

COMMUNITY'S RESPONSE TO THE WEBINAR

Addendum to the report of the second EHDS Secondary Use workshop.

On 1 July 2026 the initiative group convened by Dmitry Etin presented the report¹ of the second EHDS Secondary Use workshop in a public webinar hosted by IHE-Europe, chaired by Jürgen Brandstätter and joined on the panel by Fidelia Cascini, Lori Reed-Fourquet and Stefan Sauermann². The discussion that followed raised more questions than the hour could hold, and the panel undertook to continue the exchange in writing, alongside the report. This addendum gathers the questions into three themes: the durability of the community effort; the standardization and reuse of existing data; and trust in data exchanged at a distance. It sets out the community's response to each, as the panel gave it in the room and as the report's findings extend it.

The Community Endeavour and Its Permanence

The discussion returned repeatedly to whether an effort of this kind can last, and whether anything a community produces can travel upward into the frameworks that bind. The most strongly held form asked what keeps a community approach from settling into another time-limited project; a companion asked whether common semantic agreements, once derived from the communities, could be taken up at the level of the EHDS.

Standards development offered the model. Standardization is an ongoing endeavour rather than a time-limited project, and once it is rooted in a standards development organization it acquires a home that outlasts any single funding cycle. Stefan Sauermann traced the arc of the last twenty years, from the epSOS project³ to the European exchange framework⁴ in force today, where the results of successive projects were absorbed into standards and governance that remained after each project closed, to the point that current legal texts cite the standards that work produced. The endeavour the community proposes follows the same arc: it surfaces the practices that

¹ IHE-Europe, *Workshop on Interoperability in EHDS Secondary Use*, workshop paper, 30 June 2026. https://ihe-europe.net/sites/default/files/2026-06/Paper_%20IHE%20Europe%20Connectathon%202026_Workshop%20On%20Interoperability%20in%20EHDS%20Secondary%20Use_20260630_1.pdf.

² Dmitry Etin, etza GmbH; Fidelia Cascini, Italy's Representative to the EHDS Committee; Lori Reed-Fourquet, Planning Co-Chair, QRPH Domain, IHE International; Stefan Sauermann, UAS Technikum Wien, founding member of IHE Austria.

³ epSOS — Smart Open Services for European Patients (2008–2014), the EU large-scale pilot on cross-border patient summaries and ePrescriptions, co-funded under the Competitiveness and Innovation Programme (CIP ICT-PSP). CORDIS project record: <https://cordis.europa.eu/project/rcn/191699/en>.

⁴ The European cross-border health-data exchange framework operated through the eHealth Network and the MyHealth@EU infrastructure. European Commission, "eHealth Network": https://health.ec.europa.eu/ehealth-digital-health-and-care/digital-health-and-care/eu-cooperation/ehealth-network_en.

already work in research centres and laboratories, generalizes them into shared community practice, and hands what matures to the bodies equipped to carry it forward.

That handing-on answers the second concern. Work that should become normative moves towards the standards development organizations; work that should inform governance can reach national Health Data Access Bodies⁵ and the implementing authorities in the form the report proposes, as tested conformance evidence; work that should remain shared tooling moves to open repositories. Semantic agreements derived from the communities are the material that matures along the first of these paths, so their eventual uptake within the EHDS would be continuous with the model that produced them.

Fidelia Cascini added the caution that shapes the first move in any locality: given how many initiatives already run across Europe in the same direction the community's contribution should enrich rather than duplicate them. The discipline the group set itself is an output in each cycle, with the next Connectathon⁶ — the supervised event at which independent systems attempt real data exchange against a shared specification — serving as the venue where a topic passes from discussion into testing.

Standardization and the Reuse of Existing Data

The largest strand of the discussion pressed on data that already exists. Participants observed that much of the value lies in data collected over past decades, and asked who decides what is harmonized and against which need, how such data is made usable when the framing appears built for data yet to come, and whether standardization might begin from the disease areas, specialties and registries already in place. A further question, on the validation of secondary-use data flows before data reaches a processing environment, belongs with these once its premise is examined.

Reading Article 51⁷, the duty to make data available is defined by category and carries no notion of time, so an organization that has collected for decades holds decades of data under the duty, and whether a temporal threshold should exist falls to the implementing acts to settle. Against that literal reading stands the cost of preparing deep archives, which one estimate at the workshop placed at twenty-five years of accumulated data for a single vendor, much of it carrying little foreseeable use. The path the panel favoured runs through the relationship between data holder and data user that the report identified as the central operational signal: a concrete use case states what it needs, and demand rather than a blanket obligation directs where preparation effort is spent. The question of who decides resolves into that relationship.

⁵ Health Data Access Bodies as established under Regulation (EU) 2025/327 (European Health Data Space), Arts. 2 and 55: <https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng>.

⁶ The IHE-Europe Connectathon, the supervised interoperability-testing event; the next edition is IHE-Europe Connectathon Week 2027, 19–23 April 2027, The Hague (Fokker Terminal): <https://connectathon.ihe-europe.net/ihe-europe-connectathon-week-2027>.

⁷ Regulation (EU) 2025/327 (European Health Data Space), Article 51 (minimum categories of electronic health data for secondary use): <https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng>.

