

# IHE-EUROPE CONNECTATHON 2025: WORKSHOP ON EHDS SECONDARY USE STANDARDIZATION

## Workshop Summary Report

*Vienna, 12 February 2026*

## Introduction

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The IHE-Europe Connectathon 2025 took place in Vienna, Austria from 23 to 27 June 2025 and included a dedicated workshop session focused on standardization challenges for the secondary use of health data within the European Health Data Space (EHDS). The workshop was co-moderated by Dmitry Etin and Juergen Brandstätter and brought together representatives from major European initiatives including TEHDAS2, QUANTUM, EUCAIM, GDI, EOSC Entrust, IDERHA, as well as experts from Member States involved in EHDS Direct Grants execution. The European Commission's DG SANTE was represented by Fulvia Raffaelli (Unit C3), who provided valuable policy context and feedback throughout the discussions. Fidelia Cascini, chair of the EHDS Secondary Use Community of Practice, contributed perspectives from the research and public health communities.

The workshop was structured around four thematic tables, each led by a domain expert, to explore different dimensions of secondary use standardization:

**Table 1:** Standardizing Secure Processing Environments, led by Marcel Klötgen

**Table 2:** Standardizing Data Quality and Provenance, led by Enrique Bernal Delgado

**Table 3:** Standardizing Datasets for Secondary Use, led by Lorenz Dolanski-Aghamanoukjan

**Table 4:** Role of Standards Development Organizations in Profiling Secondary Use, led by Lori Fourquet

## Discussion Scope and Key Observations

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The workshop discussions revealed a landscape significantly different from primary use standardization. Participants observed that secondary use is characterized by considerable diversity in standards adoption, driven primarily by specific use cases and research requirements rather than by universal interoperability mandates. This diversity spans multiple layers:

**Data standards:** Participants questioned which semantic and syntactic standards (such as OMOP, HL7 FHIR, DICOM, or others) are most appropriate for different types of research and federated environments. The choice often depends on the research question rather than on a single "correct" standard.

**Process standards:** Discussions at the Secure Processing Environments table highlighted the administrative and resource burden of establishing compliant SPEs and explored which use case classes (such as federated analysis or federated learning) require human interaction versus automated handling. Questions were raised about permit orchestration, whether at national or data source level, and about the role of Health Data Access Bodies in the workflow.

**Infrastructure standards:** The group examined which standards for workflow execution and task orchestration (such as GA4GH for automated workflows or IHE XDW for human interactions) are most suitable for federated SPE environments.

The Data Quality and Provenance table mapped standards against the EHDS data lifecycle, identifying where communication, semantic and discovery standards intersect and how SPEs might connect primary and secondary data use. A recurring theme was the expectation towards data holders to make datasets more attractive for reuse by providing robust documentation on data provenance and standardized metadata, while acknowledging that ultimate fitness for purpose depends on the specific research needs.

The discussions made clear that, unlike primary use where interoperability is a clinical necessity, secondary use accommodates and even requires flexibility. Research communities use what is needed according to their research questions. This presents both a challenge and an opportunity: the challenge of ensuring cross-border reproducibility, including consistent data preparation as datasets move from data holders to (secure) processing environments and portability of analytical methods across those environments, without imposing rigid uniformity, and the opportunity to identify where targeted coordination and profiling can add the most value.

## Ongoing IHE Work Supporting Secondary Use

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The workshop also highlighted IHE's ongoing international efforts to support secondary use through profiling and testing. Two initiatives were identified as particularly relevant:

The IHE IT Infrastructure (ITI) De-Identification Handbook is being updated to align with EHDS2 data preparation needs. Lori Fourquet proposed developing a concrete de-identification use case that would serve both as an example for the handbook and as a profile supporting EHDS requirements. Once work is completed for the handbook, IHE ITI will use the handbook as a foundation for a profile that has been proposed for De-Identification Services for Secondary Use.

The IHE Quality, Research and Public Health (QRPH) white paper "Using IHE profiles for Healthcare - Secondary Data Access" is being revised to incorporate European priorities and EHDS2 considerations. EU stakeholders have been invited to contribute to this update, ensuring that the document reflects current implementation needs.

