IHE EUROPE CONNECTATHON

BRUSSELS 2026 MARCH 23/27

Introduction to Interoperability in EHDS Secondary Use Workshop

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Guidelines for the Webinar

- Please keep your microphone muted
- Questions during the session?

  Please use the chat box. We will address the questions in the second part of the webinar
- Slides will be available on IHE-Europe Connectathon 2026 webpage
- After the webinar, you can find the recording in IHE-Europe YouTube channel

Agenda

Speakers:

Dmitry Etin, Health Data Interoperability & Governance Advisor, Austria

Fidelia Cascini, Chair of the EHDS2 Community of Practice

Stefan Sauermann, Vice Rector UAS Technikum Wien, IHE Austria Founding Member

Agenda:

- Welcome & Housekeeping
- Vienna Secondary Use workshop: motivation and setting
- National & Community perspectives on secondary use
- Key outcomes of the Vienna workshop
- From Vienna to Brussels: next steps
- Q&A session

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Why did we run the EHDS2 workshop in Vienna

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Stefan Sauermann,
IHE Austria

a word from Austria

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Community perspectives on secondary use

Fidelia Cascini

Chair of the EHDS2 Community of Practice

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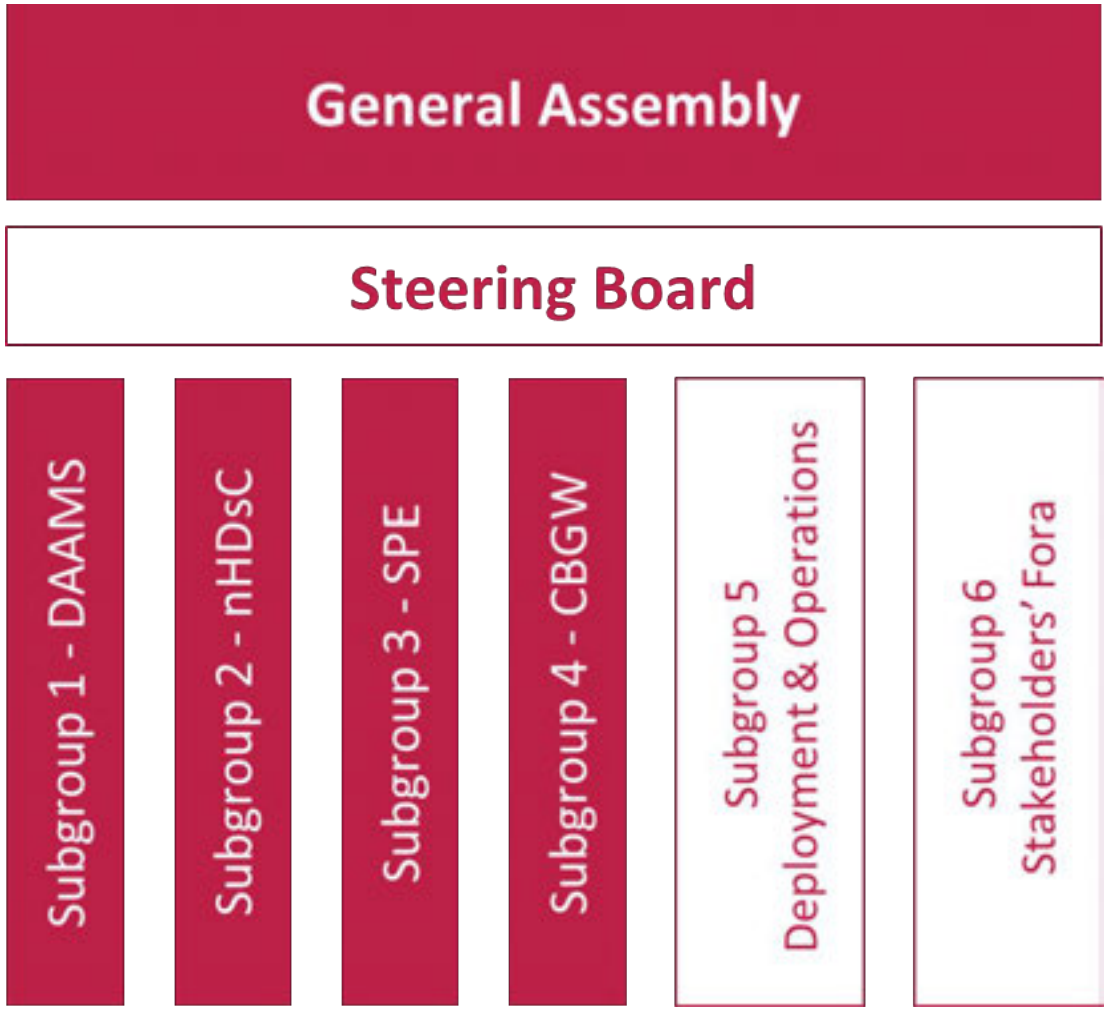
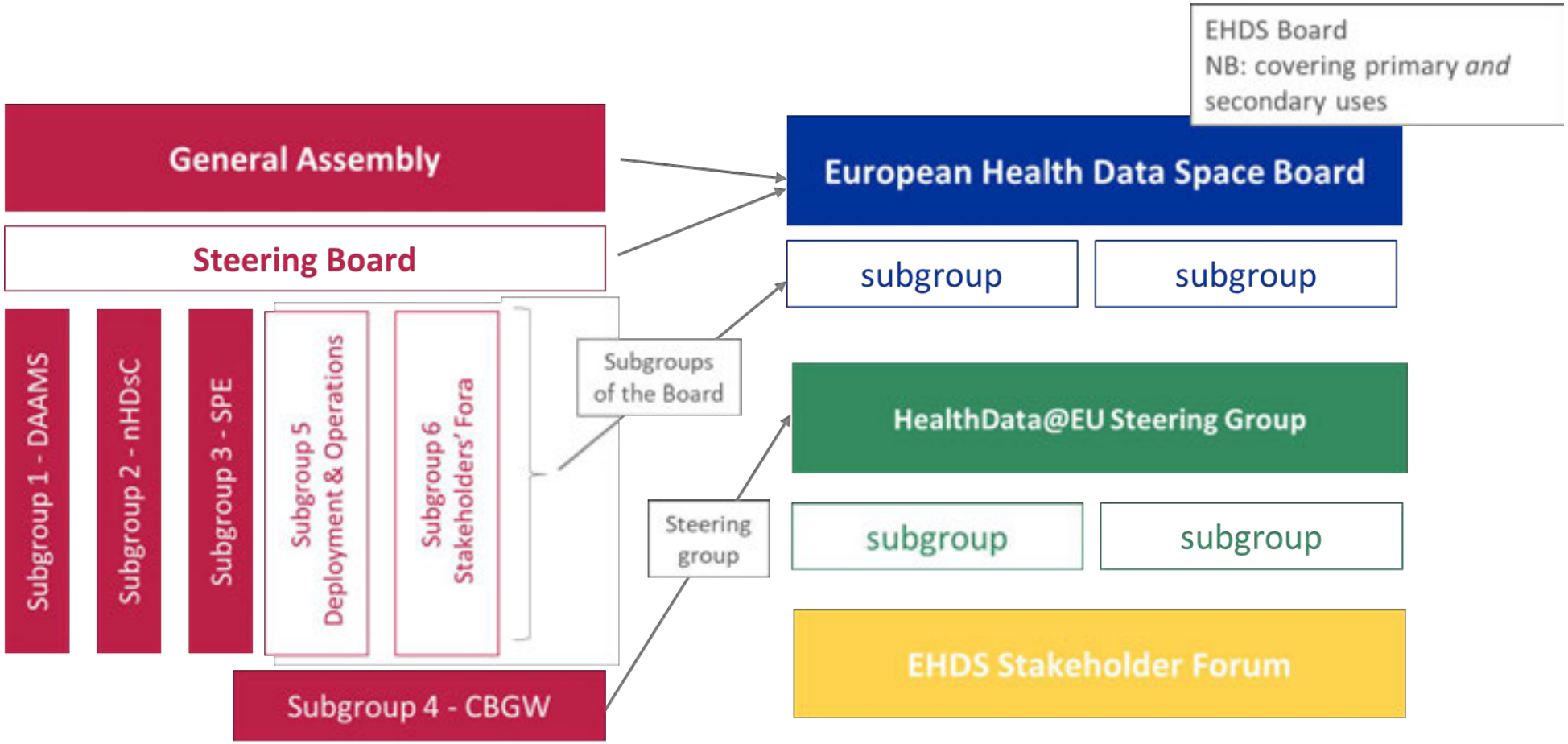
- Support MSs in **setting up Health Data Access Bodies (HDABs)**

