

Workshop 6.G. The European Health Data Space 2: is Europe ready to maximise the re-use of health data?

European Public Health Conference 2022

Friday 11 November, 11:40-12:40



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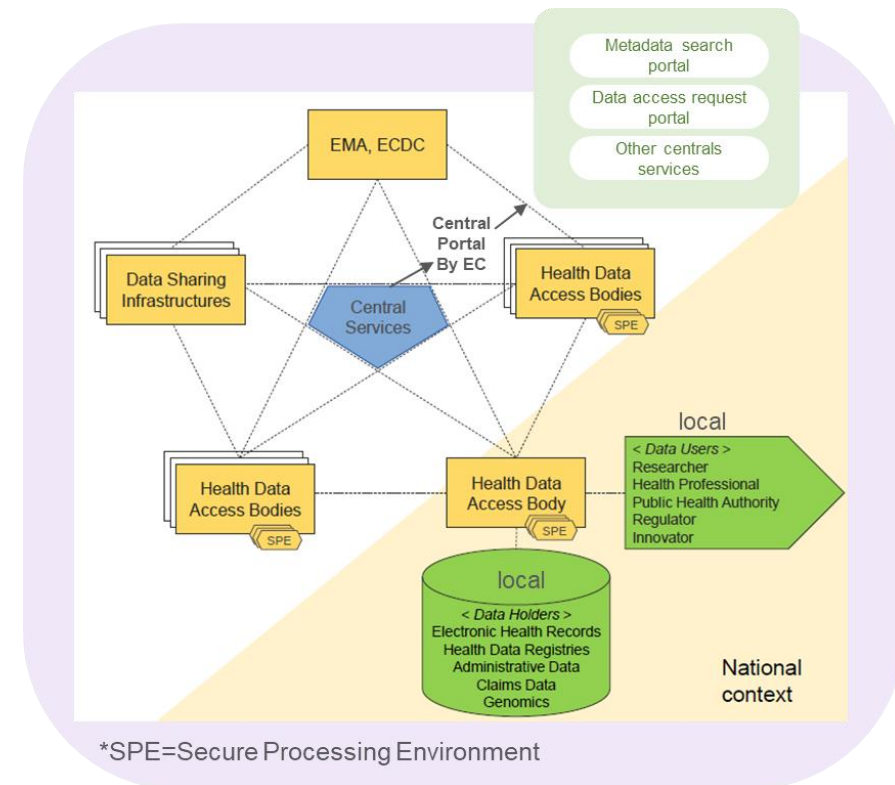
Agenda

Introduction (5-10 min)	Irene Kesisoglou (Sciensano) Shona Cosgrove (Sciensano)
Presentation 1 (10 min)	'State of play of national health data management systems in relation to the EHDS' Linda Abboud (Sciensano)
Presentation 2 (10 min)	'Barriers for cross-border sharing of health data for secondary use and options to overcome these' Rosie Richards (NHS Confederation)
Presentation 3 (10 min)	'EHDS2 pilot infrastructure for the secondary use of health data' Camille Cloitre (French Health Data Hub)
Presentation 4 (10 min)	'The role of PHIRI within HealthData@EU' Enrique Bernal Delgado (IACS)
Q&A (10-15 min)	All

Background

The **European Health Data Space** (EHDS) legislative proposal was published by the European Commission in May 2022.

- EHDS for primary use: exchange of ePrescriptions and ePatient summaries, continuity of care.
- EHDS for secondary use: proposes the development of an infrastructure to facilitate the re-use of health data for research and policy making:





- ✓ TEHDAS Joint Action: Towards a European Health Data Space
- ✓ Supports Member States and the Commission in developing and promoting concepts for sharing of data for secondary use
- ✓ Provides options for the EHDS for secondary use

- ✓ EHDS2 Pilot Project
- ✓ Aims to develop, deploy and test the technical infrastructure of the European Health Data Space for secondary use
- ✓ Addresses the challenges surrounding access to health data throughout the EU



- ✓ PHIRI: Population Health Information Research Infrastructure
- ✓ Facilitates and generates evidence for research on health and well-being of populations impacted by COVID-19
- ✓ Supports research across Europe through the identification, access, assessment and reuse of population health and non-health data to underpin public health policy decisions

The projects

Aim of the workshop

1. Provide a general overview of the EHDS for secondary use.
2. Identify the needs and expectations of stakeholders and member states and their preparedness to join the EHDS.
3. Inform and align participants on the current work on the technical infrastructure of the EHDS being developed by the pilot project.
4. Explore the current situation and experiences from research projects, including the potential role of research infrastructures in the EHDS2.

Presentation 1



State of play of national health data
management systems in relation to the EHDS
Linda Abboud (Sciensano)

State-of-play of national health data management systems in relation to the European Health Data Space

Linda Abboud

European Public Health Conference, 11 November 2022

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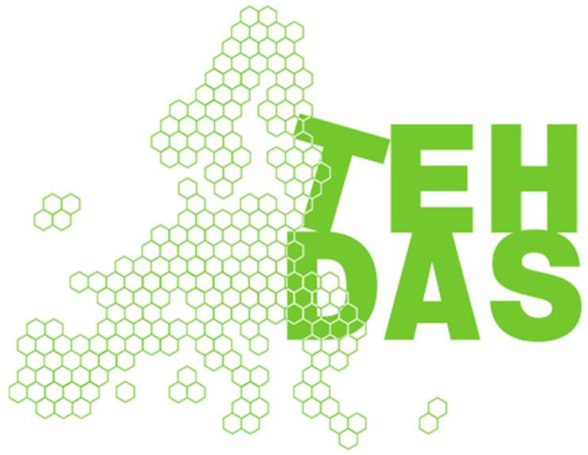


Aim & scope

- To engage with national stakeholders and map the state-of-play of the national health data management systems in relation to a future European Health Data Space for secondary use (EHDS2)
- To reflect on needs and expectations at national level with regards to EHDS

Scope: data sources, data quality, data infrastructure, data governance, resources and capacity, EHDS preparedness.



