

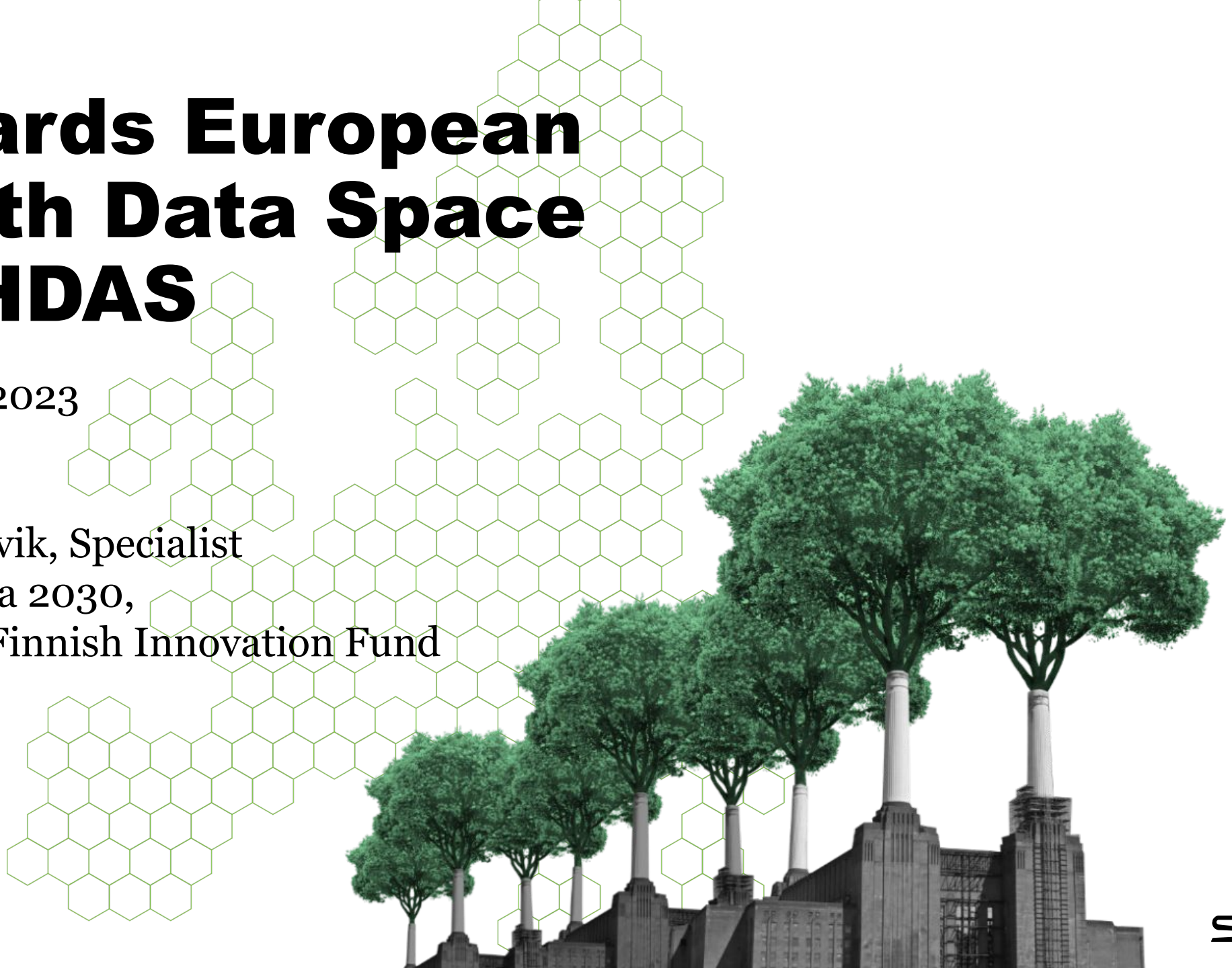
Towards European Health Data Space - TEHDAS

