EHDS and TEHDAS

8.6.2021

Markus Kalliola, Project Director, Sitra
TEHDAS Coordinator

Co-funded by
The Health Programme
of the European Union

1. Context
2. Introduction to TEHDAS
3. Topical issues

Co-funded by
The Health Programme
of the European Union

Digital transformation of health and care

We need to make the most of the potential of e-health to provide ***high-quality healthcare and reduce inequalities.***

I want you to work on the creation of a ***European Health Data Space*** *to* ***promote health-data exchange*** *and* ***support research*** *on* ***new preventive strategies****, as well as on* ***treatments, medicines, medical devices and outcomes****.*

As part of this, you should ensure ***citizens have control*** *over their own* ***personal data****.*

Mission letter of Stella Kyriakides
Commissioner for Health

- Health challenges
  - Accessibility, affordability and availability of care
  - Health threats (COVID-19)
  - Ageing population
  - Chronic diseases
  - Cancer (Europe's Cancer Beating Plan)
  - Mental health
  - *And so many other…*

European Commission

Rich pool of data
with a varying degree of accessibility

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

Free flow of data
across sectors and countries

Health | **Industry** | **Agri-culture** | **Finance** | **Mobility** | **Green Deal** | **Energy** | **Public admin.** | **Skills**

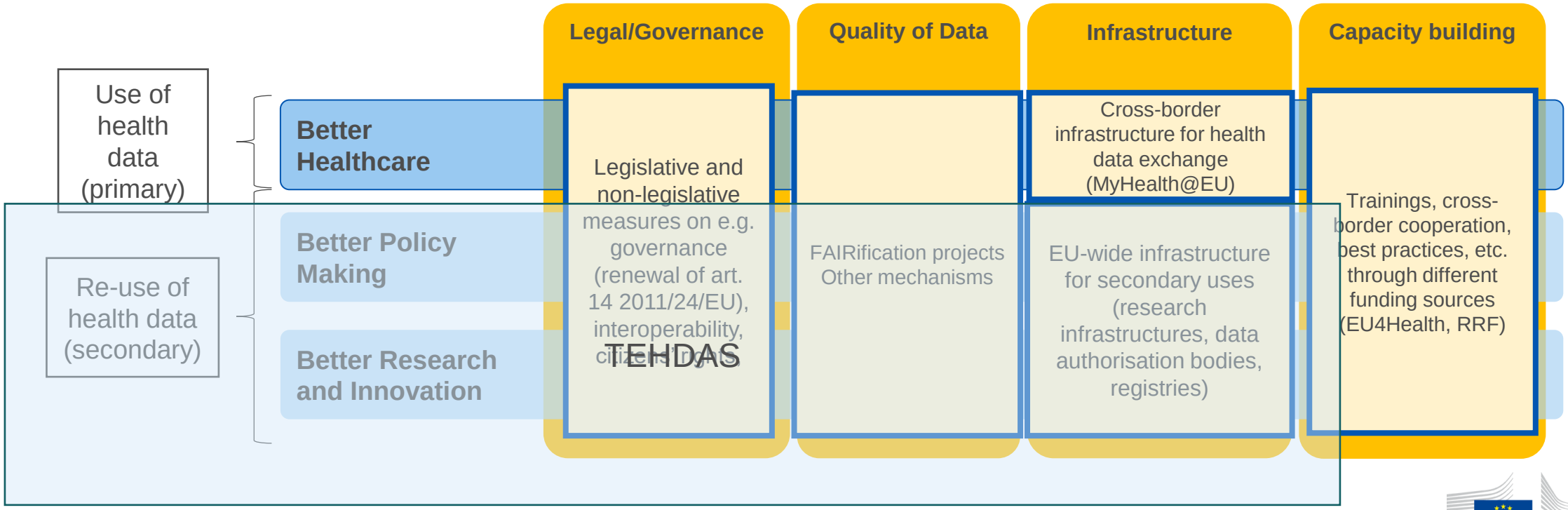
GDPR, DSA, DGA, AI, Data Act et al.
and their full respect

Horizontal framework
for data governance and data access

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

Co-funded by
The Health Programme
of the European Union

Primary and secondary uses of health data



European Commission

What has been missing?