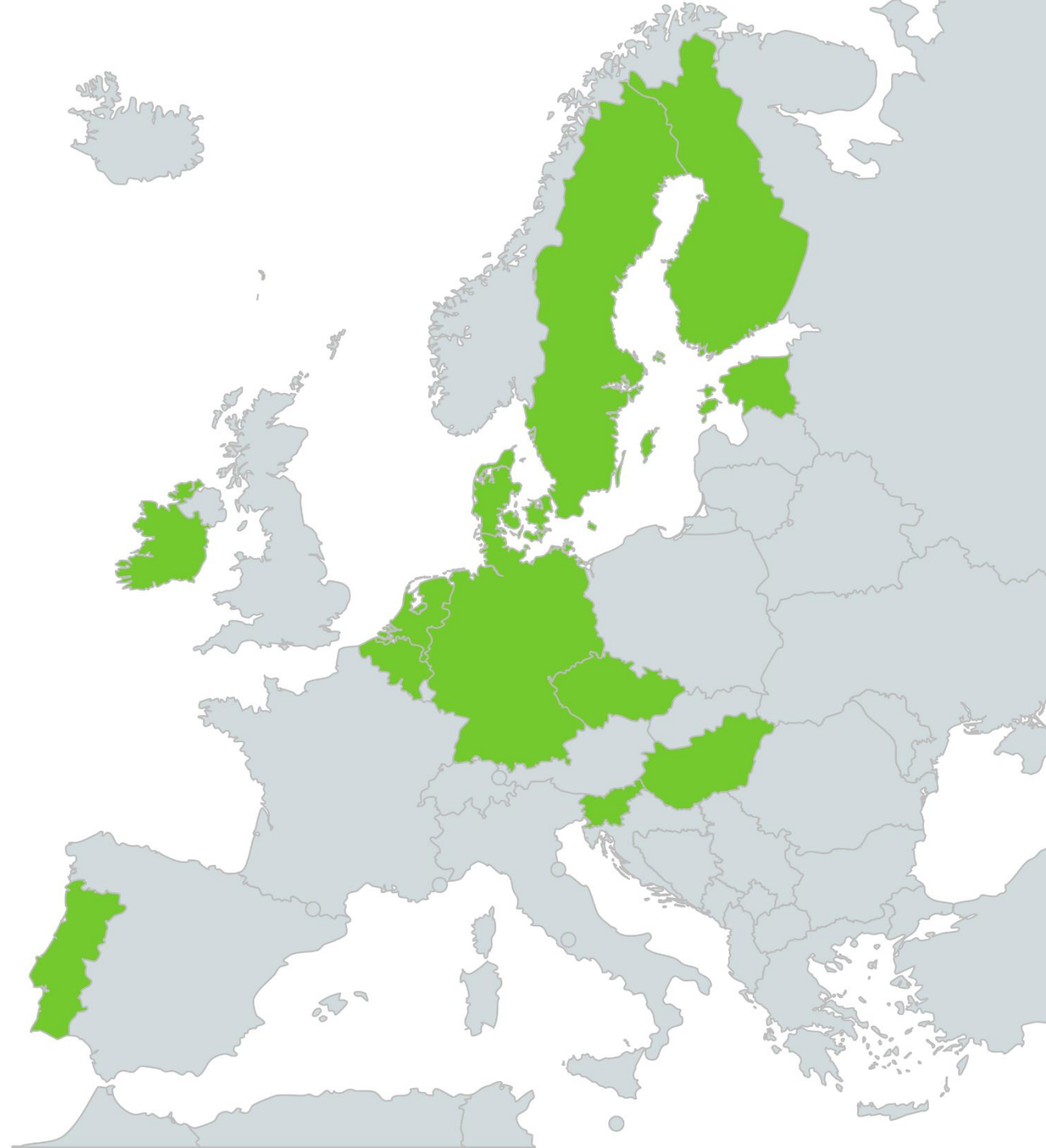


Towards
European
Health
Data
Space



Timeline:

December 2021 – December 2022



Methodology

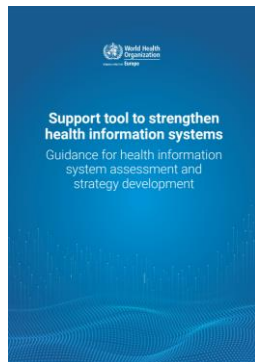
1. Preparatory desk review

- Preparatory report
- Stakeholders selection



2. Country visit

- Semi structured-interviews using the adapted assessment tool



3. Debriefing meetings

- Multi-stakeholder meeting



4. Reporting

- Report
- [One-pager](#)



Preparedness for the EHDS

- Digitalised health data (9 / 11)
- Common metadata catalogue in place or work ongoing (5/ 11)
- Universal usage of a unique personal identifier for health (10 / 11)
- Remote secure processing environments (7 / 11)
- Wide use of internationally recognised standards (4 / 11)
- Semantic interoperability (9 / 11)
- Similar access rights for national and foreign researchers (9 / 11)
- Political will to join the EHDS (11 / 11)
- Potential national contact point for the EHDS2 already existing (3 / 11)



Challenges

Organisational

Technical

Legal





Challenges


Organisational


Technical

Legal

-  Paper-based records

-  No unique personal ID

-  Data gaps

-  Interpretations of the GDPR

Challenges

Organisational

Technical

Legal



Inconsistent use of internationally recognised standards



Unstructured data



Lack of interoperability

Challenges

Organisational

Technical

Legal



Limited foreign users access



Unclear definition of anonymisation or pseudonymisation



Lack of legal framework for secondary use

Needs

Organisational

Manual providing
**overview of
national data
management
systems** in EU
countries

Technical

Semantic
interoperability
across Europe
Support with **secure
processing
environments**

Legal

Guidelines for **safe
sharing** and
secondary use of
data

RESOURCES

(Financial, Technical, Human)



Conclusion

In general, positive views on the impact and added value of the EHDS for secondary use, and willingness to join.

- ✓ Consider the diversity and local sensitivities
- ✓ Ensure equal benefit for all countries and stakeholders
- ✓ Focus on cybersecurity and trust
- ✓ Improve transparency in access processes and decisions
- ✓ Communicate with all stakeholders and citizens



Contact us

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<https://tehdas.eu/packages/package-4-outreach-engagement-and-sustainability/tehdas-country-visits/>

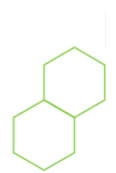
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#HealthData



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Presentation 2



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

Rosie Richards (NHS Confederation)

TEHDAS

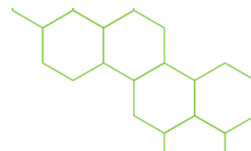
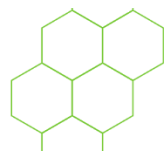
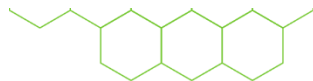
Towards
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**Barriers on cross-border sharing of health data
for secondary use and options to overcome these**

Rosie Richards (NHS Confederation)