6 October 2023

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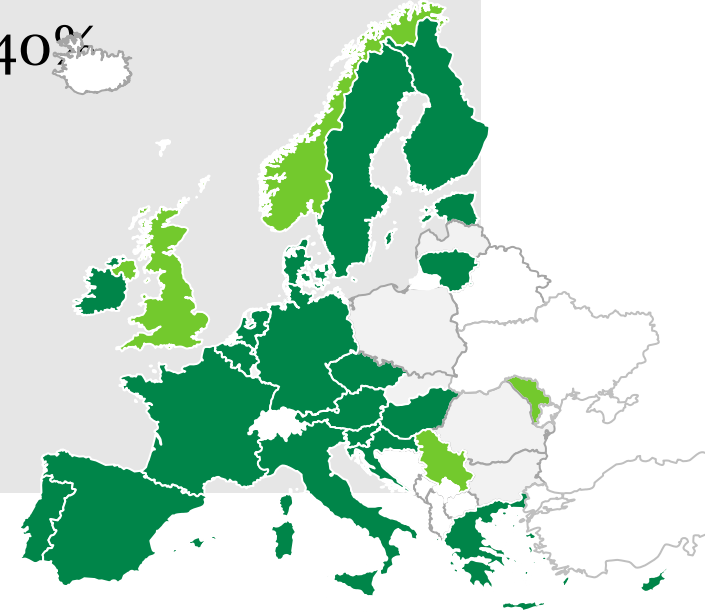
Co-funded by
The Health Programme
of the European Union



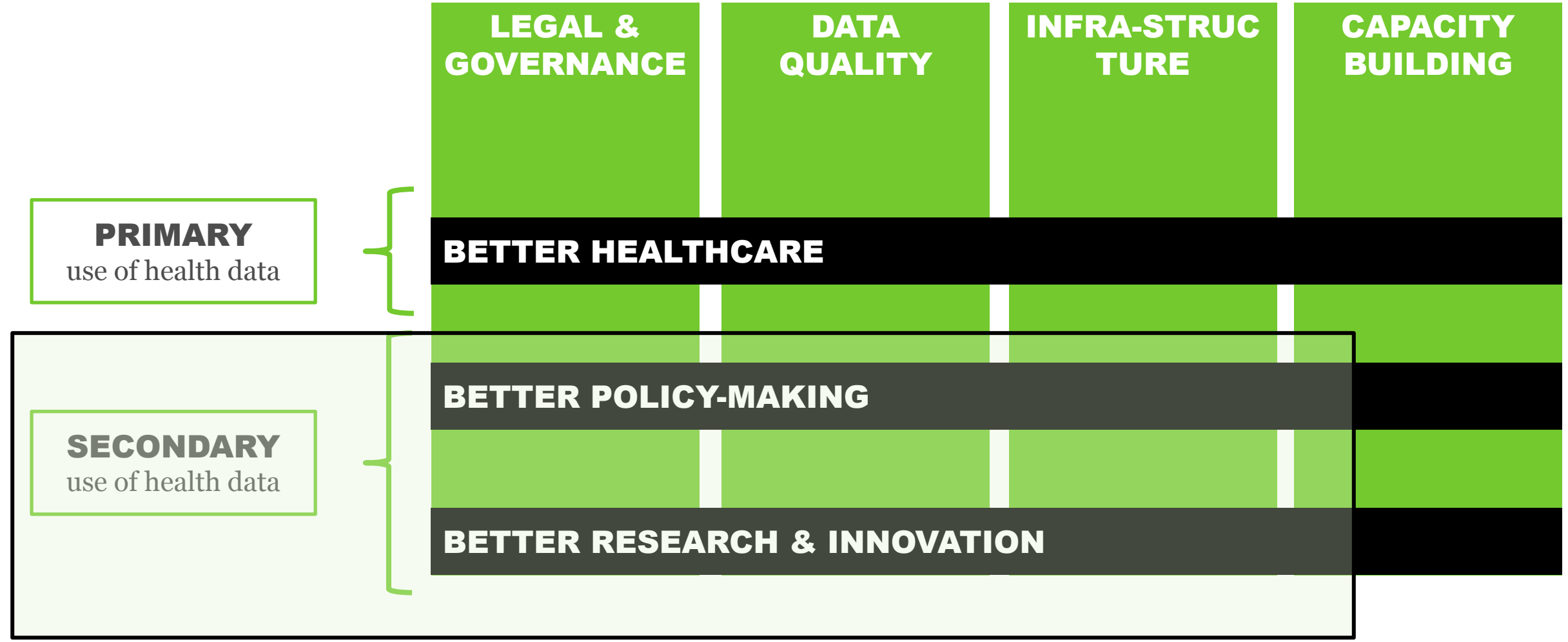
Joint Action Towards the European Health Data Space



