



CONNECTATHON[®]

BRUSSELS  **2026** MARCH 23/27



Workshop: Interoperability in EHDS Secondary Use

Bringing up community practices and needs for coordination

Moderators: Dmitry Etin (de@etza.eu), Stefan Sauermann,

Observer: Fidelia Cascini



1. Input presentations:

- TEHDAS2 joint action: Deliverables for the future implementing acts and good practices (Speaker: Sofia Peltola)
- IHE Profiles Supporting EHDS secondary use (Speaker: Lori Fourquet)
- SPIDER: a tool for HDABs (Speaker: David Asturiol)
- Outcomes of IHE Connectathon Workshop 2025 on secondary use in Viena (Speaker: Stefan Sauermann)

2. Table discussions

3. Wrap-up and planning community work

Table 1 — Good Data Practice for Vendors and Innovators

Hosts: Tim Jongen, John Brennan

Table 2 — Secure Processing Environments

Hosts: Irimi Kessissoglou, Dmitry Etin

Table 3 — Standards Coordination and Profiling

Hosts: Lori Fourquet, Stefan Sauermann

Table 4 — Governing “Code Meets Data” in the EHDS

Host: Nienke Schutte



IHE[®] EXPERIENCE
EUROPE DAYS

BRUSSELS 2026

25-26 MARCH 

TEHDAS2 joint action

Deliverables for the future
implementing acts and
good practices

26/03/2026

Sofia Peltola

*Specialist at the Finnish
Innovation Fund Sitra*

TEHDAS2 coordination team

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Today's Agenda

- TEHDAS2 – what is it about?
- TEHDAS2 deliverables from standards perspective
- Overview of documents
- How to stay updated and provide feedback



TEHDAS2 areas of work

EXPECTED RESULTS

Guidelines and technical specifications
for
data users, data holders and health data access bodies



EXPECTED IMPACTS

Better preparedness for implementing EHDS,
less fragmentation on practices for secondary use of health data,
support to the European Commission in the drafting of EHDS implementing acts



TEHDAS2 deliverables from *standards* perspective

- Practical, (legally) non-binding, implementation guidance
- **How-to** reference points and **recommended practices** for EHDS2 actors
- Minimum **mandatory requirements**
- Reducing fragmentation and supporting interoperability
- Increase Member State **preparedness** for cross-border secondary use of health data
- Most documents guide **health data access bodies (HDABs)**
- Also, documents that guide **health data users** and **health data holders**

Documents being finalised just now 1/2

- Guideline for Health Data Access Bodies on **fees** and **penalties** for non-compliance related to the EHDS regulation
- Guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data (*includes **allowed** and **prohibited** use, **IPRs**, **trade secrets***)
- Guideline for data holders on **making** personal and non-personal electronic **health data available** for reuse
- Guideline for Health Data Access Bodies on the **procedures** and **formats** for data access
- **Data Access Application Management System (DAAMS)** - Technical specification for health data access bodies

Documents being finalised just now 2/2

- Guideline for Health Data Access Bodies on data **minimisation, pseudonymisation, anonymisation and synthetic data**
- Technical specification for Health Data Access Bodies on the implementation of the **common IT infrastructure**
- Technical specification for Health Data Access Bodies on the implementation of **secure processing environments**
- Guideline for Health Data Access Bodies on implementing **opt-out** from the secondary use of health data
- Guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a **significant finding** from the secondary use of health data

Documents already available on tehdas.eu

- Guideline for data holders on **data description**
- Technical specification for Health Data Access Bodies on the national **metadata catalogue**
- Guideline for data users on good **application and access practice**
- Guideline for data users on how to **use data in a secure processing environment**



Documents still to be produced (project ends on 31/12/2026)

- Guideline for Health Data Access Bodies on collaboration with other parties
- Guideline for Health Data Access Bodies on international and third country access and transfer of electronic health data
- Guideline for data enrichment for Health Data Access Bodies, data holder and data user
- Guideline for data user navigating the catalogue
- Guideline for Health Data Access Bodies on linkage of health datasets
- Draft guideline for Health Data Access Bodies on informing natural persons about the use of health data – “Citizen Information Point”
- Draft guideline for data users on handling research outcomes

Have your say! Stay updated on TEHDAS2 work!

- The next batch of TEHDAS2 draft documents to be presented in the **stakeholder event “European Health Union for a Connected Health Data Space Ecosystem”** welcome!
 - To take place in Limassol, Cyprus + online
 - Organised alongside Cypriot EU Presidency event
 - Invitations out very soon!
- **The last public consultation** will open around May–June 2026
 - Reading the documents and filling in the related web surveys on tehdas.eu/public-consultations

tehdas.eu/results

Thank you!

Follow TEHDAS2 work:

- TEHDAS2 website: tehdas.eu
- TEHDAS2 LinkedIn: [TEHDAS2 joint action](#)
- Contact TEHDAS2 coordination team: tehdascoordination@sitra.fi





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SPIDER: a tool for HDABs

David Asturiol

Programme Manager at DG JRC



SPIDER a tool for HDABs

Introduction and uses of SPIDER in EHDS

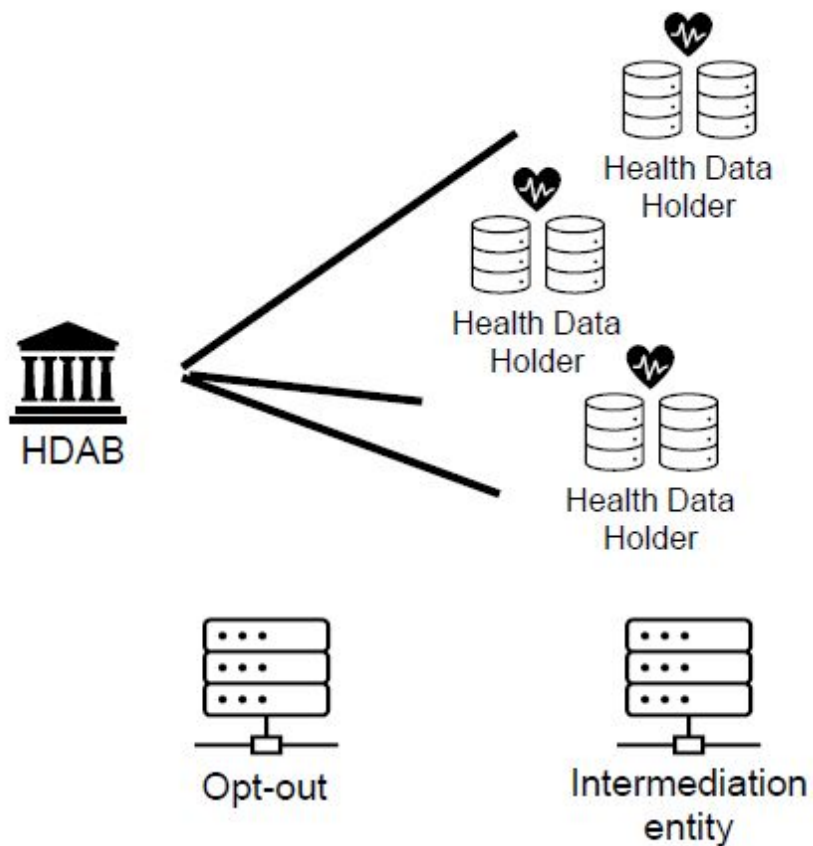


David Asturiol, PhD.

