IHE-EUROPE CONNECTATHON 2026: WORKSHOP ON INTEROPERABILITY IN EHDS SECONDARY USE — BRINGING UP COMMUNITY PRACTICES AND NEEDS FOR COORDINATION

Workshop Summary Report

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Introduction

The IHE-Europe Connectathon 2026 took place in Brussels, Belgium, and included a dedicated workshop session on the secondary use of health data within the European Health Data Space (EHDS), held under the theme "Bringing up community practices and needs for coordination". Building directly on the discussions of the Vienna workshop in June 2025 and the online meetings that followed, the Brussels session brought together data holders and data users connecting vendors, industry innovators, standards development experts, policy implementers and researchers to translate EHDS policy ambitions into practical approaches. The workshop was co-moderated by Dmitry Etin and Stefan Sauermann, with Fidelia Cascini, chair of the EHDS Secondary Use Community of Practice, as an observer and contributor to the discussions.

The Brussels session continued the initiative group's deliberate effort to engage practitioners with real-world implementation experience before proposing concrete coordination mechanisms. Where Vienna set out to map the landscape of secondary use standardization, Brussels set out to listen — to bring different voices to each table and observe how the community responded to them. The session was structured around four thematic tables:

Table 1: Good Data Practice for Vendors and Innovators, led by Tim Jongen and Fidelia Cascini.

Table 2: Secure Processing Environments, led by Irini Kessissoglou and supported by Dmitry Etin.

Table 3: Standards Coordination and Profiling, led by Lori Fourquet and Stefan Sauermann.

Table 4: Governing "Code Meets Data" in the EHDS, led by Nienke Schutte.

A theme cut across all four tables: the EHDS discourse is expanding its focus towards data usability. Along the FAIR principles, making datasets accessible is key but does not, in itself, make them usable for secondary use. Standardization, trust frameworks, governance and economic incentives must advance together if availability is to translate into research and public-health value. As one participant put it, the workshop marked the first time the community really

began to discuss and acknowledge the value that lies hidden in the data already held — a benefit it is high time to explore.

Discussion Scope and Key Observation

With data usability as the transversal focus, a second observation framed much of the discussion.

Across the three areas the workshop examined — standardization, trust and operations — a great deal of work is already under way, distributed across a wide field of European initiatives: the discoverability metadata standard HealthDCAT-AP normative and maintained by the European Commission on code.europa.eu, TEHDAS2 issues technical specifications and guidelines that will support the drafting of the implementing acts, QUANTUM defined what quality and utility label may look like. There are pan European projects like Virtual Human Twin Platform, EBRAINS, EUCAIM or the Genomic Data Infrastructure building federated networks for imaging and genomic data reuse along with the governance models; DARWIN EU supports the European Medicines Agency with OMOP-based observational studies; EOSC-ENTRUST shaping much of the thinking on secure processing environments that flows into European specifications. The community's difficulty is therefore the abundance of this work rather than its absence. Many initiatives resolve the questions they must within the boundary of their own mandate and lifetime, then record the answer as a project-specific deliverable that is hard for an outsider to locate, interpret and re-adapt, and when the project ends much of that practical knowledge stops travelling. The community read this fragmentation as the central obstacle to usability, and as the space in which targeted coordination can add the most value.

On standardization, participants agreed that no universal standard fits the diverse categories in scope — administrative data, electronic health records, clinical trials, genomics, environmental and claims data. Standardizing legacy data is costly, and with no obligation to do so, data holders have weak incentives. Retrospective harmonization is cost intensive and not always justified. The favoured response was a category-specific, step-by-step approach, prioritizing prospective data collection: identify priority categories, define tailored standards, and improve usability alongside availability, drawing on mature initiatives such as the EHDEN Foundation. Existing standards deriving from primary use, including HL7 FHIR, can be leveraged immediately, while harmonization to OMOP and dedicated mapping services remains a clear need, with the caveat that even OMOP does not cover all data types. Beginning with low-complexity, high-impact use cases such as infectious diseases was preferred over the most demanding end-to-end pathways, like cancer. A recurring question beneath the discussion was whether a single standard is even the right instrument — in practice no single profile covers a secondary-use pathway, and several interoperability profiles must work together: for much secondary-use work, a sufficiently detailed dataset specification — with an anonymized or synthetic sample where one can be prepared — may serve the researcher better than a standard imposed across categories that do not share a shape.

On trust and secure processing, responsibility for providing Secure Processing Environments (SPEs) remains unclear as a market of providers emerges, and with only auditing rather than

certification in place, a trust deficit persists across systems and countries. An initiative is already under way to develop a compliance and audit matrix for SPEs, which signals both the demand for assurance and the absence so far of a shared scheme. A critical concern attaches to artificial intelligence: models trained inside SPEs may retain personal data, and although extraction is permitted only when a model is fully anonymised, no tools yet exist to verify this. Participants called for certification schemes that go beyond audits, minimum technical and governance requirements, investment in model-validation and privacy-leakage tools, and federation of SPEs through shared trust frameworks.

On governance and federation, data holders — as domain experts — were seen as insufficiently involved in how their data is used, analysed and interpreted. Metadata is central: it signals data quality and the purposes a dataset is fit for, surfacing the data holder's domain knowledge of whether a given dataset genuinely suits a user's intended use — knowledge the EHDS currently underuses. Pre-access negotiation models, such as Finland's, where Findata, the upcoming Health Data Access Body, engages data holders before a request is submitted, were highlighted, alongside permits that define analytical boundaries and de-identification levels. Elaborating on the topic of federated access and use, the community sees harmonization go beyond the data standards and require cross country alignment on processing environments and methods used within SPEs, yet maturity levels differ and central coordination is lacking; variable-level metadata helps but shifts a retrospective-alignment burden onto data users. The consensus was that harmonization cannot be avoided — AI alone cannot resolve structural inconsistencies — and that top-down guidance combined with bottom-up implementation, working backwards from concrete use cases, is the most effective path.