Joint Action	Supports the Member States and the Commission
Participants	Nominated authorities from 25 European countries
Duration	30 months from February 2021 – July 2023
Co-funding	€4 million - EU 60%, Member States 40%
Project coordinator	Sitra, Finnish Innovation Fund



Four pillars of the European Health Data Space



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

2020 - 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

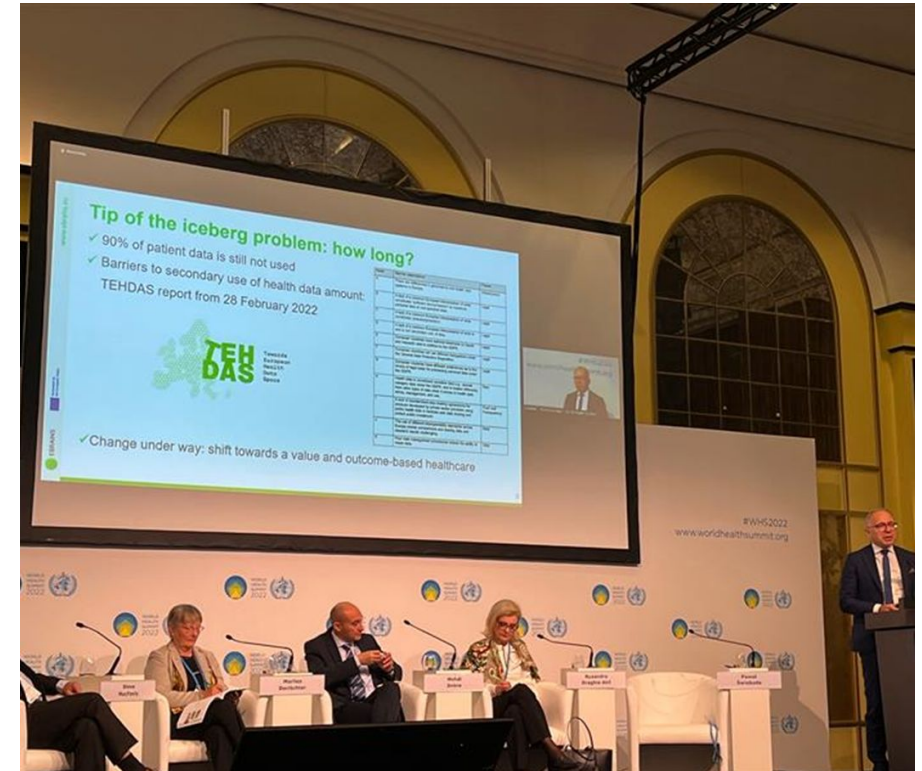
**GDPR
enters
in force
May 2018**



**European Union
Data related measures**

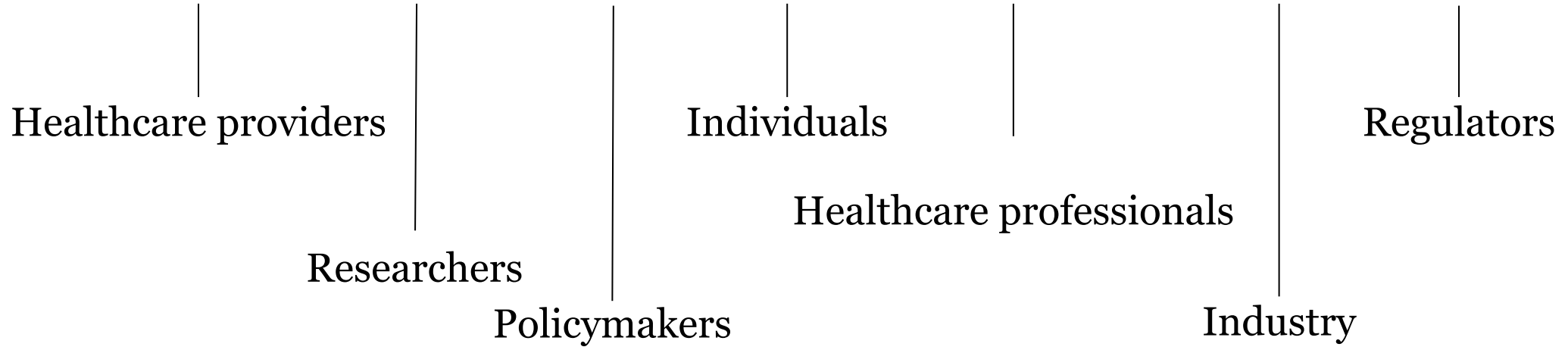
Barriers on cross-border sharing of health data for secondary use and options to overcome these

- 47 papers reviewed by 4 reviewers to identify barriers
- from 89 barriers 20 went through detailed analysis and **11 barriers were prioritized**
- 23 European countries provided 113 case studies to give real-life examples of the 11 barriers on impact, issues and solutions
- **6 were legal**
- 3 were data/semantic related
- 1 infrastructure
- **1 trust**