These efforts demonstrate that IHE, as a methodology for profiling and testing, can provide a practical platform for translating policy requirements into implementable and testable specifications. IHE profiles and testing results can serve as credible conformance evidence for EHDS governance structures, including the EHDS Board, implementing acts and national Health Data Access Bodies.

## Outcomes and Next Steps

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The Vienna workshop exposed the breadth and diversity of the secondary use community and the range of standards currently in play. Rather than attempting to create new standards or meta-standards, participants recognized the need for better coordination and profiling of existing standards at the interfaces where different systems and approaches meet. However, achieving this coordination requires input from a broader set of stakeholders representing different use cases, implementation experiences and national contexts.

Following the Vienna discussions, the initiative group held several online meetings in September and October 2025 to reflect on the workshop findings and plan next steps. The group concluded that deeper engagement with practitioners who have real-world implementation experience is essential before proposing concrete coordination mechanisms. Specific examples demonstrating the consequences of lacking coordination frameworks were identified as critical to making a compelling case for action.

Key themes that emerged from the post-workshop discussions include the distinction between "fit for use" on the data holder side (a concept promoted by EHDS policy) and "fit for purpose" (the practical determination by researchers of whether a dataset meets their specific needs). Alexander Deggelseggler raised a need for more practical, connectathon-like workshops to allow data holders and data users stress-test HealthData@EU infrastructure, metadata and labeling specification with real-world use-cases. Enrique Bernal Delgado emphasized the need to explore how to enhance mobilisation of primary data towards secondary use, recognising that different types of primary data may face distinct legal, ethical, semantic, organisational and technological requirements. Stefan Sauermann noted that EHDS, for the first time, brings primary and secondary use together under a shared framework, and suggested that IHE profiles could help formalise these transitions. However, he emphasised that secondary use introduces organisational and provenance challenges requiring collaboration beyond purely technical measures. Fidelia Cascini stressed the importance of exploring and analysing concrete real-world examples in the Secondary Use to pin-point the gaps in coordination and interoperability.

The group agreed to use the next IHE-Europe Connectathon, scheduled for March 2026 in Brussels, as a key milestone to engage additional stakeholders and gather more diverse perspectives. The Brussels event will provide an opportunity for practitioners, vendors, policy makers and researchers to contribute their experiences and help shape pragmatic approaches to secondary use standardization.

## Invitation to the Community

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The diversity of the EHDS2 and broader secondary use community is both a strength and a challenge. It reflects the varied purposes for which health data can be reused, from pharmacoepidemiology to policy evaluation to multi-modal population research. Addressing this diversity requires more stakeholders around the table to identify challenges, share implementation experiences and find practical balance among the many standards in use.

IHE invites members of the secondary use community, including data holders, researchers, technology vendors, standards development organizations and policy implementers, to continue this dialogue at the IHE-Europe Connectathon in Brussels in March 2026. Bringing diverse use cases and real-world experience to the discussion will be essential for developing profiles and coordination approaches that genuinely serve the needs of cross-border secondary use under EHDS.

## Acknowledgments

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Following the Vienna workshop, the initiative group held several online meetings in September and October 2025 to further develop the workshop findings. The organisers wish to thank all participants in these post-workshop discussions for their valuable contributions: Enrique Bernal-Delgado (Institute for Health Sciences in Aragon, representing QUANTUM and EUCAIM), Juergen Brandstätter (IHE-Europe), Stefan Buttigieg (Ministry for Health, Malta, Manager of the National Contact Point for eHealth), Fidelia Cascini (Università Cattolica del Sacro Cuore, Chair of the Steering Board of the EHDS Secondary Use Community of Practice), Alexander Degelsegger-Márquez (Head of Department, Gesundheit Österreich GmbH), Lori Fourquet (IHE International), Marcel Klötgen (Fraunhofer ISST, representing IDERHA and EOSC initiatives), and Stefan Sauermann (University of Applied Sciences Technikum Wien, founding member of IHE Austria).

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