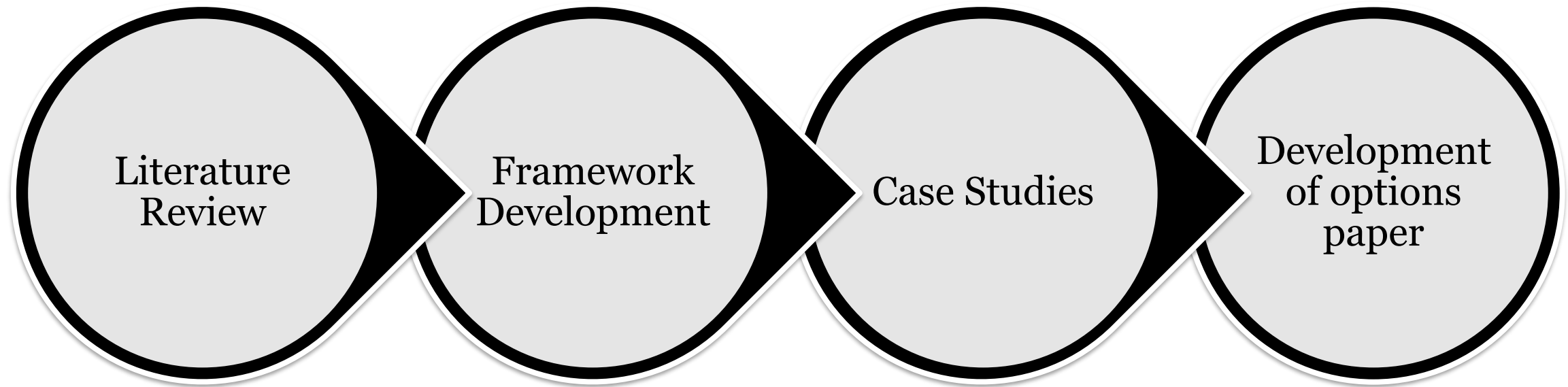


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SITRA

Methodology

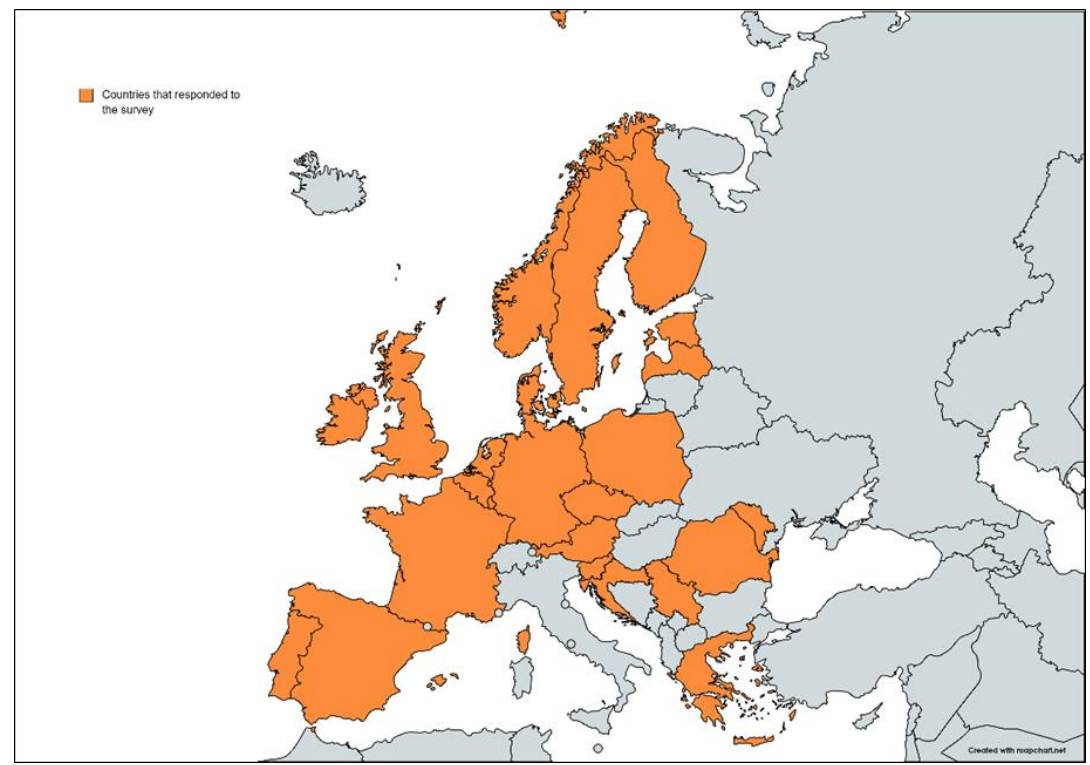
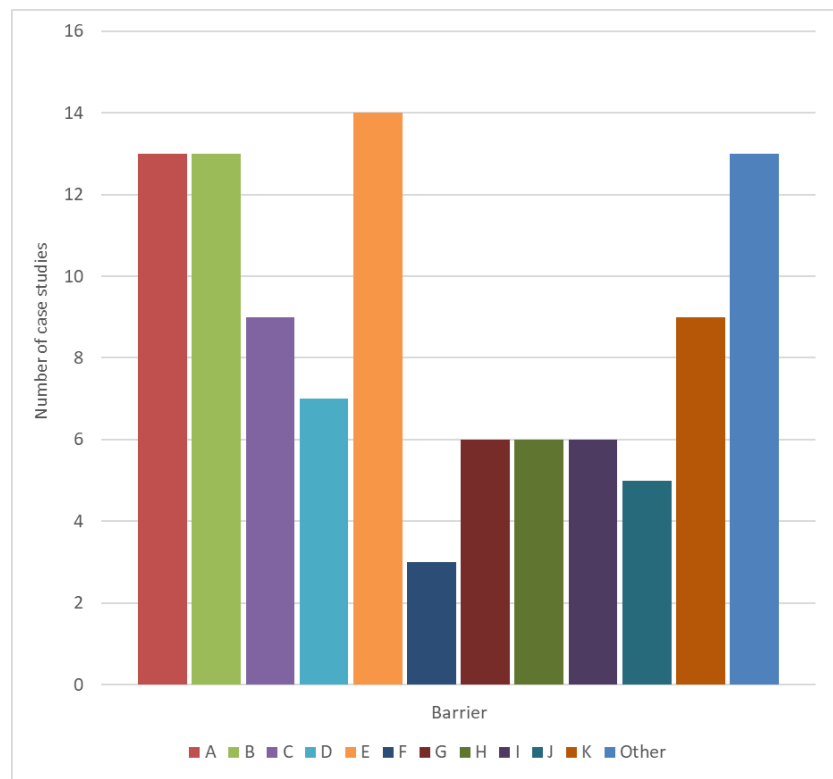


Results: Framework

Rank	Barrier description	Theme
A	There are differences in governance and health data systems in Europe	Infrastructure
B	A lack of a common European interpretation of what constitutes ‘sufficient anonymisation’ to transform personal data to non-personal data	Legal
C	A lack of a common European interpretation of what constitutes ‘pseudonymisation’	Legal
D	A lack of a common European interpretation of what is and is not ‘secondary use’ of data	Legal
E	European countries have national laws/rules on health and research data in addition to the GDPR	Legal
F	European countries can set different derogations under the GDPR	Legal
G	European countries have different preferences as to the choice of legal basis for processing under the GDPR	Legal
H	Health data is considered sensitive data e.g., special category data under the GDPR, and is treated differently from other types of data when it comes to health data ethics, management, and use	Data
I	A lack of standardised data sharing agreements for products developed by private sector providers using public health data to facilitate safe data sharing and protect public investment	Trust
J	The use of different interoperability standards across Europe makes comparisons and sharing data and research results challenging	Data
K	Poor data management procedures reduce the ability to reuse data	Data

Results: Case studies

A total of 23 European countries provided 113 case studies between April and August 2021.



Good representation across Europe

Options



A lack of a common European interpretation of what is and is not ‘secondary use’ of data

	TEHDAS recommended that....	The Commission responded by...
1	The EC creates legislation that clearly outlines rules for collection, use and sharing of health data for secondary use in the EHDS.	Setting out the minimum categories of electronic health data for secondary use (Chapter IV)
2	The EC and MSs agree to a high-level definition of secondary use of health data at EU level, in consultation with domain experts and the European Data Protection Board, and ensure its application.	Defining the secondary use of electronic health data (Article 2 Definitions)
3	Member States implement national level processes to clarify what constitutes secondary use of data domestically.	



Options



The use of different interoperability standards across Europe makes comparisons and sharing data and research results challenging

No.	Options
1	The Commission adopts a single interoperability standard for the European Health Data.
2	The Commission recommends adoption of a predetermined list of a few common interoperability standards including terminologies, ontologies and classification systems.
3	The Commission develops a reference document outlining all the standards used by each MS to describe health data. This would make it possible to create common data models or ways of translating one standard into the other.
6	Do nothing .

Mentimeter

Go to: slido.com

Enter code: #2072 046

Passcode: EHDS

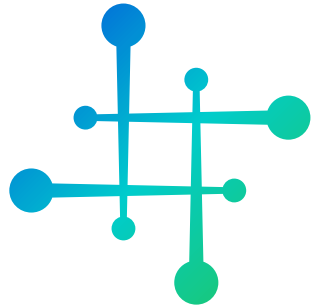


Presentation 3



EHDS2 pilot infrastructure for the
secondary use of health data

Camille Cloitre (French Health Data Hub)



EHDS

HealthData@EU Pilot

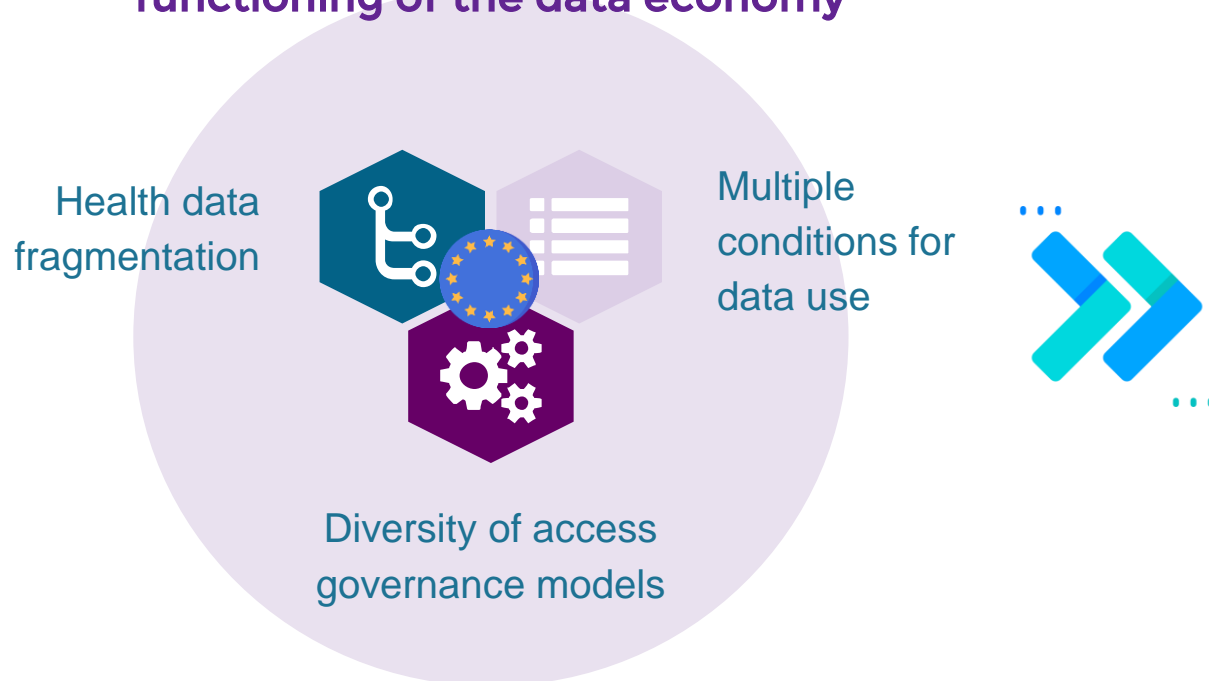
Berlin | November 11th 2022



Health data sharing, a major priority for the European Commission and European health policy