Key players of the European Health Data Space

European Health Data Space

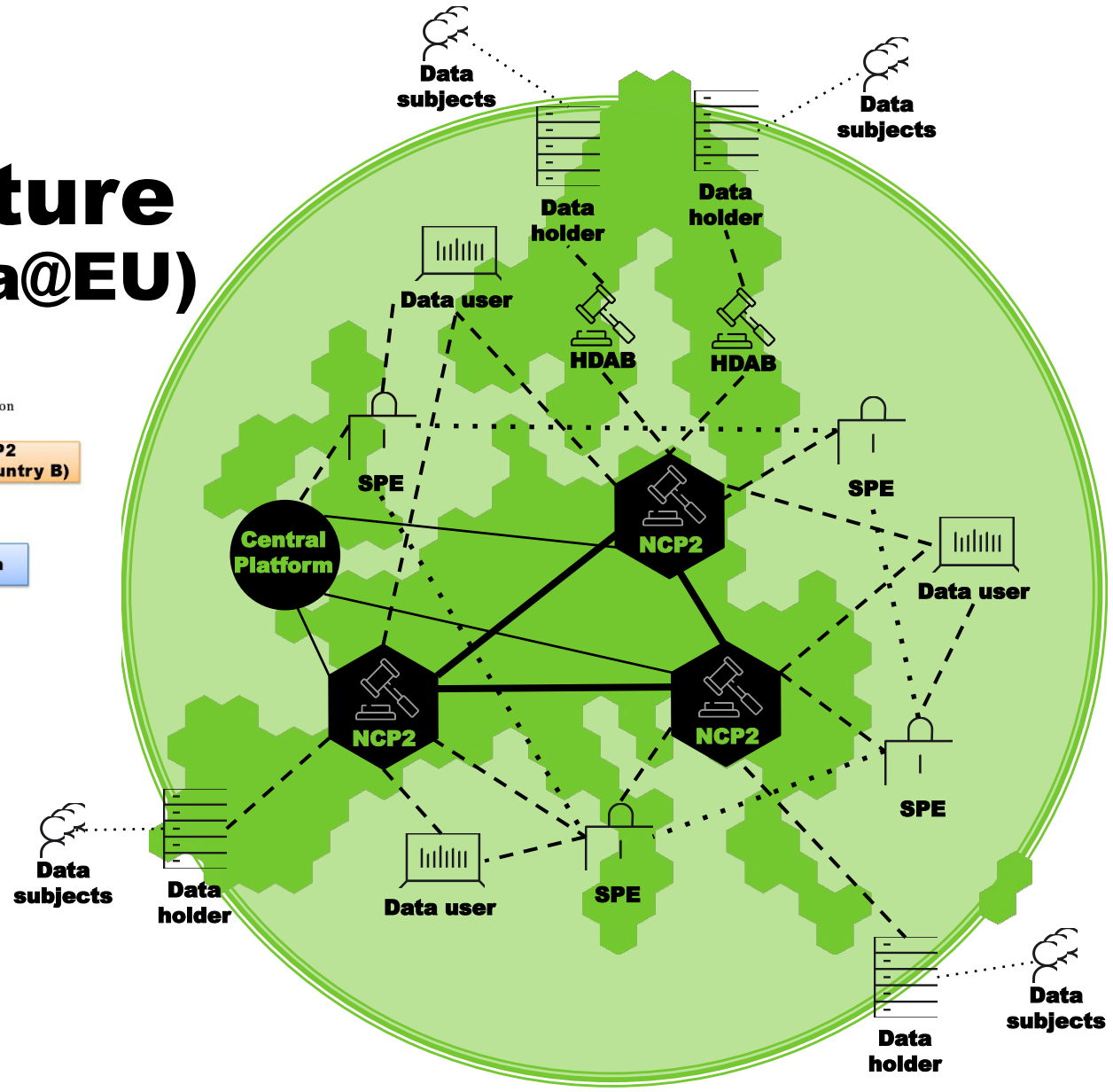
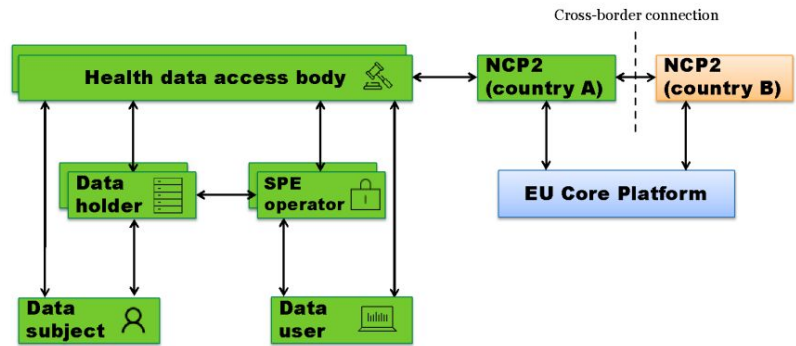