Across the workshop and in the conversations that followed, an important signal was identified: EHDS' impact on the relationship between data user and data holder. By opening dataset access to any qualifying applicant, the EHDS enables analysis across distances far beyond existing local cooperations, and with it a separation between data user and data holder, many times cross-country and multi-stakeholder, that local collaboration did not have — an applicant may receive access to a dataset seen only through its description, then has to interpret it inside an SPE with limited shared context. Closing that distance is itself a practice that exists today in real projects yet has not been made visible or transferable, and because the interaction is highly use-case-specific it resists capture by a single standard and is better served by reproducible practice.

From Gaps to Needs

Vienna surfaced gaps across the dimensions of secondary use standardization its four tables examined, yet the group had no means to act on them, having not yet evaluated what the community needed. A year of workshops and webinars has organized that terrain into three areas — standardization, trust and operations — and refined the reading. As the workshop discussions confirmed, the same three areas are better understood not as gaps, which suggest holes of unknown remedy, but as community needs — articulated requirements that can be addressed. The shift reflects that the community now knows what it is asking for, even where the means are not yet in place.

- **Standardization** — the need for category-specific standards and terminology harmonization, and, where no standard fits, for dataset specifications detailed enough to make a dataset usable to a researcher who has never seen it.
- **Trust** — the need for validation or certification that goes beyond audit, for verifiable assurance that data and AI models leaving an SPE carry no personal data, and for federation of SPEs under shared trust frameworks.
- **Operations** — the need for visible, transferable practices, shared methods and specifications that let data holders and data users meet across the new distance the EHDS introduces and higher complexity federations bring, including the tools, workflows and incentives that make reuse practical.

The strength of each need varied across the tables, and the variation is itself a finding. Some needs — pseudonymisation, the tension between moving data and keeping it in place, the basic question of how to prepare a dataset and how to use an SPE — recurred across tables and sectors with high amplitude, marking them as shared concerns rather than isolated ones. Other questions found less traction, suggesting the community has not yet converged on a view or is still in an early phase of engagement. The relative consolidation of these needs, against the fragmentation of the work addressing them, is the clearest result the workshop produced.

Outcomes and Next Steps

The Brussels workshop in 2026 confirmed the breadth and diversity of the secondary use community first observed in Vienna in 2025, and reinforced the conclusion that the most valuable work lies in a community level coordination and profiling existing practices, use of standards and specifications at the interfaces where systems and approaches meet, rather than inventing new frameworks. The four tables demonstrated that this coordination must be pursued simultaneously across technical, governance and economic dimensions.

The closing round-table sharpened where coordination is most needed, and by whom. The room agreed that the community should not expect every answer from the European Commission: top-down governance is required, yet it has to be filled in with practical artefacts, the more so where the support arrangements for secondary use carry a lighter assignment than their primary-use counterpart.

IHE, as Stefan Sauermann put it, can mandate and moderate a standards process but cannot do the work for the community; it depends on active contributions from the projects and implementers, and quality labels and similar mechanisms may help motivate participation. Coordination among the large funded projects is properly the work of those who fund and steer them; the community's own need is more immediate: to surface the practices that already work in the field today and make them usable beyond the project that produced them. The same pattern shows in questions that sit beneath the data layer, such as consent and opt-out workflows: the obligation to honour patient choice is set in law, yet how consent is collected, applied and

interpreted across borders is not written down — consent profiles such as IHE BPPC, APPC and Privacy Consent on FHIR exist, so the gap is the cross-border policy bridging rather than the profiles themselves — even where equivalent models have served primary use for years.

Projects routinely create governance arrangements among their partners — Working Agreements, by whatever name — that describe how data are shared and handled, though these end with the project and are rarely repurposed.

In closing, the initiative group put forward a concrete next step: to convene volunteers, work backwards from a small number of concrete research use cases, and generalize such project-level practices into project-agnostic, community-based practices published within the three areas the workshop examined. This is a deliberately modest path toward a good data practice, described at the table as a community activity rather than a top-down deliverable, drawing on IHE alongside HL7, DICOM and GA4GH where the questions cross into the processing environment and the algorithmic methods. It begins with two or three real practices on a shared problem and assembles a usable pattern from them, rather than attempting a comprehensive framework the community has neither asked for nor resourced. The initiative group will keep working with the table chairs, as it did after Vienna, and welcomes anyone willing to contribute.

As a methodology for profiling and testing, IHE can provide a practical platform for translating these requirements into implementable and testable specifications, and 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. Participants pointed to the proposed stakeholder platform for knowledge and best-practice exchange — targeted for around 2027 — as a concrete vehicle for sustaining this collaboration. The initiative group will continue to engage practitioners, vendors, policy makers and researchers to refine pragmatic approaches to secondary use standardization under the EHDS.

Invitation to the Community

The diversity of the EHDS 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. As Fidelia Cascini observed in closing, these initiatives are not isolated, and the value lies in connecting them into a wider network where experience can be shared and stakeholder participation broadened. The community is also welcome to contribute through the IHE domain committees, where this profiling work is taken forward. The community is rich in real implementation experience, yet much of that experience stays locked inside the projects that generated it. The work ahead is to bring that experience into the open, where it can be compared, generalized and reused.

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This report was prepared by the workshop hosts, Dmitry Etin and Eugenia Lvova, on behalf of the IHE-Europe community.

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