- Provide a structured platform to exchange information, align approaches, and ensure coherent design, implementation, piloting, and transition **to build secondary-use within the EHDS framework**

- Health Data Access Application and Management Systems
- Health Datasets Metadata Catalogue and Data Quality and Utility
- Secure Processing Environments
- Cross-border Gateways HealthData@EU services



Transition from CoP to the EHDS Board



HDABs - Work in progress

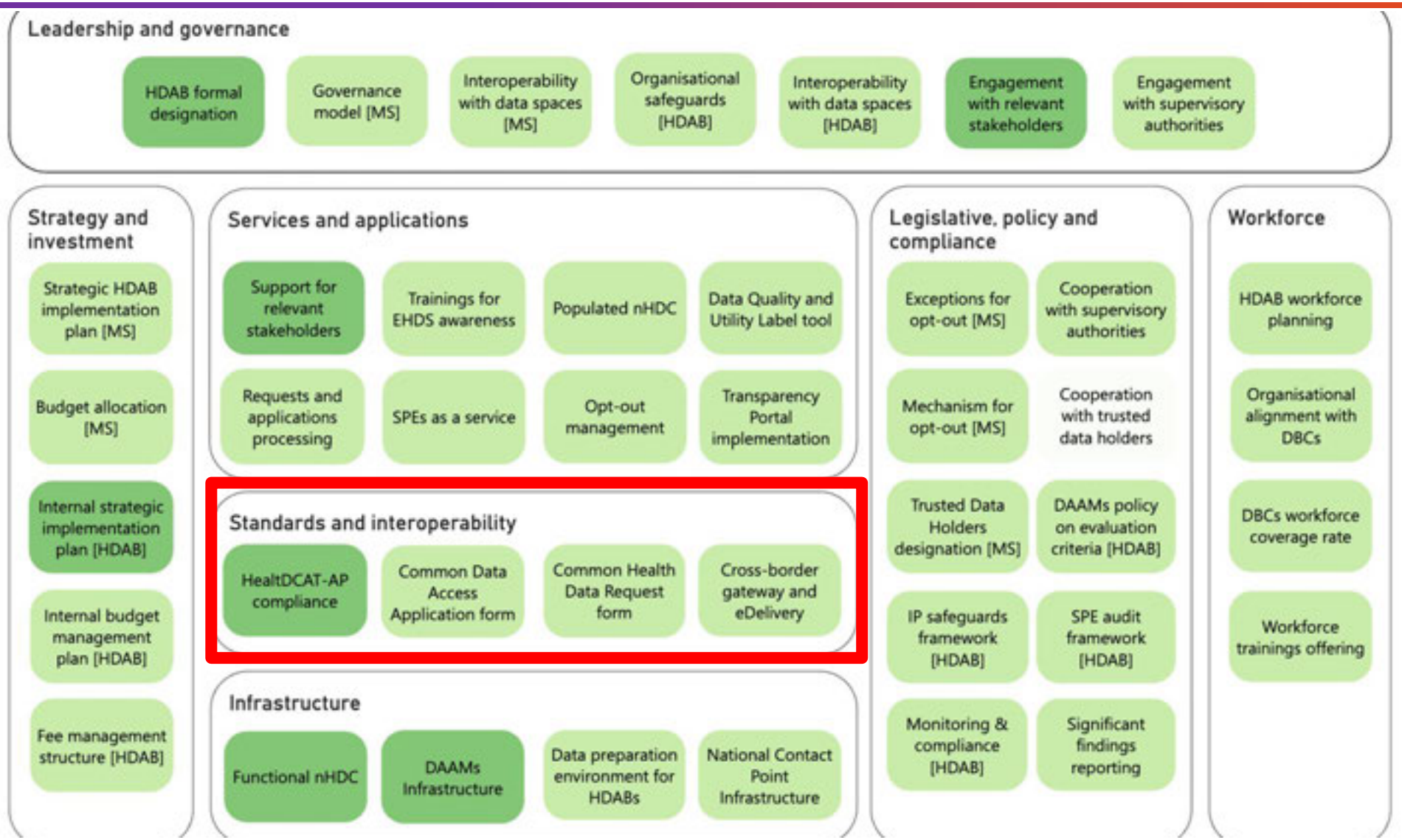
Challenges/Experiences

- National implementation of EHDS2 in progress
- Large majority of MSs at an early stage