A steady flow of outputs in 2021-2023

<p>Milestone 5.4 Description of steps in an individual-level data for non-EU researchers in a selected centralised systems and decentralised systems 4 April 2022</p>	<p>Milestone 5.5 Guidelines for a peer-to-peer cross-border partnership secondary use of health data 31 March 2022</p>	<p>Deliverable 5.1 Report on secondary use data through European cross-border Data Space Barriers on cross-border sharing data for secondary use and opportunities to overcome these 28 February 2022</p>	<p>Milestone 5.8 Potential health data mechanisms for European Data Space 1 September 2021</p>	<p>Summary of Milestones 5.1 & 5.2 Summary of results: case studies on barriers to cross-border health data for secondary use 28 September 2021</p>	<p>Milestone 5.7 Why health is a special case for data governance 23 June 2021</p>
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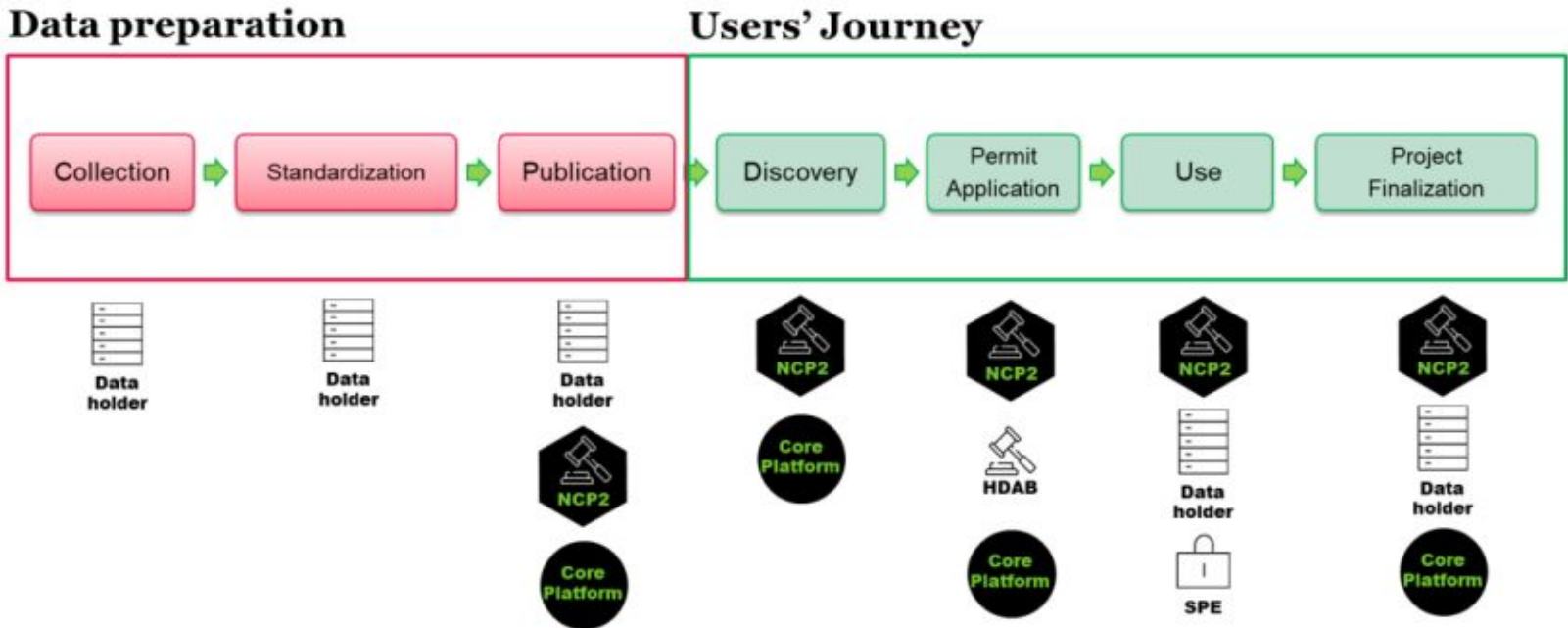


EHDS Architecture (HealthData@EU)



-  **Secure Processing Environment (Art.60)**
SPE
-  **Health Data Access Body (Art.36)**
HDAB
-  **National Contact Point for Secondary Use of Health Data (Art.52)**
NCP2

TEHDAS DATA LIFE-CYCLE



Highlights of TEHDAS proposals related to infrastructure

Recommendations were voted on and prioritised to reflect the views of the TEHDAS partners.

- Data integration: in favour of data **integration taking place at the level of the health data access** bodies that grant access to data and prepare it for use rather than at the level of data holders.
- SPEs: both the **security standards** of the secure processing environments and the **auditing mechanisms** to audit them should be agreed at the European level to ensure proper uptake.
- **An SPE on EU level** is provided **in addition** to the country level SPEs
- **Support and training services** needed at both levels - HDABs offer support to its users, which is coordinated with the EU core platform.

Overall finding: **Clear guidelines are needed how SPEs would be used in the case of cross-border and multi-country projects.**



Thank you!

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**RISE TO
SHINE!**