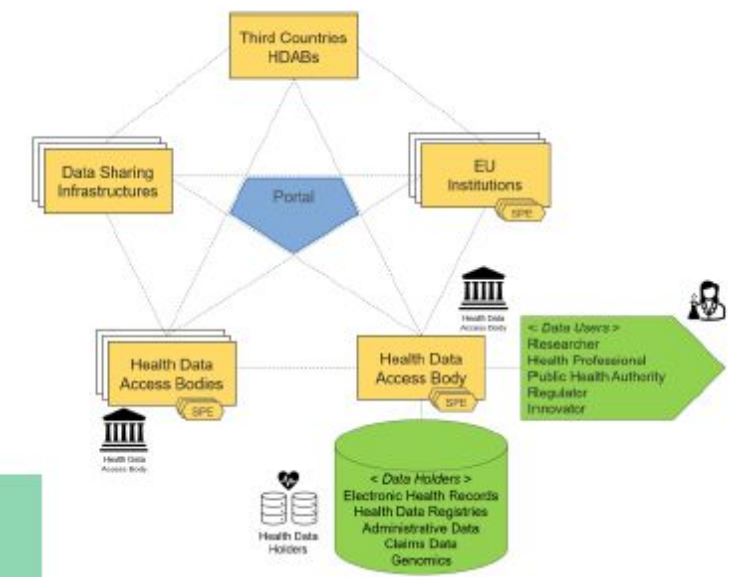
EC – JRC - Disease prevention unit (F1)

david.asturiol@ec.europa.eu





COMING SOON
2029






HOW? 

- ### HDAB's Tasks
- Pseudonymise
 - Join 2 different datasets
 - Check if patient is in a **opt-out** list






What is SPIDER

Secure Privacy-preserving Identity management in Distributed Environments for Research




- Free Software developed by EC (JRC) 
- Trusted network (local/national/international) 
- Increased privacy and security of sensitive data (e.g. health) when sharing or exchanging data 

What can SPIDER do?

Spider provides services:

- Pseudonymisation 
- Linkage of pseudonymised individuals 
- Encrypted data transfer 

Allows to:

- Find same patient in other nodes 
- Create cohorts of patients 
- Exchange data 

Pseudonymised !

End-to-end encrypted

Already in use



Perform tasks

- **Join 2 different datasets**
- Check if patient is in a **opt-out** list
- Filter out patients

Using only each
node's pseudonyms



How does linkage work?



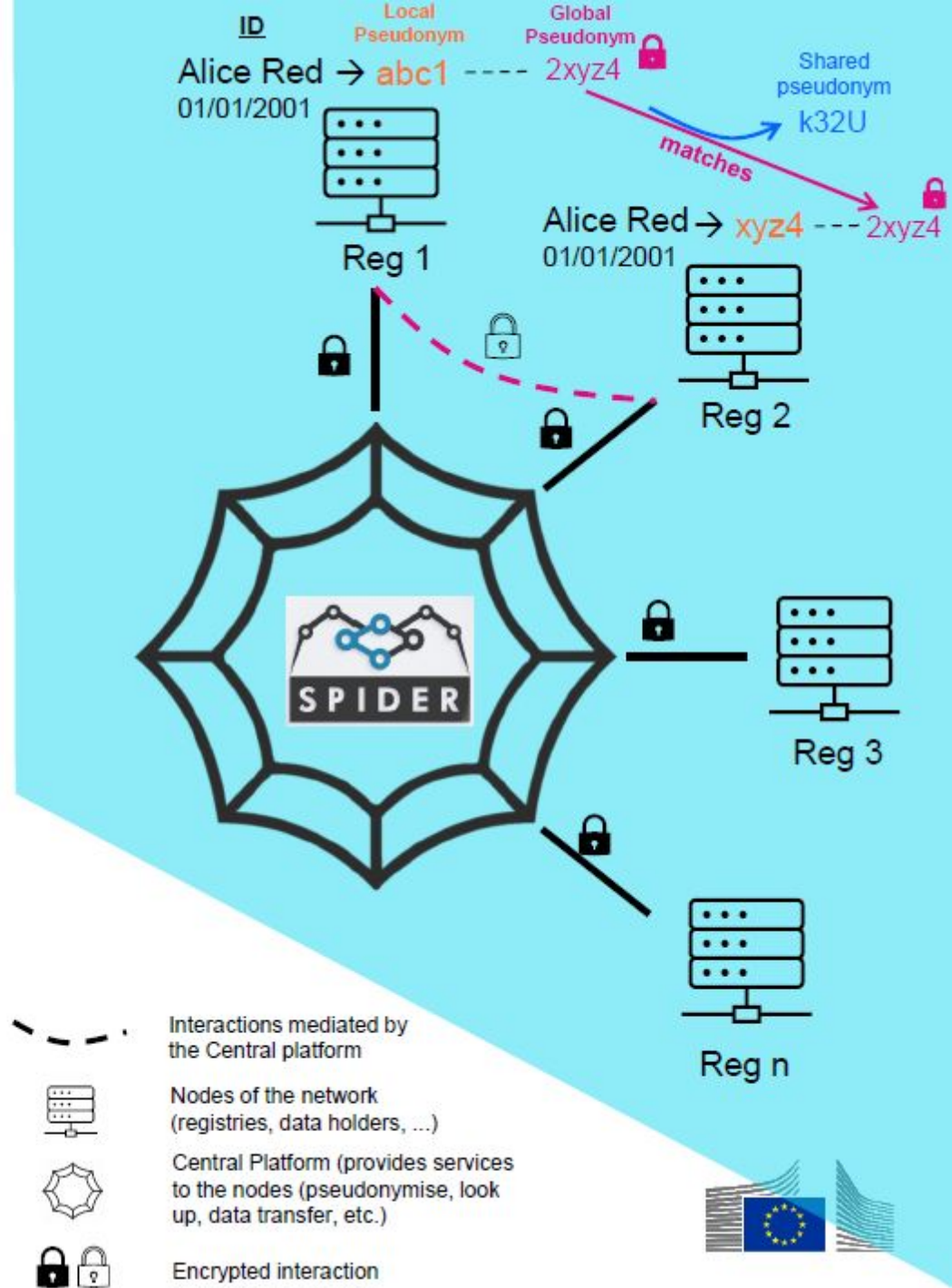
• Nodes

- Store patient data (identifiers (ID), data)
- Create encrypted key (hash) from ID (pbkdf2)
- Requests Central platform a **Local Pseudonym (LP)**
- Store relations between pseudonyms ID-LP-GP
- Submit requests to:
 - Find same patient in the network, create cohorts, share data
 - Define data access policies, metadata descriptions