Political will

Mindset

Enabling infrastructure

Common rules

Co-funded by
The Health Programme
of the European Union

TEHDAS

2020-09-16, Commission President von der Leyen, State of the Union	• ”We need common data spaces - for example, in the energy or healthcare sectors. This will support innovation ecosystems in which universities, companies and researchers can access and collaborate on data.”
2020-10-02, European Council, Summit Conclusions	• ”The European Council welcomes the creation of common **European data spaces** in strategic sectors, and in particular invites the Commission to give priority to the health data, which should be set up by the end of 2021.”
2020-10-19, Commission work programme 2021	• Plan: Legislative proposal for **the European health data space**, incl. impact assessment, Articles 114 and 168 TFEU, Q4 2021
2021-03-30 President of the European Council and the Director-General of the WHO	• World leaders call for new international treaty to improve pandemic response. “..enhancing international cooperation to improve, for example, alert systems, data-sharing, research..”
2021-04-20, Angela Merkel	• “EU ‘probably’ needs treaty changes, especially for health policy”
2021-04-21, Commissioner Stella Kyriakides	• “We’re putting the structures in place,” “We cannot work with ad-hoc solutions anymore.”
2021-06-04, G7 Health Ministers Declaration	• Sharing health data internationally is crucial to health policy, delivery of care, and regulatory and surveillance activities, data intensive technologies on common purposes and in a defined secured framework, such as the **European Health Data Space**.

Co-funded by
The Health Programme
of the European Union

SITRA

Why EU?

Yes we can

Treaty changes?

TFEU 114
Internal markets

TFEU 16
Data protection

TFEU 168
Cross-border
healthcare

Co-funded by
The Health Programme
of the European Union

1 Context

2 Introduction to TEHDAS

3 Topical issues

Co-funded by
The Health Programme
of the European Union

TEHDAS in a nutshell

Project coordinator	The Finnish Innovation Fund Sitra
Project acronym	TEHDAS
Start date	1 February 2021
Duration	30 months
Participants	25 European countries
Co-funding	€4.16 M (EU €2.5 + MS €1.66)
Work packages	8
Websites	www.tehdas.eu
Contact	tehdascoordination@sitra.fi

Co-funded by
The Health Programme
of the European Union

Vision and mission

Co-funded by
The Health Programme
of the European Union

The Joint Action helps the Members States and the Commission in

developing and promoting concepts for sharing of data in secondary use for purposes

for citizens' health, public health, as well as health research & innovation in Europe.

Co-funded by
The Health Programme
of the European Union

In the future Europe, citizens, communities and companies benefit from a

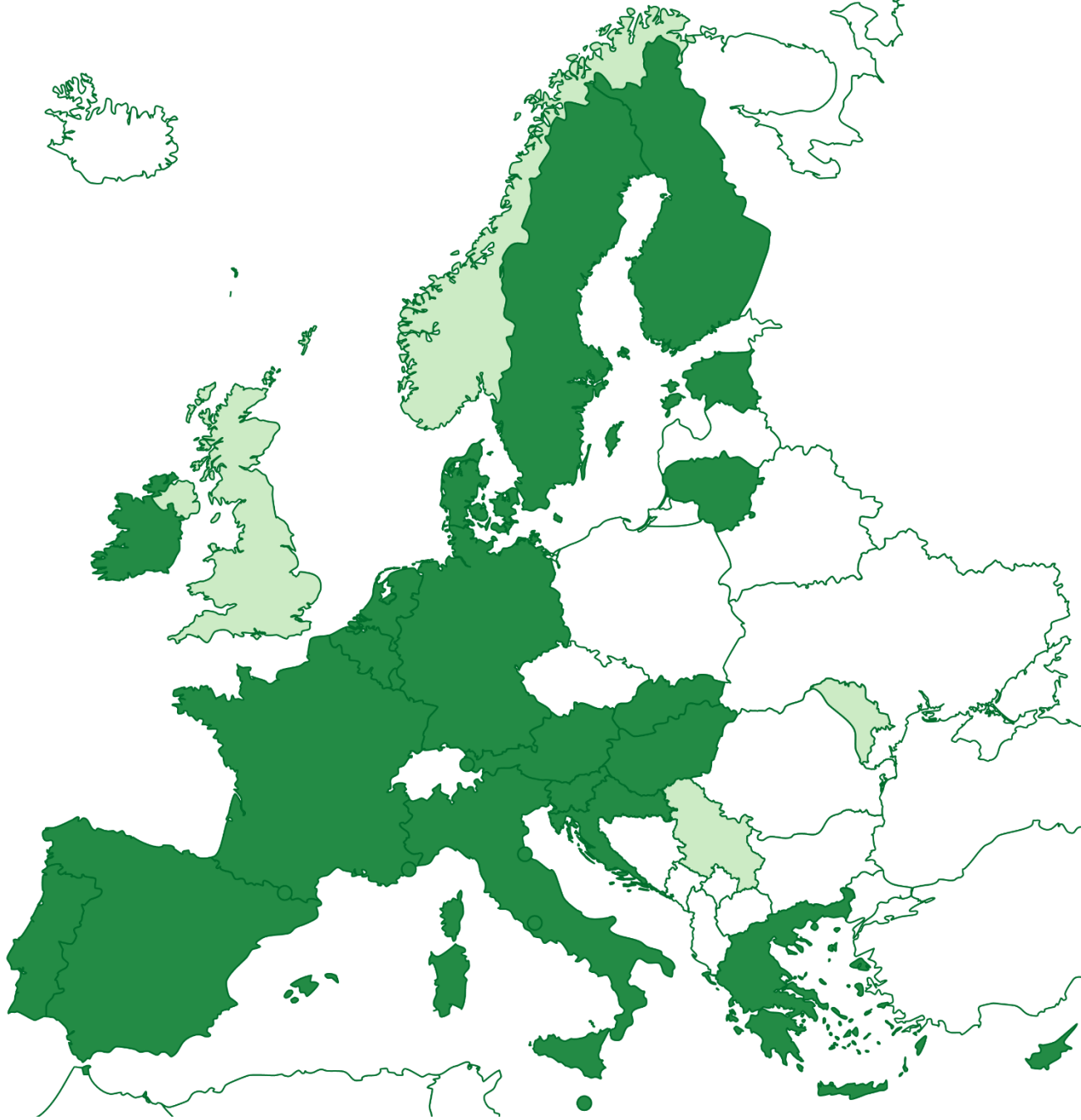
protected and secure access to seamless health data