It follows that access to existing data can rest on standardizing the interface through which the data is queried, leaving the data itself in place, with transformation reserved for the categories where a use case justifies its cost and the choice made dataset by dataset. Registries and clinical-trial datasets form the natural point of departure, since decades of regulated collaboration disciplined them into a maturity the other categories will have to construct deliberately. On cost recovery, a harmonized fee structure⁸ needs empirical grounding if it is to reflect the preparation work done inside each hospital, registry and laboratory; the contribution the community can make is comparable, documented evidence of what that work actually costs, giving Member States the measured reality against which to calibrate their schedules.

The question on validation repays separate attention, because it exposes the harder problem the report named as the distance between fitness for purpose and fitness for use. HL7 FHIR — the health-data exchange standard the report identifies as available for immediate reuse — is a dominant one in primary use, where data is generated at the point of care for the purpose of care, and validation is constructed around that original purpose. Secondary use puts a different question to the same data, whether it is fit for a purpose it was never collected to serve, and the processing environment through which secondary use runs is at this stage indifferent to the standard in which data arrives. Which parts of primary-use validation carry across that distance is an open question for the community to take up, and the scaffolding that would let an environment test incoming data against a secondary-use expectation has yet to be designed.

Trust in Data Exchanged at a Distance

The final strand concerned trust⁹, which the workshops set beside standardization and governance as a condition of reuse. Participants asked what allows a data user to rely on a dataset seen only through its description, held by parties never met, and whether the IHE de-identification handbook¹⁰ now in preparation treats the approved use of the data as a factor in how it is prepared. Both are, at root, questions about what makes data credible to someone who did not produce it.

The report had already located this distance as the effect the EHDS has on the relationship between data user and data holder, where access may be granted to a dataset seen only through its description and then interpreted inside a secure processing environment with limited shared context. Trust across that distance is a matter of mechanism rather than acquaintance. It rests first on conformance-tested interfaces and published profiles — the constrained, shared specifications that systems can be tested against — the basis on which ten independent systems exchanged the same profile at this year's European Connectathon. It rests next on the metadata the report placed at the centre of governance, the descriptions and the quality and utility labels

⁸ TEHDAS2 Joint Action, *D4.1 Guideline for health data access bodies on fees and penalties for non-compliance related to the EHDS regulation* (February 2026): <https://doi.org/10.5281/zenodo.20267597>

⁹ Michael Bouzinier, Dmitry Etin, Naeem Khoshnevis, Max Shad and Scott Yockel, *Research Data that Can Be Trusted*, SpringerBriefs in Computer Science (Springer): <https://doi.org/10.1007/978-3-032-21032-6>.

¹⁰ IHE IT Infrastructure Technical Committee, *Healthcare De-Identification Handbook*, published for public comment 12 June – 12 July 2026: <https://build.fhir.org/IHE/ITI.DelIdHandbook/branches/main/index.html>.

through which a dataset declares what it is fit for, so that the catalogue entry becomes the object a user examines before requesting access. It rests further on the Health Data Access Body, which in the pre-access model that Finland's Findata exemplifies¹¹ engages data holders before a request is lodged, brokering the metadata exchange and establishing regulatory trust ahead of any disclosure.

These mechanisms describe the assurance available today, and they leave open a deeper question the community is placed to hold rather than to close prematurely: how far trust can be discharged by conformance and by labelling, and how much of it rests on provenance and on judgement that no label fully captures.

In the handbook, the answer is affirmative and structural. The IHE De-Identification Handbook, open for public comment through July and available for the community to review and comment on, opens its process with an analysis of context that fixes the purpose, the recipients and the data flow, and states that the intended uses of the data determine both the extent of de-identification and the acceptable level of risk, with that risk calibrated to the sharing model. De-identification is therefore governed by the approved use from the outset, so that preparation stripping more than the purpose requires leaves data that no longer answers the question it was released to answer — the balance the question identifies. Independent practitioner work reaches the same position, arguing for auditable disclosure controls calibrated to the approved purpose, evidence the community treats as exactly the comparable practice it exists to gather.

Invitation to the Community

Taken together, these are the community's undertakings:

- map the initiatives already running in the same direction and enrich them,
- gather comparable, documented evidence of data-preparation practice,
- strengthen collaboration with the standards development organizations,
- develop reusable implementation guidance to support consistent EHDS implementation across Member States.

This addendum extends the report of the "Brussels" second workshop¹², with the community's response to the questions the session could not reach within the hour. The work continues toward an autumn session. Anyone willing to contribute a practice, a use case or a question is invited to contact the organisers.

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¹¹ Findata (Finnish Social and Health Data Permit Authority), "Data permits": <https://findata.fi/en/permits/data-permits/>.

¹² The report of the second EHDS Secondary Use workshop (Brussels, 25 March 2026), published by IHE-Europe; the workshop paper cited above at note 2: https://ihe-europe.net/sites/default/files/2026-06/Paper_%20IHE%20Europe%20Connectathon%202026_Workshop%20On%20Interoperability%20in%20EHDS%20Secondary%20Use_20260630_1.pdf.