• Central Platform

- Computes pseudonyms from encrypted keys (hash)
 - **Local Pseudonym (LP)**, **Global Pseudonym (GP)**, **Shared Pseudonym (SP)**
- Stores registry metadata descriptions
- Stores relation **GP** – Registry – access policy
- Looks up patients in other registries
- Authenticates and authorises access to the network
- Provides Trust Certificates (PKI)
- Provides encryption keys
- Allows end-to-end encrypted transfers



Application in EHDS

Secondary use

Data processing tasks for HDABs and/or data holders

- Anonymise/pseudonymise
- Combine datasets
- Filter out opted-out individuals
- Communicate significant findings

SPIDER could allow

1. Transfer of pseudonymised data from data holders to HDABs/intermediation entities
2. HDABs/data holders to link data from multiple datasets and data holders
3. Allows HDABs/data holders to filter out opted-out pseudonymised individuals
4. Easily delegate tasks to intermediation entities

More privacy
Higher security

Same patient,
different data holder
different pseudonyms

Patient ID &
pseudonym keys
stays with data holder

HDABs can work
without patient IDs

Simplified architecture
& workflows

HDABs can delegate
tasks to data holders

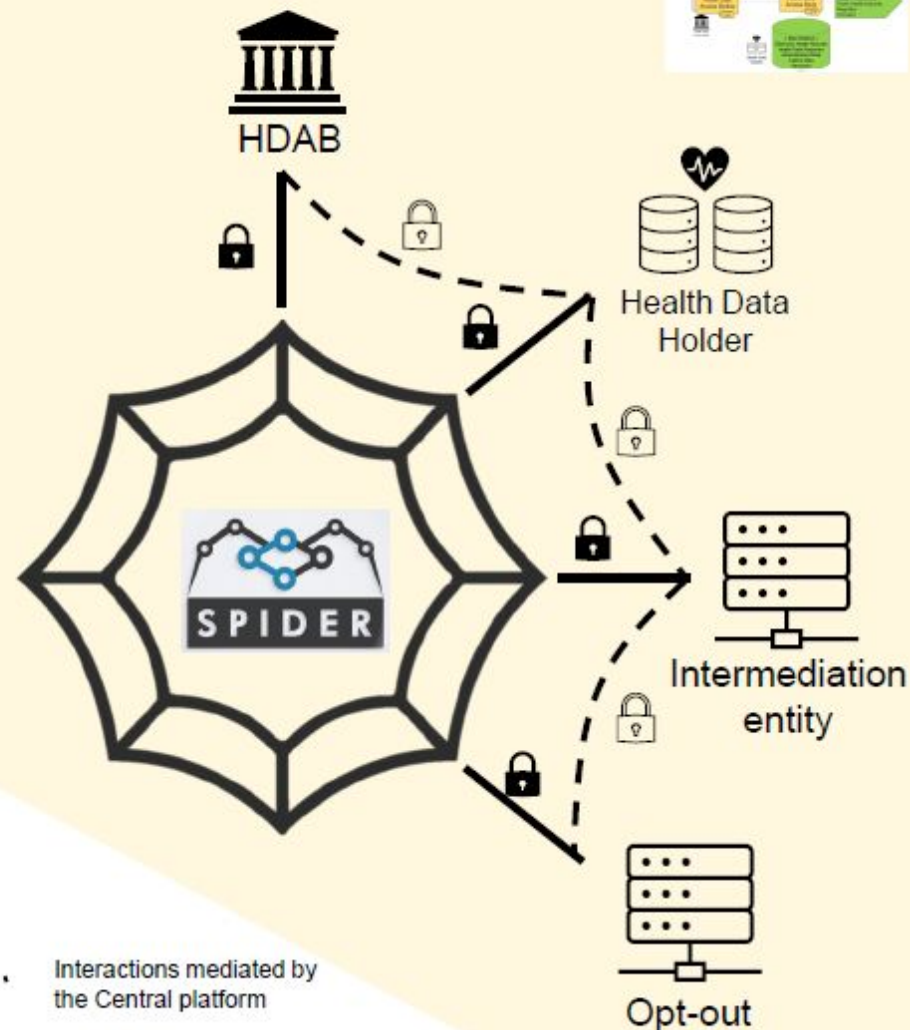
Simplifies data
request tasks

Simplifies federated
structures

Decentralised
opt-out

Better integration of
intermediation entities

Can be used in
GDPR



Interactions mediated by
the Central platform

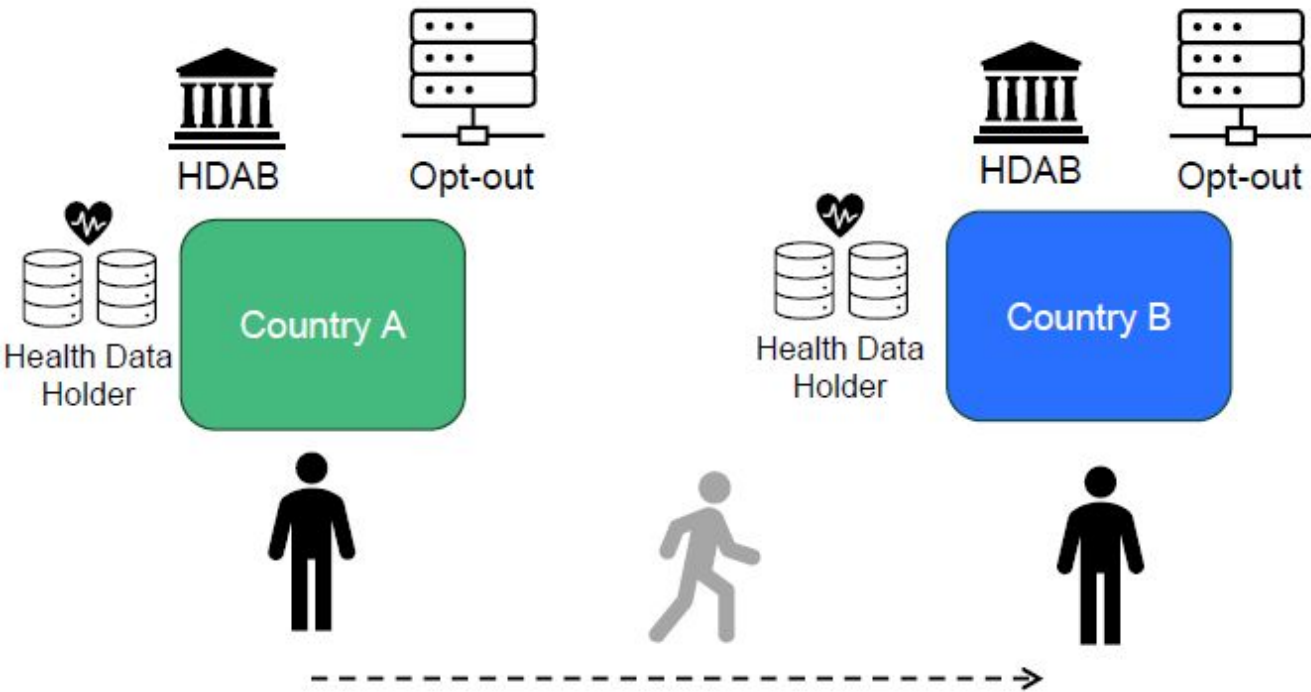
Nodes of the network (registries,
data holders, HDABs, ...)