Objective

remove obstacles to the smooth functioning of the data economy



Solutions

create an EU-wide governance framework for data access and use

- 2020 Data Governance Act proposal
- 2021 Joint Action TEHDAS “Towards a European Health Data Space”
- 2021 Pilot version of European Health Data Space: call for proposals financed up to 5m€
- 2022 Proposed European Health Data Space legislation

The HDH, leader of a European consortium to build and operate a first version of the EHDS (1/5)



HealthData@EUpilot

17 partners, 9 countries

2 years

5 million euros of European fundings

Create and test a beta version of the European Health Data Space



Build a network of data platforms on a European scale...

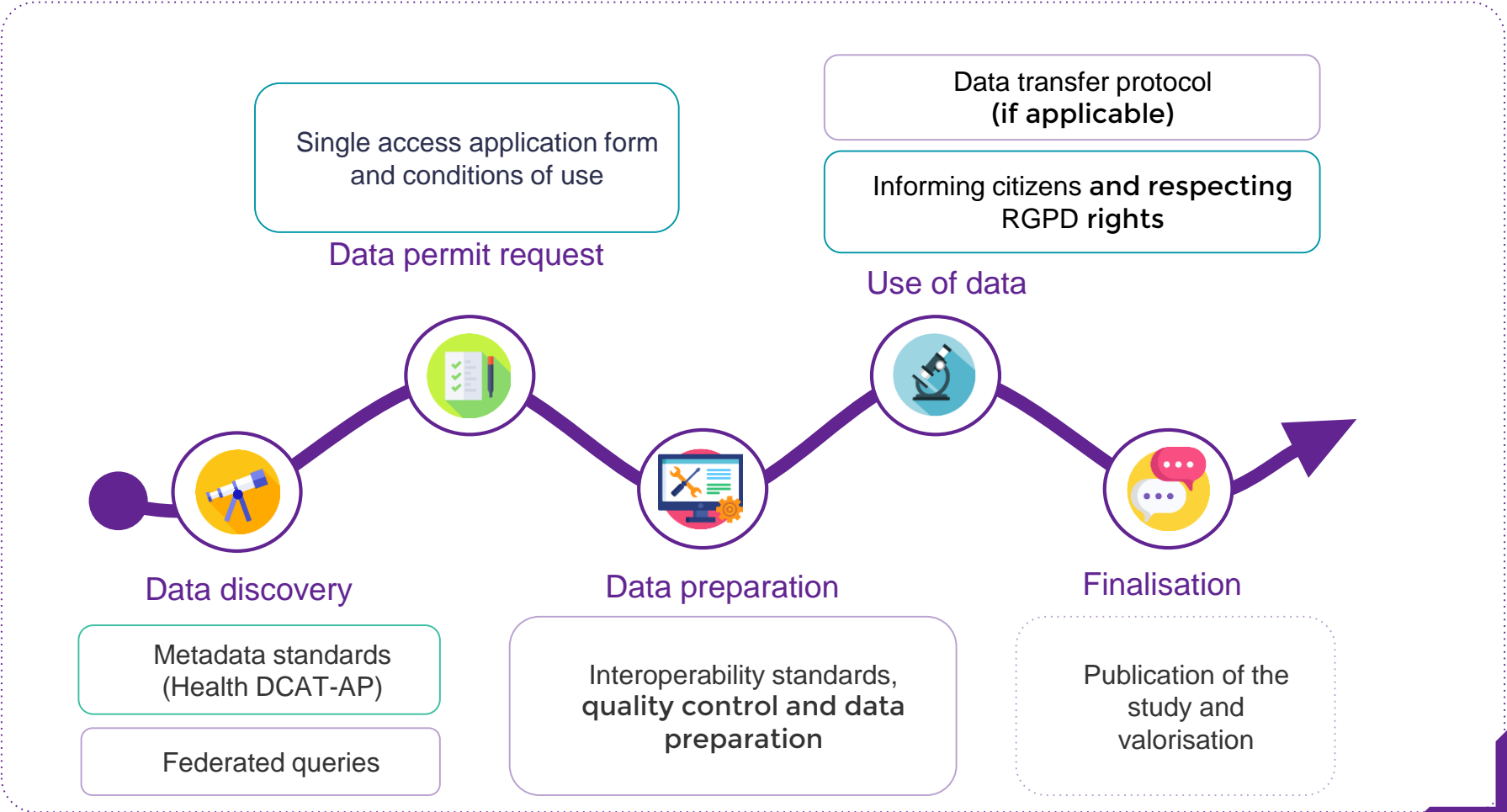


...tested by concrete cross-border use cases



The HDH, leader of a European consortium to build and operate a first version of the EHDS (2/5)

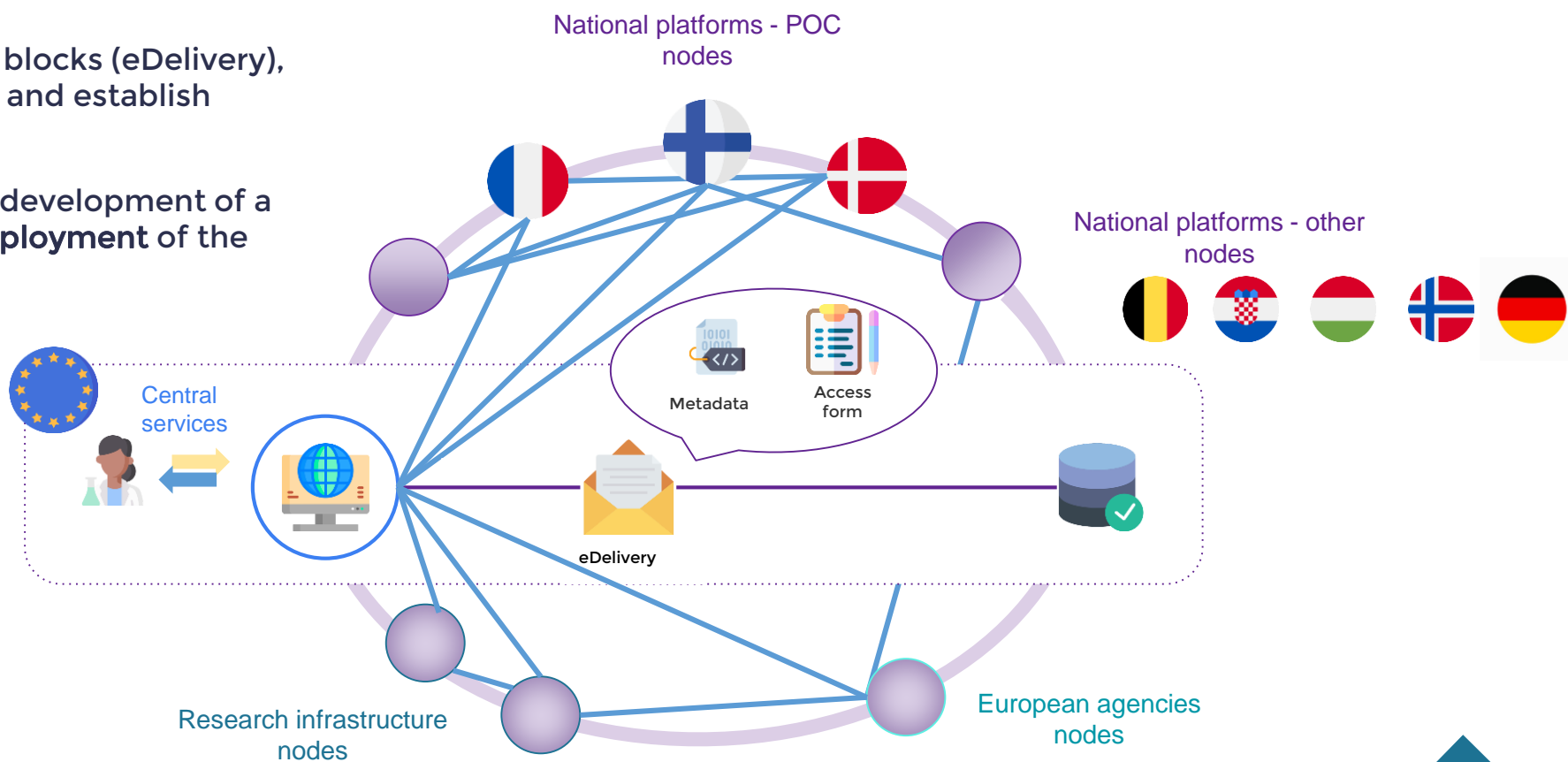
Create a first user experience of the European Health Data Space...