Measures of efficiency/competitiveness

- Health Data Access Body capacity
- Approval timelines
- Transparency mechanisms
- Data harmonization capacity

HDAB Maturity Model – current framework



EHDS2 Health Data Categories

electronic health data from **EHRs**;

healthcare-related **administrative data**, including dispensation, claims and **reimbursement** data

human **genetic, epigenomic and genomic** data;

other **human molecular** data such as proteomic transcriptomic, metabolomic, lipidomic and other omic data;

automatically generated personal electronic health data, through **medical devices**;

data from **wellness applications**;

other health data from medical devices.

Data on factors impacting health, including **socio-economic, environmental and behavioural determinants** of health;

Aggregated data on **healthcare needs**, **resources** allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;

Pathogen data, impacting on human health

population-based health data **registries** (public health registries);

data from medical registries and **mortality registries**;

data from registries for medicinal products and medical devices;

health data from **biobanks** and associated databases.

data from **clinical trials**, **clinical studies** and clinical investigations subject to Regulation (EU) 536/2014, Regulation [SOHO], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively;

data from **research cohorts, questionnaires** and surveys related to health, after the first publication of results

Permitted purposes

- **Public interest in the area of public and occupational health**
- **Policy making and regulatory activities**
- **Statistics**

- **education or teaching activities**
- **Scientific research** including:
  - development and innovation activities for products or services;
  - training, testing and evaluating of algorithms, including in medical devices, in-vitro diagnostic medical devices, AI systems and digital health applications ;
- **improving delivery of care, treatment optimization**

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Workshop Outcomes

Dmitry Etin

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Workshop composition

- Research Infrastructures
- Research and Innovation Actions

- Regulators (EC and national)

- Standardization development community

- Developers
- Experts

Starting Hypothesis

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)

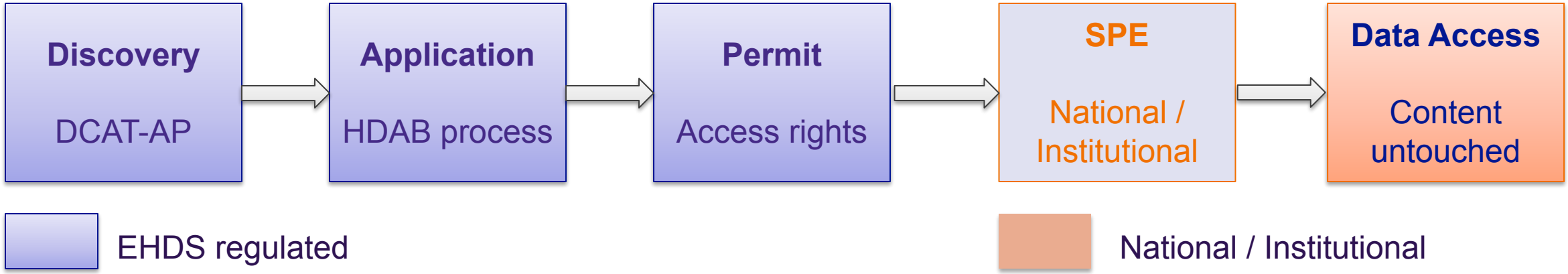
Secondary Use (2U)

- 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

The Data Journey: Where EHDS Regulates

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.

What the Workshop Validated

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) ≠ 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.

Current Reality: How 2U Standards Decisions Happen

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.

Work You Can Engage With

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.

What We Acknowledge

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

Venue for 2026 Interoperability in EHDS Secondary Use Workshop

During the IHE-Europe Connectathon Week 2026

Thursday, 26 March 2026

14:00 - 17:00

Where?

The EGG, Rue Bara 175, 1070 Brussels

About a 10-minute walk from Brussels-South Station (Gare du Midi)

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Questions?

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Thank you for your attention

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