Central Platform (provides services
to the nodes (pseudonymise, look
up, data transfer, etc.))

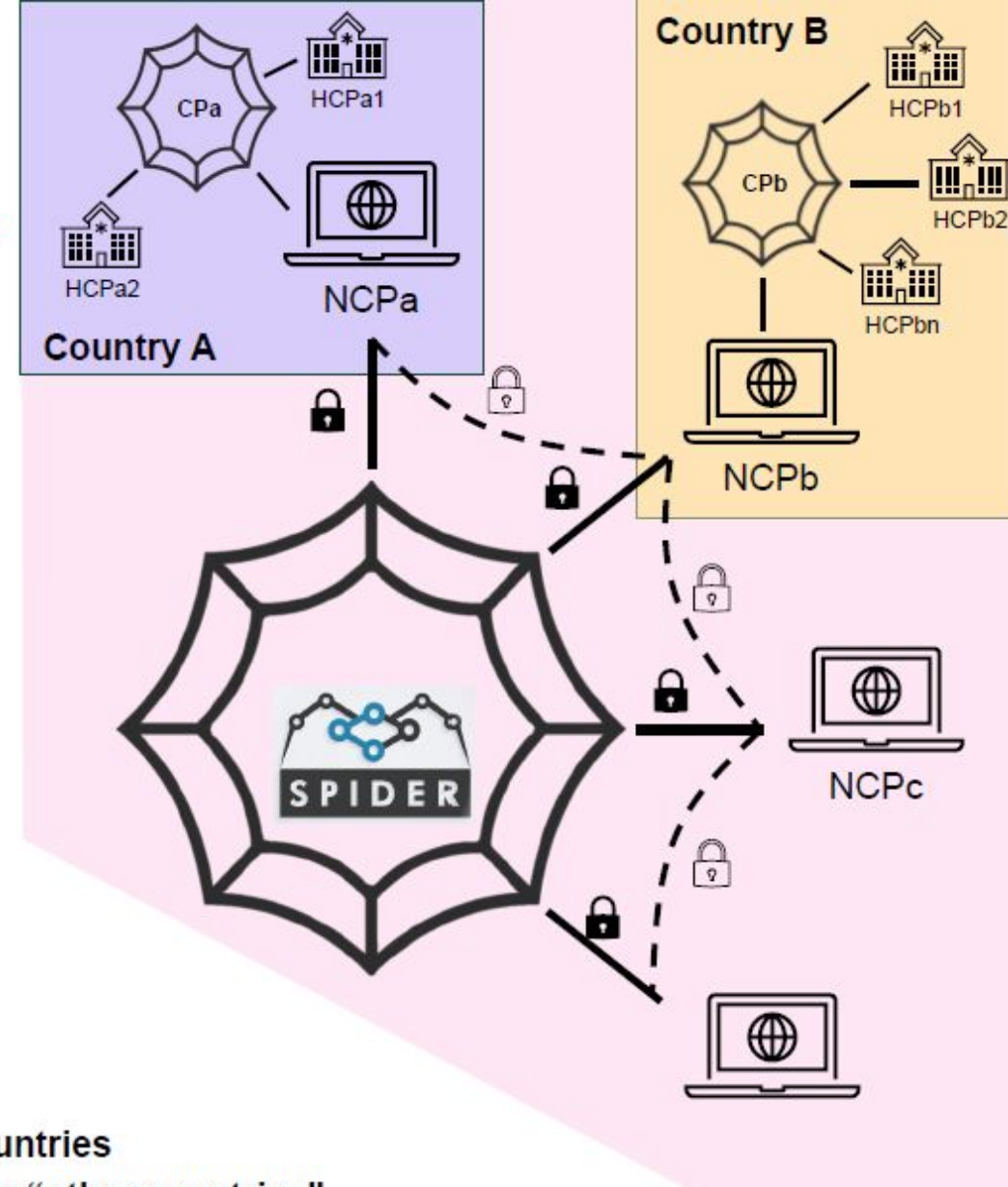
Encrypted interaction



Global opt-out?



Secondary use



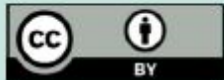
- **Citizens** will have difficulties understanding they have to opt-out in different countries
- With time, more and more data of patients used in primary care will be held in “other countries”
- **What about cross-border registries?** → patients will not even know their data is in another country
- SPIDER could solve that

SPIDER, extra info

- **Multiple instances of SPIDER** can be run by the **same system**
- **SPIDER** can be **containerised** and **decentralised**
- All **communications** within spider are **encrypted**
- SPIDER **Central Platform** manages the **users of the network**
- SPIDER **Central Platform** stores **encrypted lists of pseudonyms** (generated from hashed identifiers), cannot be linked to real patient IDs
- **SPIDER** can **match identities** in **probabilistic/deterministic** manner *
- Personal information that defines hashed ID and Global Pseudonym, can vary (e.g. “Name + surname + date birth”, “name + surname + date birth + national id”) *
- **Watch this webinar for further information**
 - <https://eu-rd-platform.jrc.ec.europa.eu/spider/>



Thank you



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IHE Profiles Supporting EHDS2