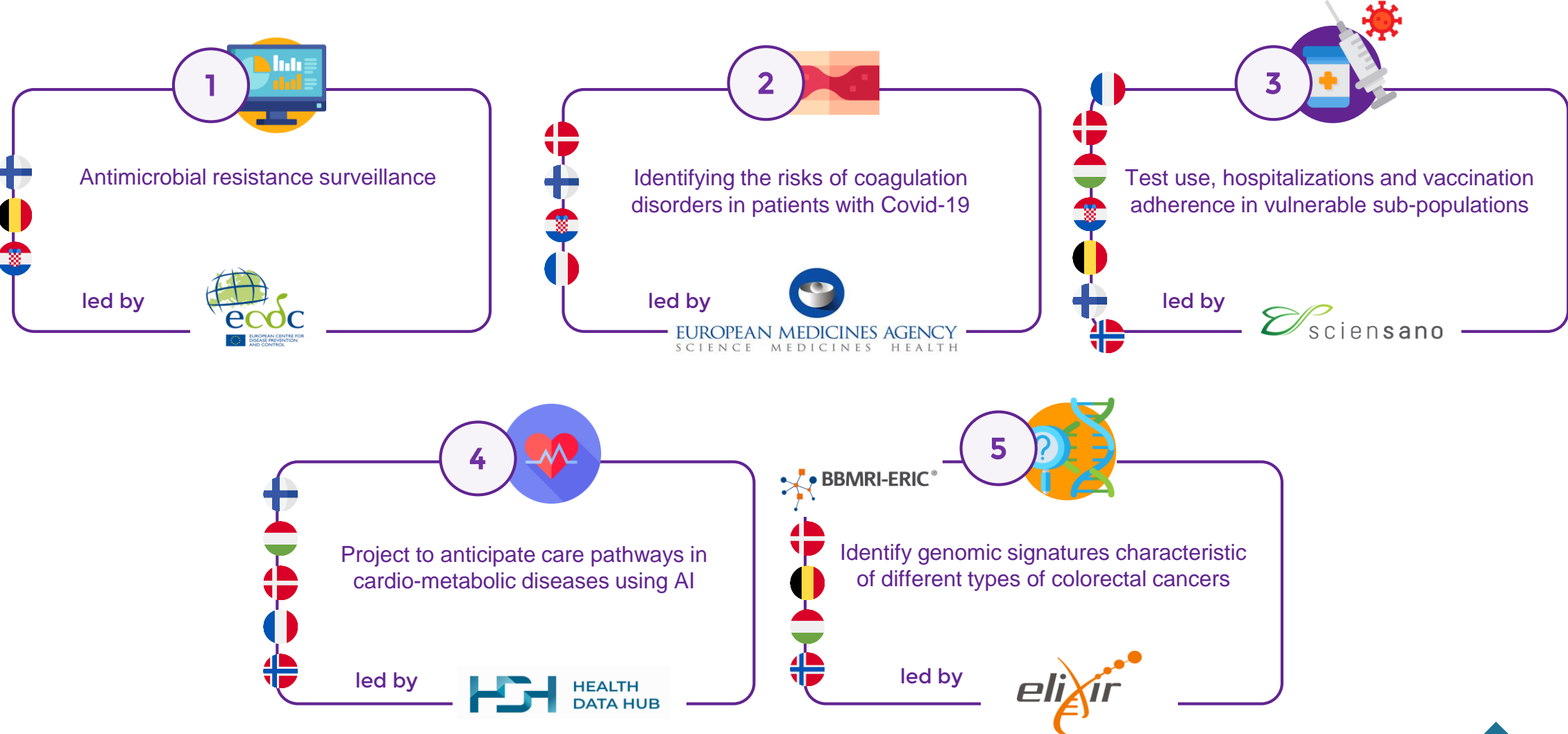
The HDH, leader of a European consortium to build and operate a first version of the EHDS (3/5)

... based on a technical infrastructure allowing the exchange of information between nodes

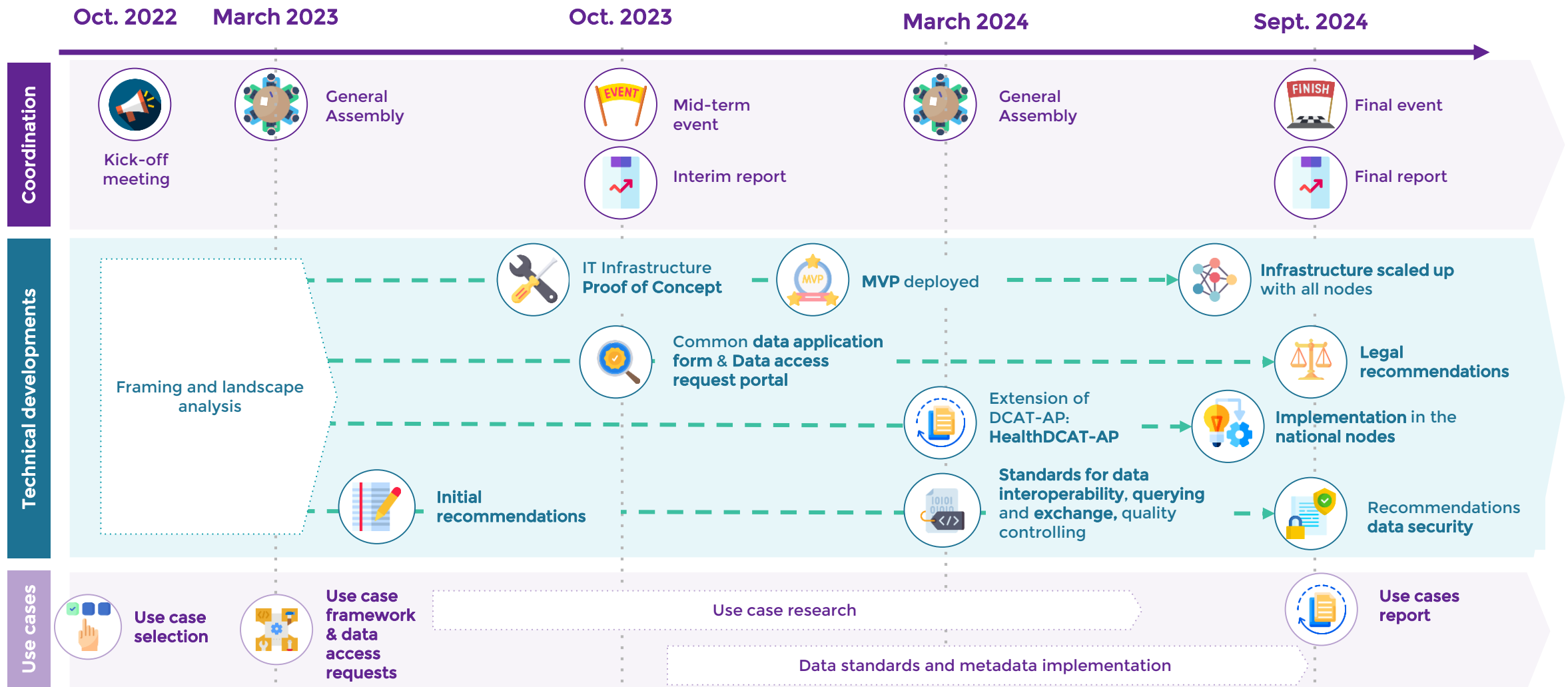
- ✓ Design and deploy a **technical infrastructure** for the **network of nodes** and the link with **central services**
- ✓ Use European building blocks (eDelivery), open source standards and establish **security standards**
- ✓ After a **scoping phase**, development of a **POC**, then **MVP** and **deployment** of the network