regardless where it is stored.

Co-funded by
The Health Programme
of the European Union

Participants

- EU member states (21)
- Non-EU member states (4)
- Non-participating states



Co-funded by
The Health Programme
of the European Union

What TEHDAS is

1. Creates concepts for the secondary use of health data in Europe
2. A preparatory body
3. A project between beneficiaries nominated by Member States
4. Co-funded by the EU Health Programme
5. Clear scope with defined Deliverables and timeline

Co-funded by
The Health Programme
of the European Union

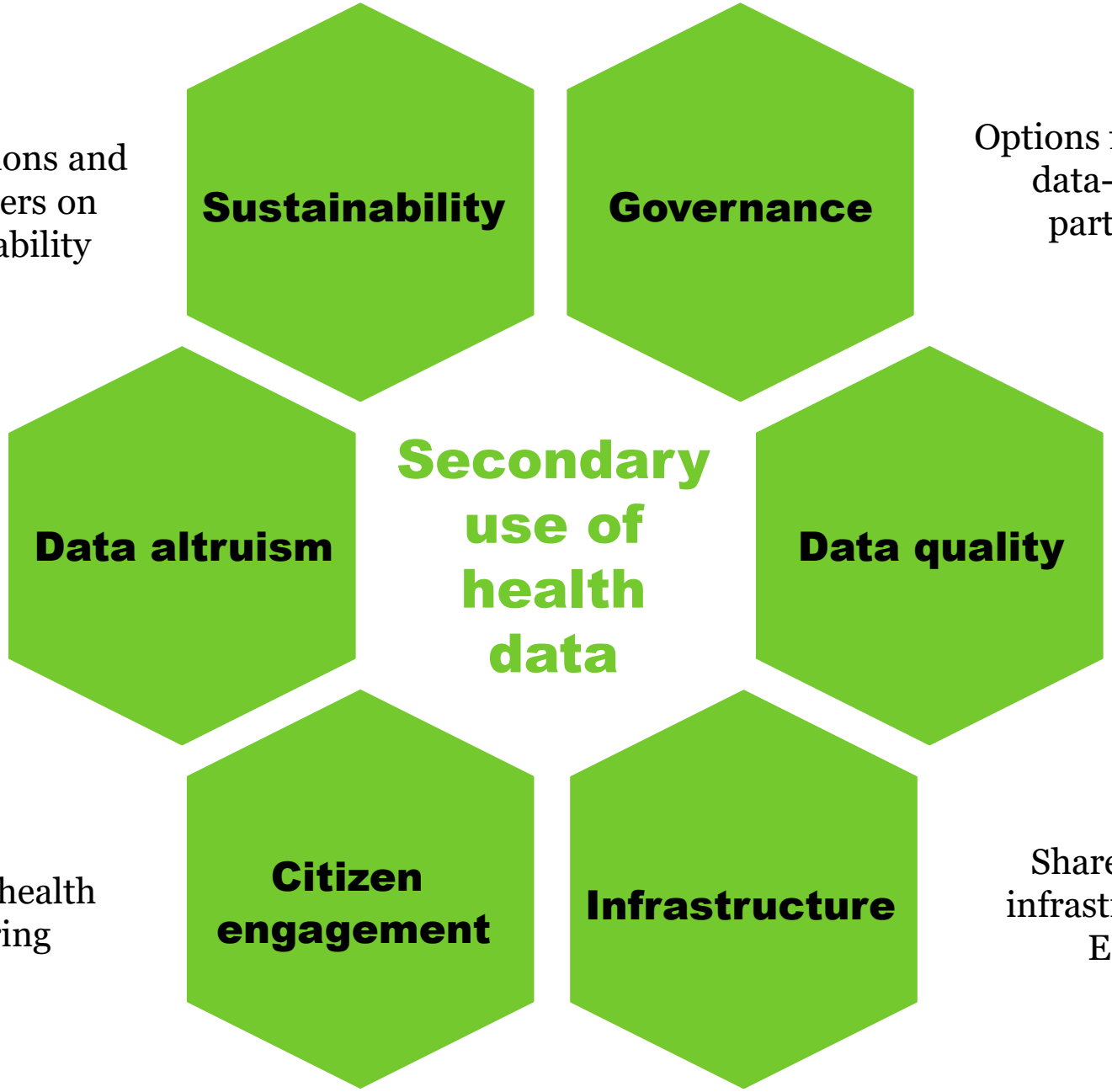
What TEHDAS is not

1. Creates concepts for primary use of health data in Europe
2. A legislative/executive body
3. Defines the EHDS
4. Builds working IT solutions
5. Pilots use-cases / exchange data
6. Part of Horizon Europe
7. Creates a code of conduct for health data usage

SITRA

TEHDAS

Secondary use of health data



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

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)

Co-funded by
The Health Programme
of the European Union

SITRA

First result out in June!

- Why Health is a Special Case for Data Governance? (June)

Table of Contents

1 Executive summary 4

2 Context 5

3 Legislation relevant to secondary use of health data 6

4 Why health data is a specific case in legislation? 8

5 Elements of health data specificity 9

5.1 Element 1: The Patient 9
5.2 Element 2: Public Health 10