Lori Fourquet
IHE International

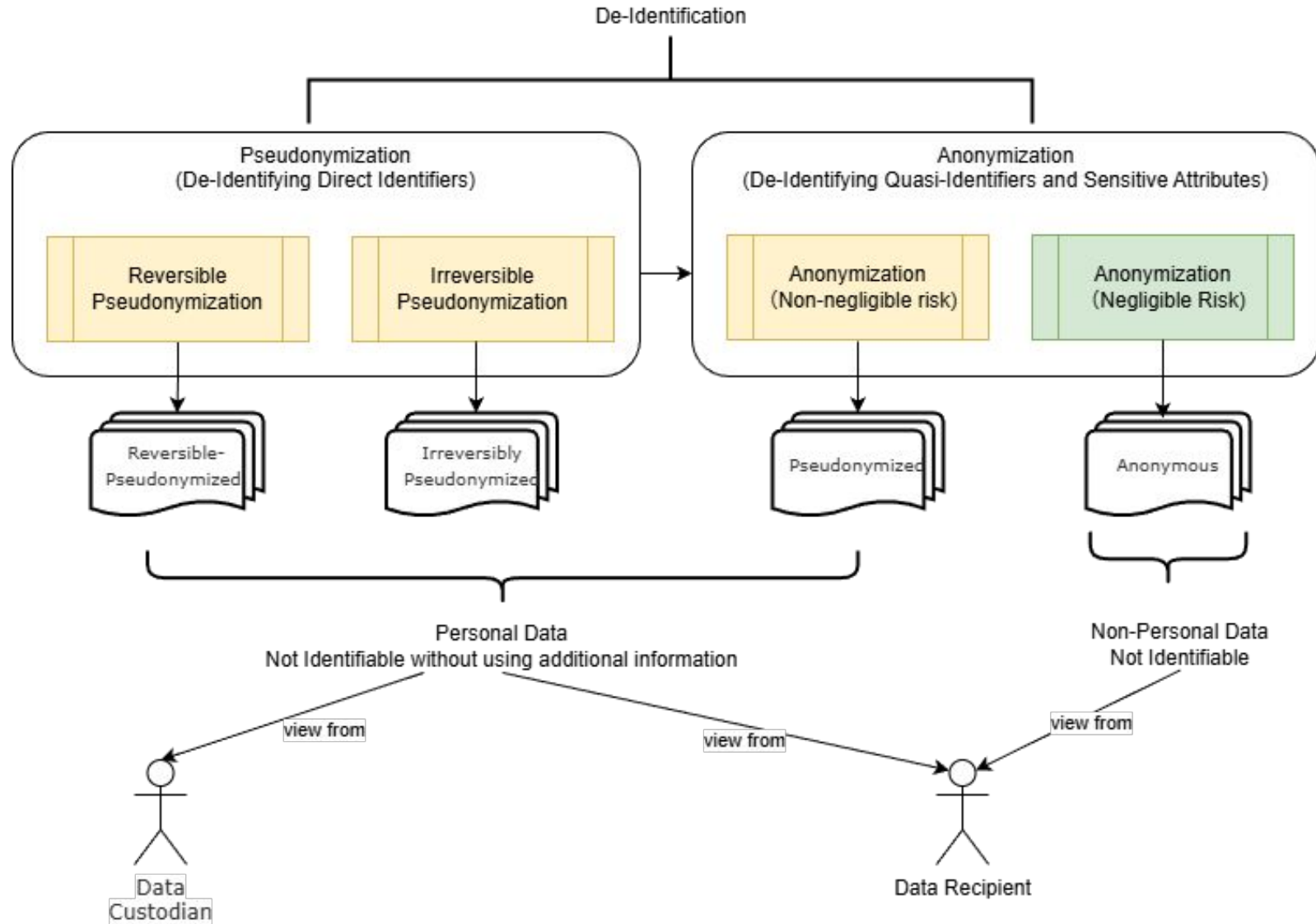


Integrating
the Healthcare
Enterprise

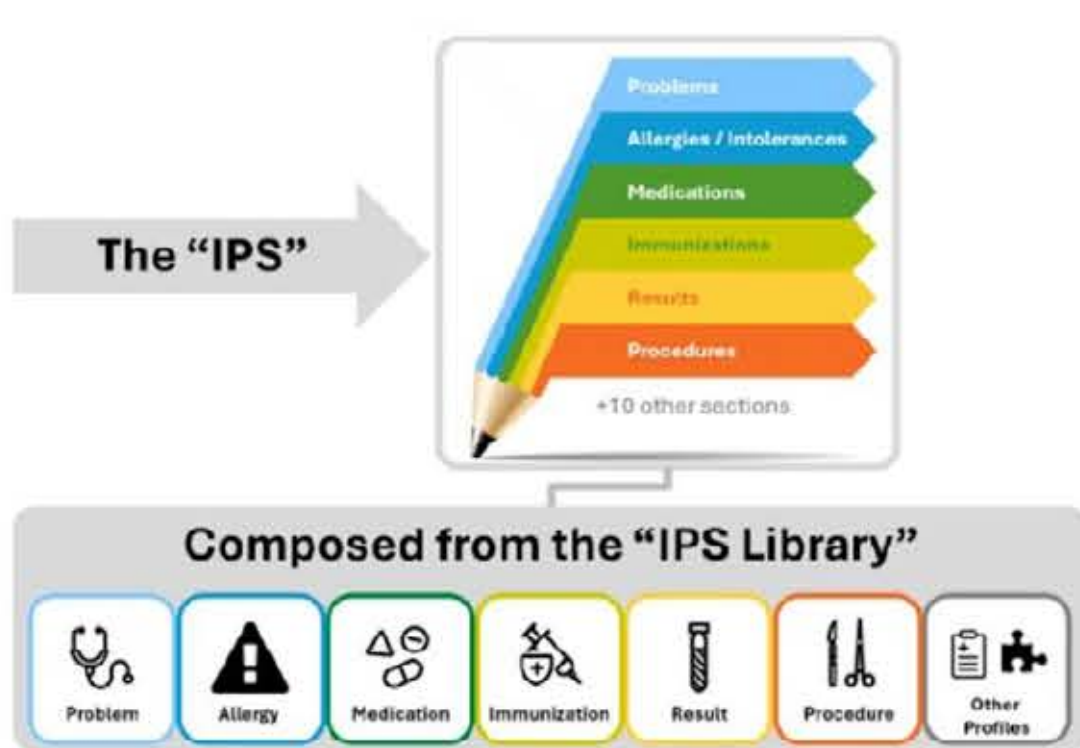



IHE Current Profiles/White Papers Identified

- De-Identification Handbook (Under revision)
 - Participated in technical updates to verify the updated content should support EHDS2 goals (as published in TEHDAS2 Public Comment Material)
 - Added an Epidemiology use case example that conforms to EHDS2 requirements
 - Targeted for 30-day Public Comment in April
- Using IHE profiles for Healthcare - Secondary Data Access (2016)
 - Reviewed for necessary updates (e.g. FHIR, additional content profiles, ITI Enhancements)
 - Change proposal submitted
 - Updates to align with newly approved work item supporting EHDS2



- Defines process of de-identification along with standard de-identification techniques. Updates to Examples in progress: Family Planning, V2, DICOM, FHIR/CDA.
- FHIR Epidemiological Example using the International Patient Summary (IPS) for standard content and Vital Records Death Reporting (VRDR) for mortality data exchange in progress (EHDS2).