The HDH, leader of a European consortium to build and operate a first version of the EHDS (4/5)



The HDH, leader of a European consortium to build and operate a first version of the EHDS (5/5)





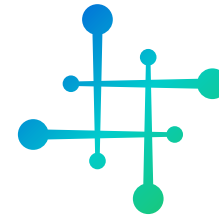
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EHDS

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Presentation 4



The role of PHIRI within
HealthData@EU

Enrique Bernal Delgado (IACS)



PHIRI

Population Health Information
Research Infrastructure



BERLIN | 9-12 NOVEMBER 2022

The role of PHIRI within HealthData@EU

Enrique Bernal-Delgado
on behalf of the PHIRI team
ebernal.iacs@aragon.es

PHIRI

The Population Health Information
Research Infrastructure for COVID-19:

- a **European mechanism**, that aims to
- facilitate and support **data-driven population health research**
- and **exchange of best practices**
- to support **decision making**

41

partners

30

countries

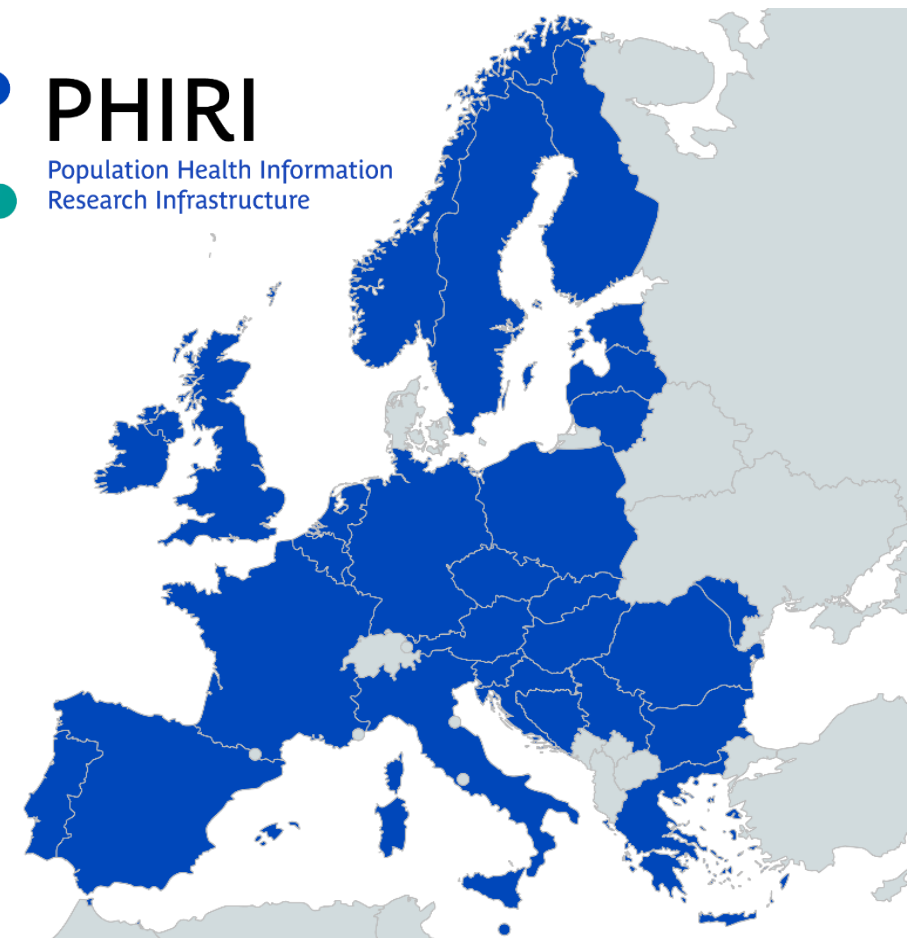
3

years



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Population Health Information
Research Infrastructure

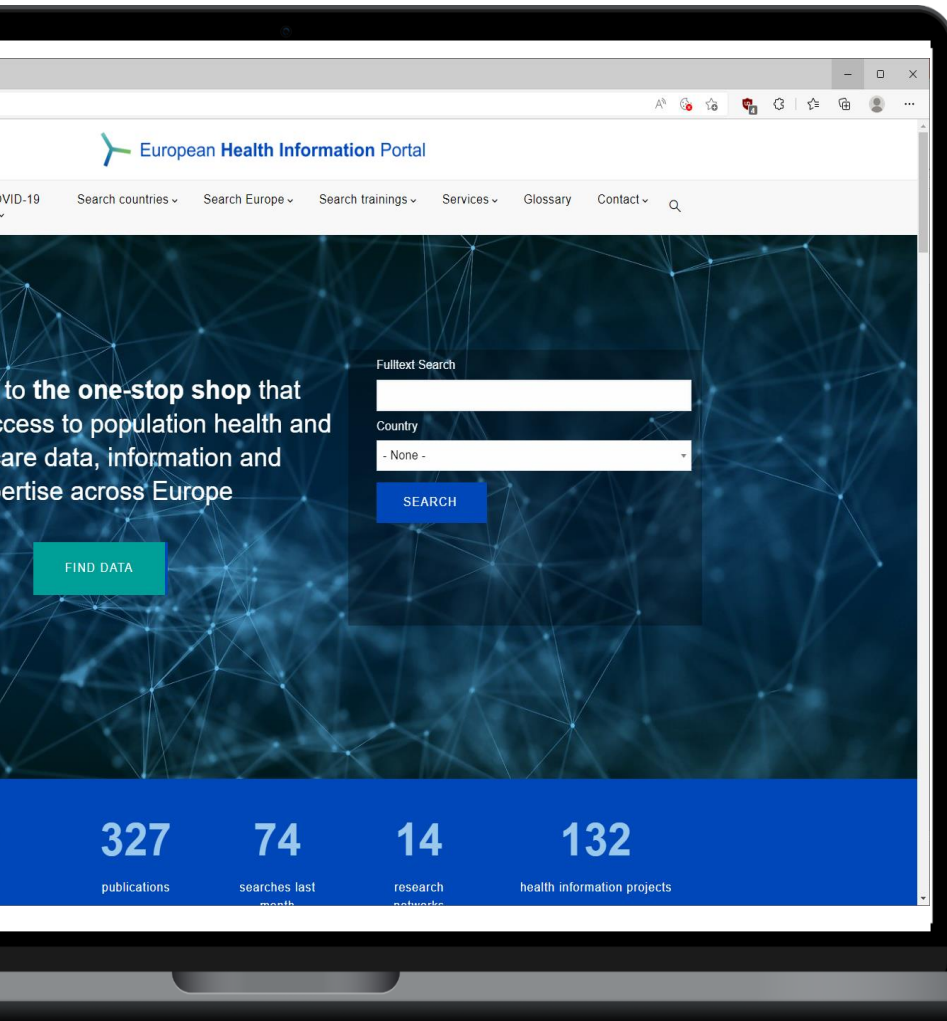



Map of PHIRI Partners


The European Health Information Portal


www.healthinformationportal.eu

A one-stop shop that facilitates access to population health and health care data, information and expertise across Europe.