5.3 Element 3: Research and specific data types 12
5.4 Element 4: Health data as highly sensitive data 14
5.5 Element 5: Data security, Cybersecurity 16
5.6 Element 6: Health data in the private sector 20
5.7 Element 7: Semantic Interoperability 21
5.8 Element 8: Regulatory frameworks at national level 23

References 26

Annex 1 27

Co-funded by
The Health Programme
of the European Union

1 Context

2 Introduction to TEHDAS

3 Topical issues

Co-funded by
The Health Programme
of the European Union

EHDS Consultation open

03 May 2021 - 26 July 2021

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-A-European-Health-Data-Space/public-consultation_en

Kansallinen asiantuntijaryhmä

23.06.2021 klo 13:00 - 15:00

https://www.sitra.fi/tapahtumat/tehdas-yhteistoimintahankkeen-kansallisen-asiantuntijaryhman-kokous-3/

TEHDAS Stakeholder Forum

October in Helsinki – Stay tuned!

Co-funded by
The Health Programme
of the European Union

Join the dialogue!

We encourage you to participate in a dialogue about the European Health Data Space. Follow us on Twitter @tehdas and tag us in your tweets.

Sign up to our TEHDAS Newsletter via our website tehdas.eu/contact.

www.tehdas.eu

Markus Kalliola
Project Director
TEHDAS Coordinator
Markus.Kalliola@sitra.fi
+358503591499
@markuskalliola

@tehdas
tehdascoordination@sitra.fi
#TEHDAS
#HealthData

Co-funded by
The Health Programme
of the European Union

TEH DAS

Co-funded by
The Health Programme
of the European Union

SITRA