IHE QRPH VRDR 

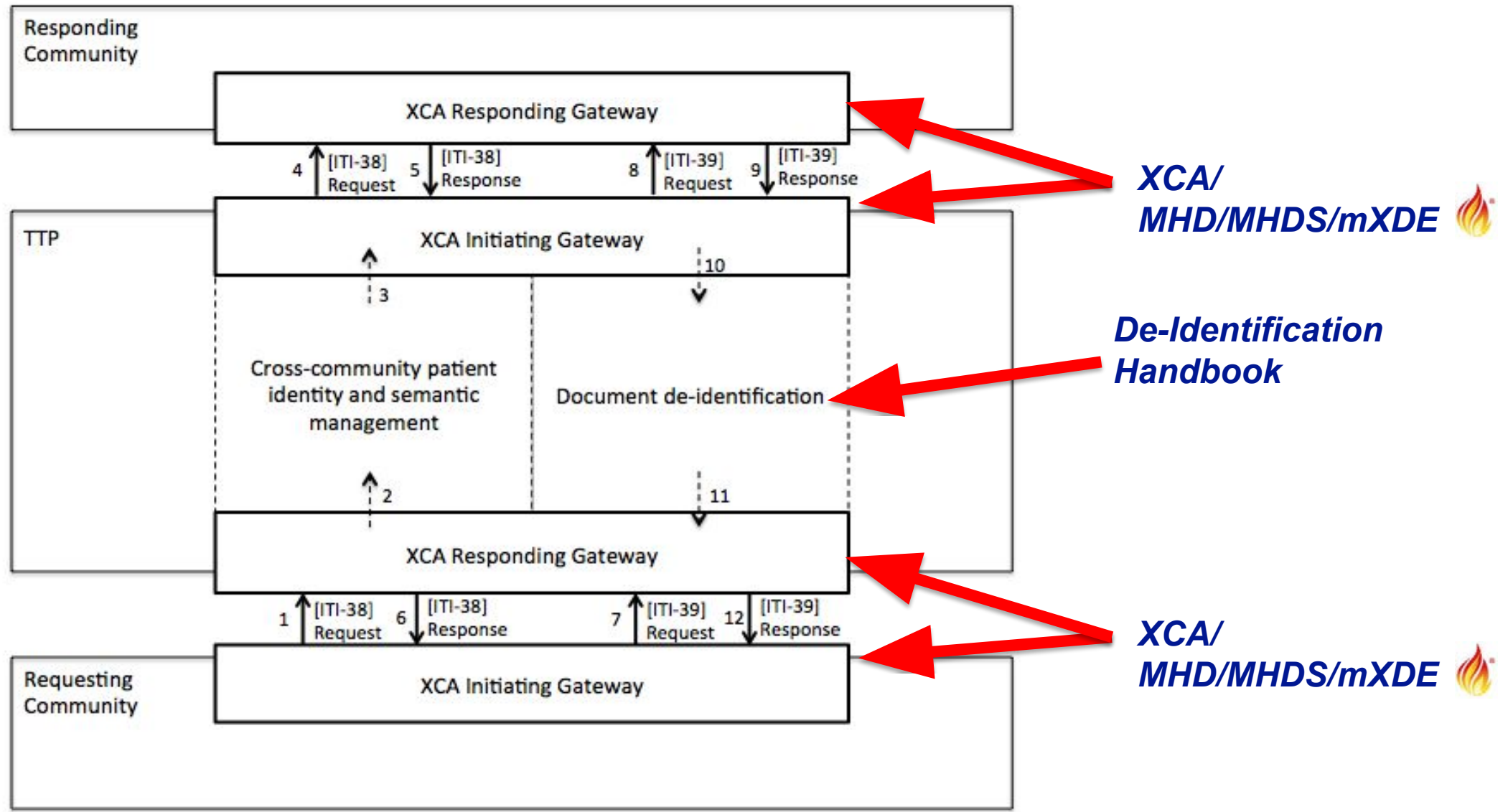
- Patient demographics
- Date of death
- Cause of death

[De-Identification Handbook Home - De-Identification Profile v0.0.1-current](#)

De-Identification Services for Secondary Use

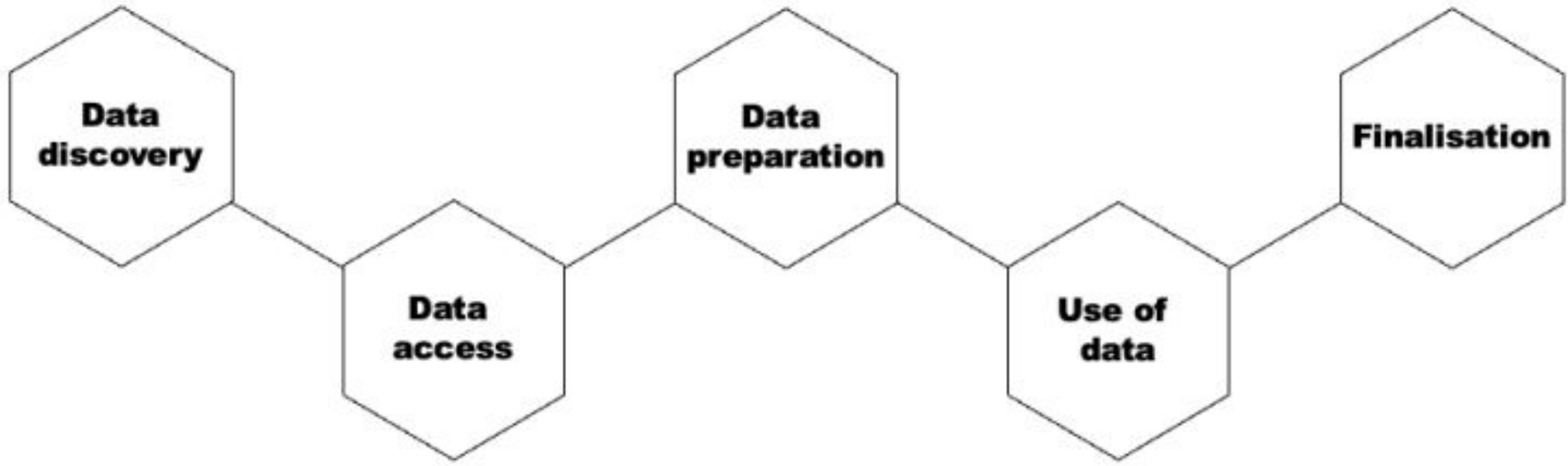
- Define interoperability actors/transactions
- Submitted to ITI
- Follows the De-Identification Handbook updates
- Hope to move forward during the April 2026 Face-to-Face
- Seeking contributors to the profile development