 **Health information (data) sources**


 **Publications**

 **Countries and national nodes**

 **Trainings in all areas of population health**

 **Research infrastructures, Research networks**





 **COVID-19 Policy measures**

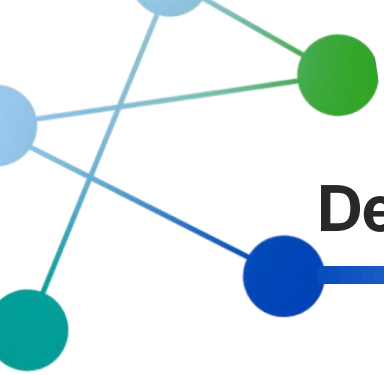
 **Health information projects**

 **COVID-19 Rapid Exchange Forum**

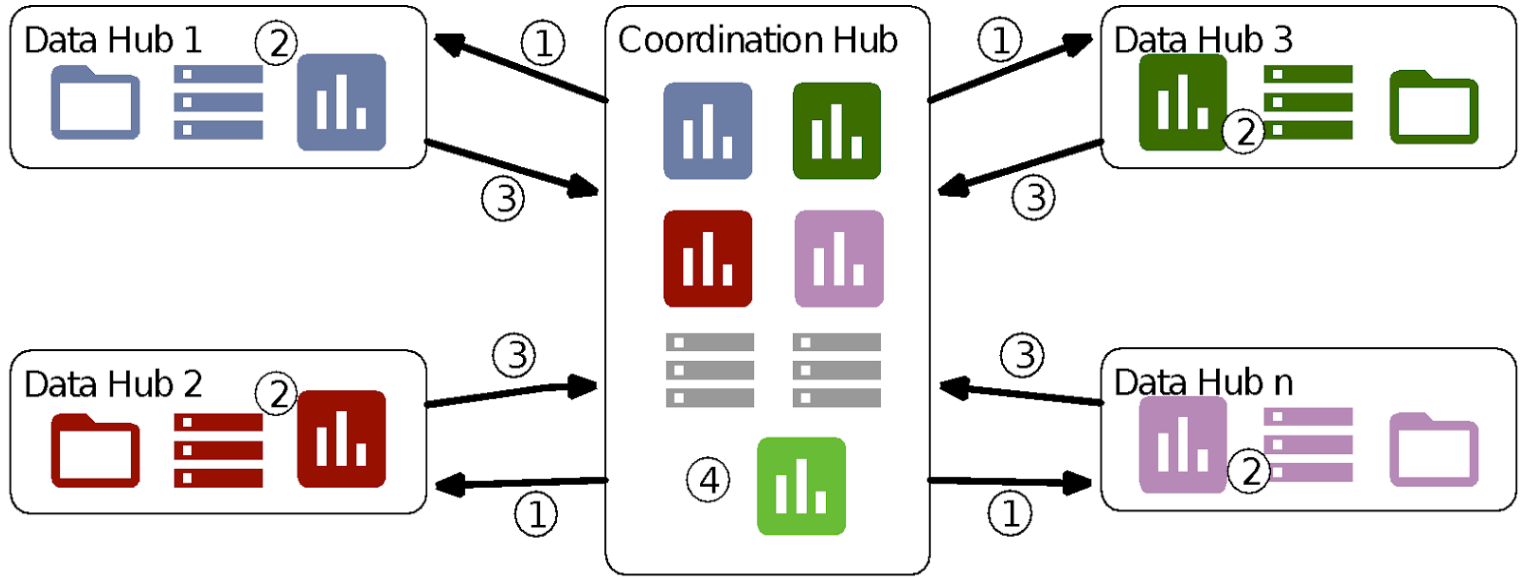
PHIRI – we have tested what the EHDS2 aims at

4 real life research use cases measuring the impact of COVID-19 on population health

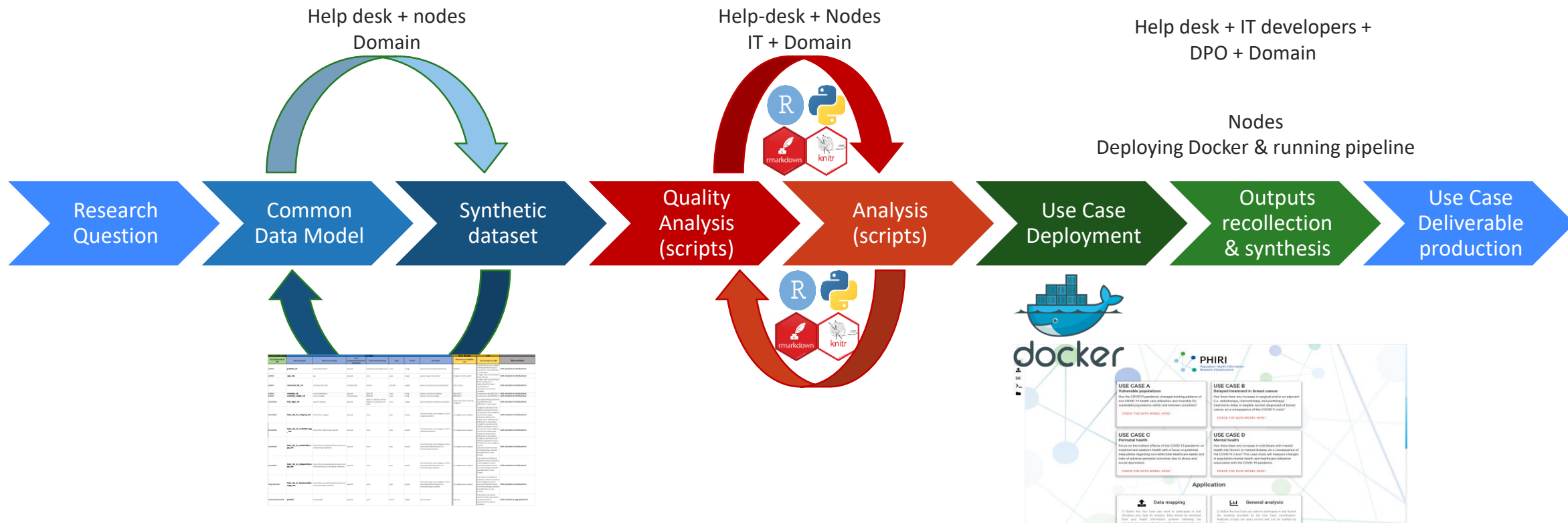
-  Direct and indirect determinants of COVID-19 infection and outcomes in vulnerable population groups with reference to inequalities
-  COVID-19 related delayed care in breast cancer patients
-  The impact of COVID-19 on perinatal health and perinatal health inequalities
-  COVID-19 related changes in population mental health



