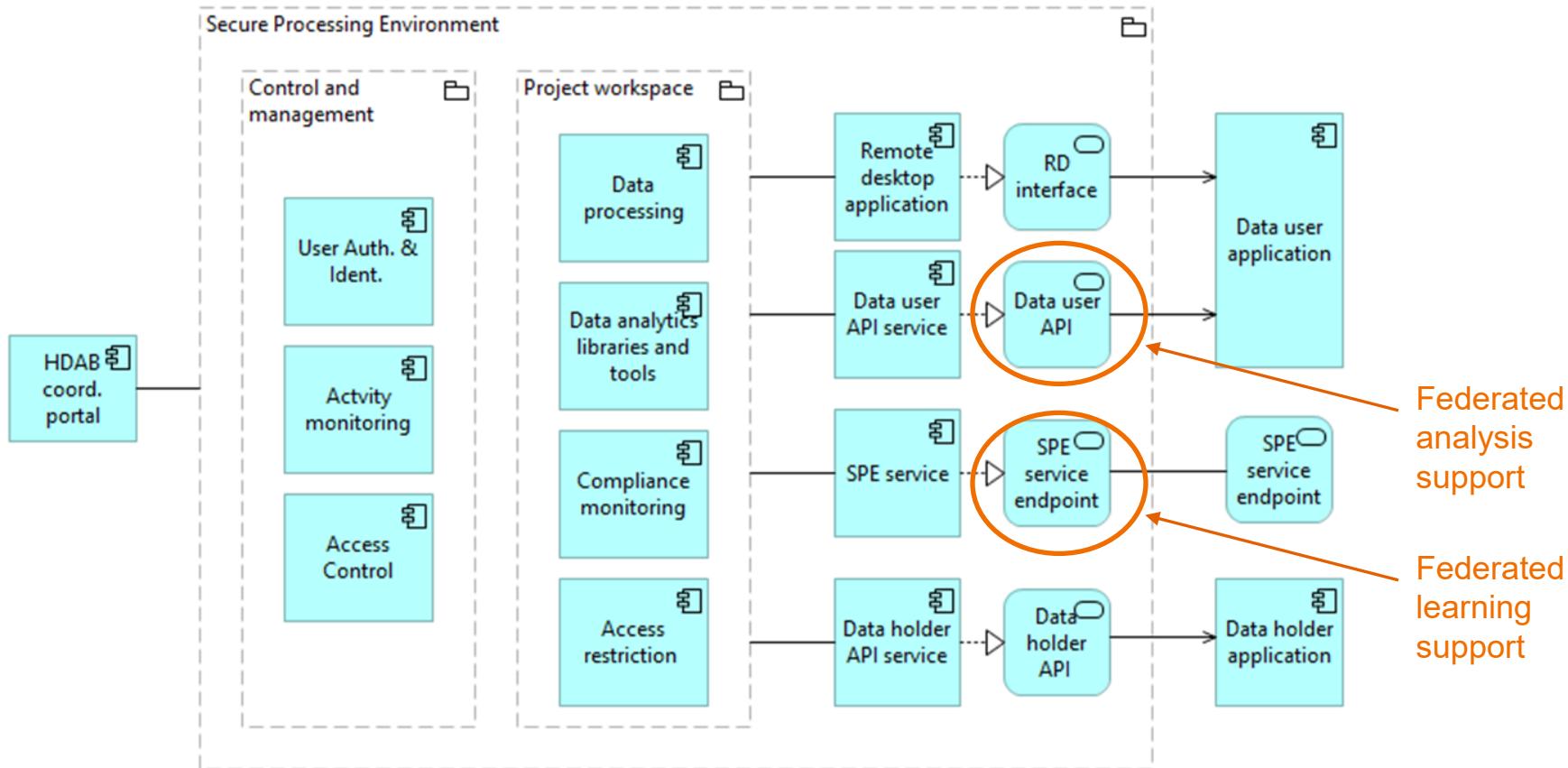
Data protection measures mapped on EHDS data user journey



HDAB: Health Data Access Body

DH: Data Holder

Proposed interoperable SPE architecture



Summary

- EHDS has been in force since March 2025 and key provision begin to apply March 2029
- Major impact to both primary and secondary use of health data
- EHDS regulation for secondary use of data has many similarities with the existing Finnish legislation
 - required changes are smaller than in many other EU member states
- National working groups have been established to drive the change
- Finnish organisations are actively involved in European projects shaping the EHDS

bey⁰nd the obvious

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