Using IHE profiles for Healthcare - Secondary Data Access



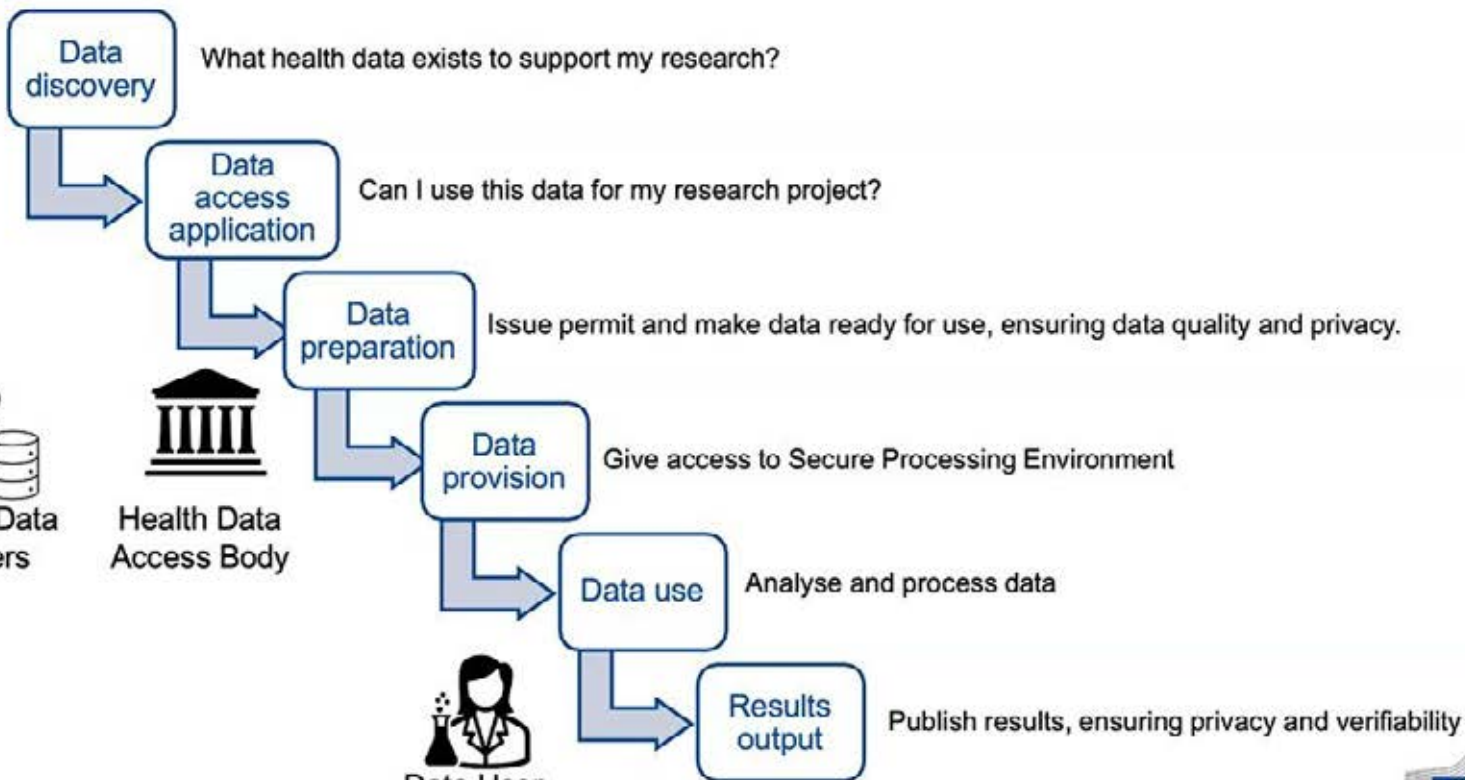
Secondary Use Data Sharing eXchange (SU-DSX)

- Expect to merge work with updates to the secondary use white paper.
- Seeking contributors/reviewers
- **UC-1 Cross-Border Research (Secondary Use)**: A research organization requests pseudonymized datasets under a governed process; data is delivered into a controlled processing environment and results are released in non-identifying form.
- **UC-2 Public Health / Policy Analytics**: A competent authority requests de-identified datasets to monitor trends and evaluate interventions, with purpose binding and full accountability.
- **UC-3 Clinical Trial / Study Support**: Study teams request and process authorized datasets under a structured protocol and permit, supporting reproducible study execution.





How can we help in the User journey?



IHE profiles supporting the user journey:

- Existing ITI profiles
- De-identification
- Catalogues management
- Linking EHDS1 and EHDS2



Defines the Query and Response requirements for FHIR data elements related to patient care

Queries for clinical data elements:

- Allergy and intolerances
- Conditions
- Diagnostic results
- Medications
- Immunizations
- Procedures,
- Encounters
- Provenance
- Observations
- Work information
 - Past or Present Job (Occupation, Industry)
 - Usual Work (Occupation, Industry)
 - Employment Status
 - Retirement Date
 - Combat Zone Period

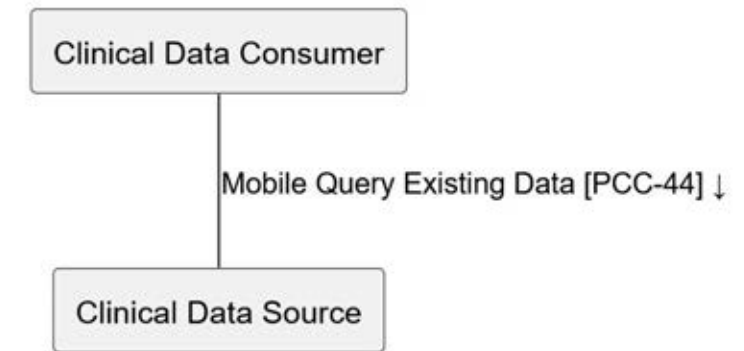
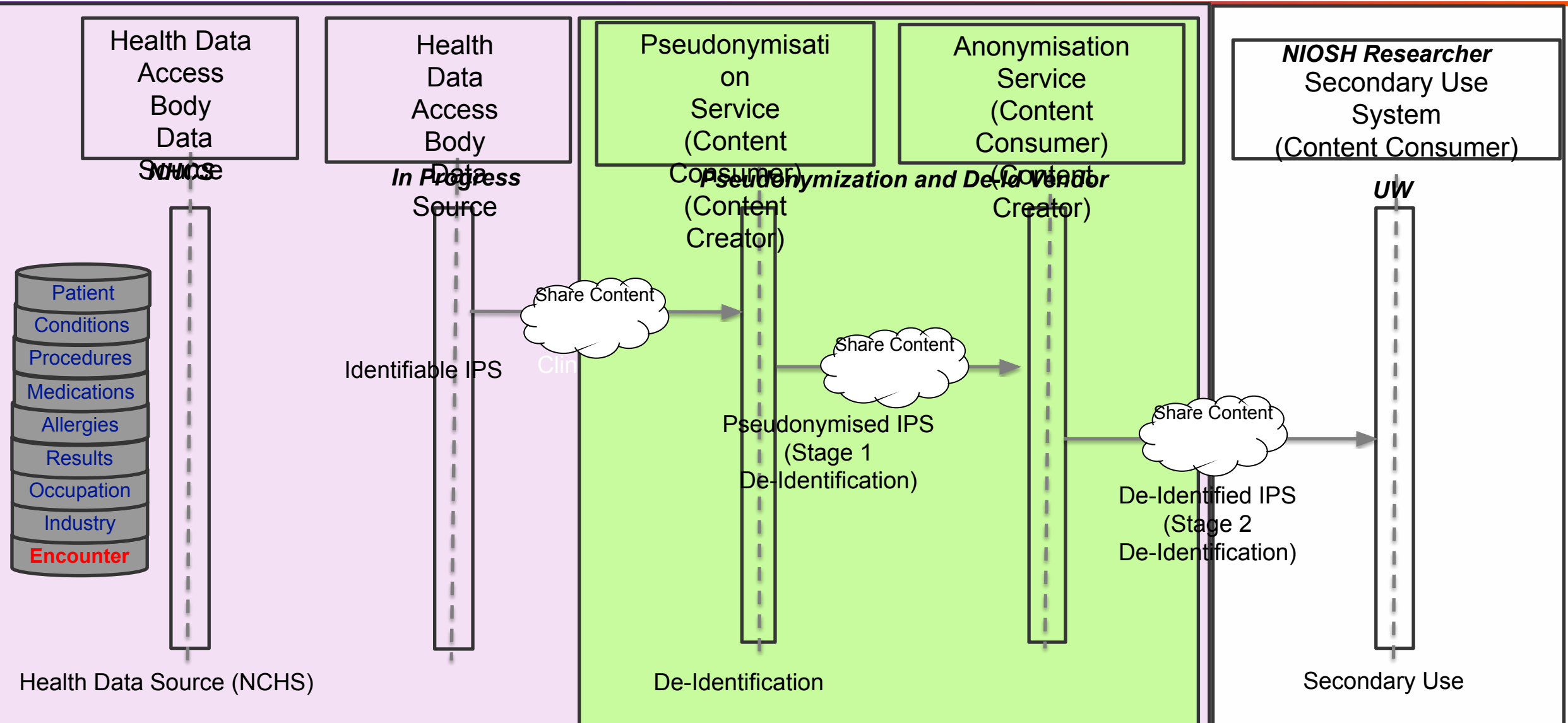