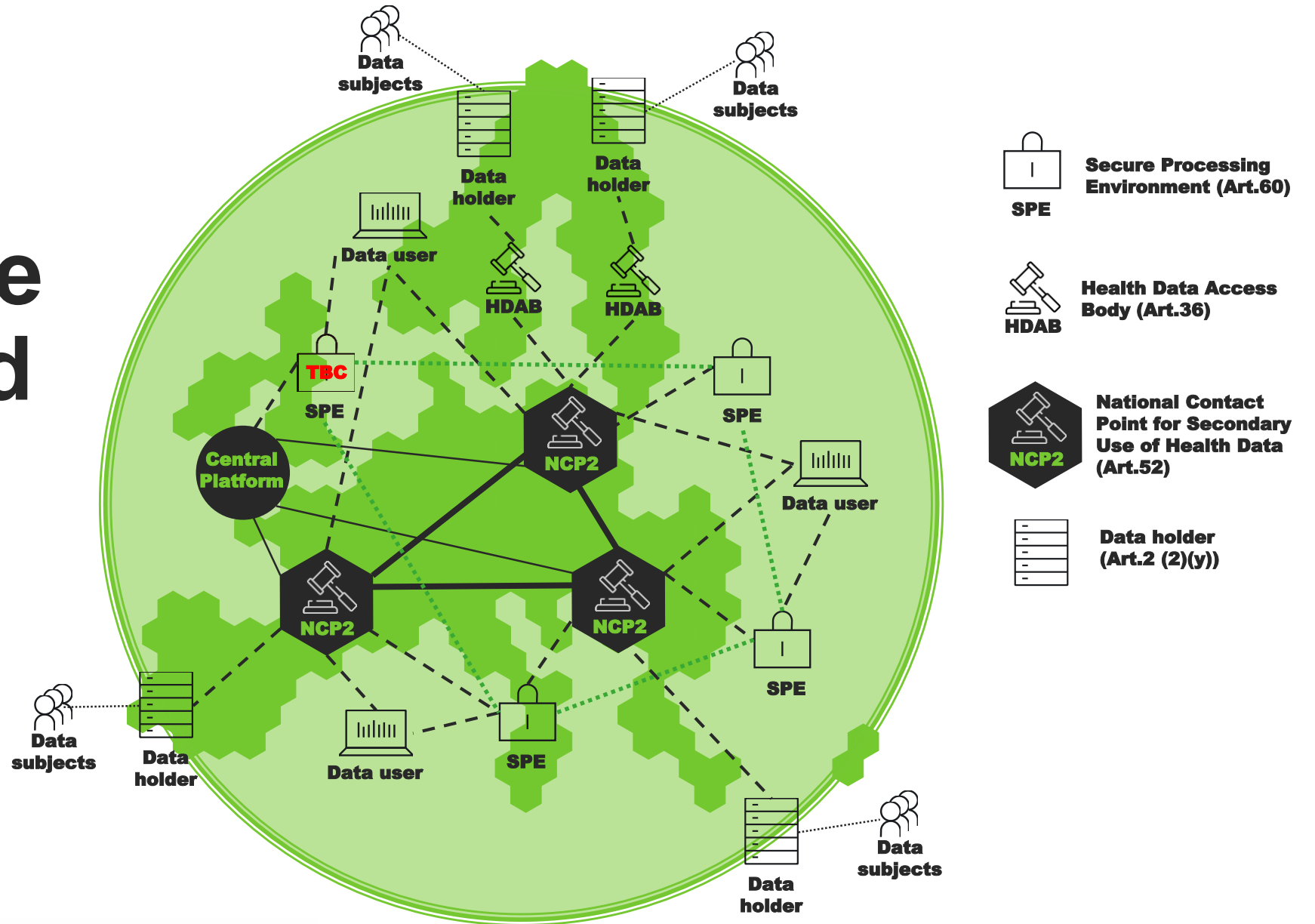
Developed a federation of nodes as in EHDS2...



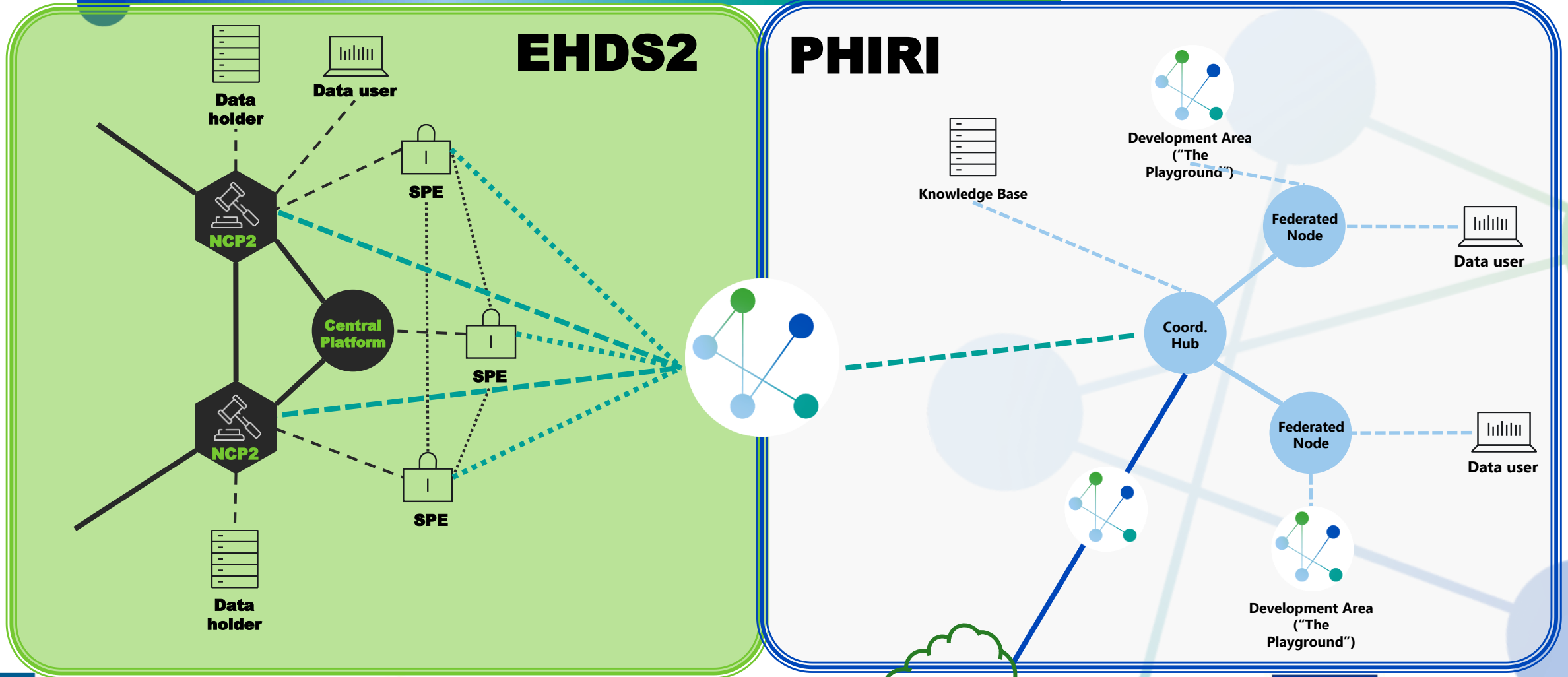
... orchestrated with a generalizable methodology GDPR, EIF and FAIR compliant



Where in the EHDS2 architecture PHIRI could fit?



As an interface between EHDS2 and PH research comm.



What are the services to provide complementing EHDS2 services?

	PHIRI Knowledge Base	PHIRI services	HealthData@EU services
Data preparation	Guidelines on data preparation for Data Holders	Consultancy	Partially
Data search (Data discovery)	Guidelines on how to use search services	Assisted search software & support	Yes
Feasibility Analysis (Data discovery)	Documentation of existing studies	Feasibility consultancy	Partially
Data Permit Request (Access Request)	Templates of successful permit requests	Access request assistant software & support	Yes
Analysis solutions development (Use)	Documentation/Manuals on algorithms develop't	Development Areas, Virtual Labs, Synthetic d'sets	No
Real-world data analysis (Use)	Guidelines on algorithms deployment and SPEs use	SPEs deployment software & support	Yes
Results manipulation (Finalisation)	Guidelines on results FAIRification	Results publication system & support	Partially
Capacity Building (All)	Structured courses on all previous topics	Training services	No
Authent'n, Authoriz'n and Identif'n (All)	N/A	AAI services	Partially
Financial Services (All)	Fees of different services from different providers	Financial management software & support	Partially

Ongoing steps towards being such an interface

- Re-thinking the PHIRI infrastructure to be highly scalable
- Increasing the findability of HIP knowledge base
- Increasing the knowledge base with analytical workflows and tools
- Developing the proof of concept for virtual labs
- Testing and implementing solutions for communication between nodes
- Aligning with EOSC community
- Building capacity



PHIRI

Population Health Information
Research Infrastructure



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Thank you

Enrique Bernal-Delgado
on behalf of the PHIRI team
ebernal.iacs@aragon.es



Questions to the speakers



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

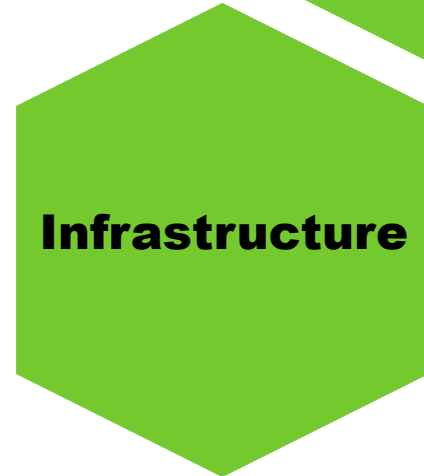


Secondary use of health data



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)