Figure: 1:18.1-1: QEDm Actor Diagram

<https://profiles.ihe.net/PCC/QEDm/index.html>

Secondary Use (Public Health) Projectathon Sketch – Reuse of Common Secondary Use Approaches



NIOSH Researcher accesses De-Identified HCS Data



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Vienna Workshop 2025 Outcomes



Full Report

Stefan Sauermann

Vice Rector UAS Technikum Wien, IHE Austria Founding Member



- **Research Infrastructures**
- **Research and Innovation Actions**

- **Regulators (EC and national)**

- **Standardization development community**

- **Developers**
- **Experts**

Standardisation for secondary use follows a different dynamic than primary use

Primary Use (1U)

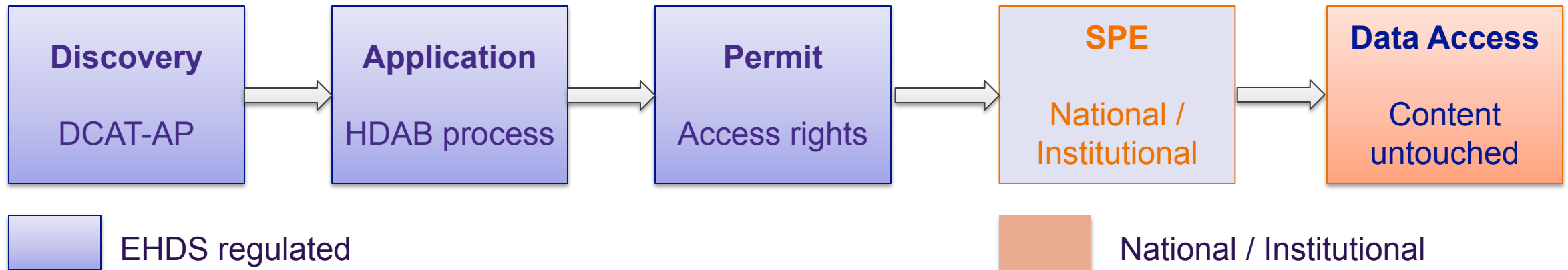
- Converging towards normative standards
- Interoperability as clinical necessity
- Mature, testable patterns (HL7 FHIR, EEHRxF, IHE profiling)

Secondary Use (2U)

- Diverse, use-case driven choices
- Flexibility accommodated and required
- Standards decided per research question

Vienna workshop in June 2025: testing this hypothesis with the community

EHDS 2U provides access framework but does not prescribe data standards



Key observation:

The only normative “data” standard for 2U so far is metadata (DCAT-AP). Information models, data residency, SPE design remain outside EU-level prescription. This is a deliberate regulatory choice.

Four thematic tables, each surfacing distinct standardisation challenges:

1. Secure Processing Environments

Interoperability is complex; permit enforceability unclear; federated vs centralised models coexist

2. Data Quality & Provenance

Fit-for-use (holder) \neq fit-for-purpose (user); provenance documentation varies widely

3. Datasets for Secondary Use

No single semantic standard prescribed; OMOP, FHIR, DICOM used per use case

4. SDO Roles in Profiling

Coordination needed at boundaries; IHE methodology can bridge testing and governance

Note: This grouping was our starting structure. Real-world practice may organise these challenges differently.

Standards choices today happen at institutional or research-group level, not through EU-wide prescription.

What we observe:

- Large initiatives converge organically (e.g. DARWIN EU → OMOP CDM)
- TEHDAS builds on EOSC Entrust, SATRE
- National decisions vary (e.g. GÖG's use of FHIR for specific use case)

Our hypothesis:

- Coordination could surface where normative decisions add value
- IHE methodology can profile different use cases with different standards
- Value must be demonstrated, not assumed

This requires considerably deeper investigation with broader community input.

Health care (1U)

- Patients are individuals
- Data arrives when it arrives
- „I“ am happy if „I“ understand where the data came from
- "Great, I have a diagnose!
We can plan your treatment."



Research (2U) – Clinical Trials

- Subjects meet inclusion criteria
- We collect data at well defined times
- We must demonstrate data provenance at all times to auditors
- "The treatment A resulted in a significant increase of Z ..."

Which questions might 1U data answer soon?

Which study designs suggest themselves?

Might we generate evidence about benefits, addressing critical needs?

IHE De-identification Handbook

- Being updated to align with EHDS data preparation needs
- Epidemiological use case developed using IPS and VRDR formats
- Public comment opening soon

IHE QRPH White Paper Update

- "Using IHE Profiles for Healthcare Secondary Data Access"
- Being revised to incorporate European priorities and EHDS considerations
- EU stakeholders invited to contribute

These are international work examples to be considered for the EHDS realm

IHE methodology provides profiling and testing processes that can translate policy requirements into implementable, testable specifications — credible conformance evidence for EHDS governance.

Limitations

- The workshop brought diverse initiatives together but could not capture all perspectives
- The 2U community is broad — especially in research and academia
- Our findings remain indicative, not conclusive

This is why we iterate

- Brussels (March 2026) is the next milestone
- Broader stakeholder engagement needed
- Your comments from this webinar will add to the agenda

Download the Full Report

Vienna Workshop Summary: EHDS Secondary Use Standardisation

Contributors acknowledged in full



Table 1 — Good Data Practice for Vendors and Innovators

Hosts: Tim Jongen, John Brennan

Table 2 — Secure Processing Environments

Hosts: Irini Kessissoglou, Dmitry Etin

Table 3 — Standards Coordination and Profiling

Hosts: Lori Fourquet, Stefan Sauermann

Table 4 — Governing “Code Meets Data” in the EHDS

Host: Nienke Schutte

What we tackled. How to turn EHDS data from available to usable across standards, secure processing environments, interoperability and governance regimes.

What we found. Three gaps to close: standardization (use case-specific), trust (certification beyond audits) and operations (tools, workflows, incentives).

What's next. We're writing up these insights into a shared report and we would love your input.

Join us to help build the path forward together, drop us a line:

