

June 28, 2026

## **Joint Statement on the TEHDAS2 Guidelines for Implementing the European Health Data Space**

A call to ensure that data access translates into meaningful real-world insights.

We, the stakeholders of this joint statement, welcome the Regulation on the European Health Data Space (EHDS) and commend the TEHDAS2 Joint Action for its sustained effort to translate this framework into operational guidance, and to ensure its outputs are relevant, balanced and practical.

The EHDS represents a unique opportunity to transform how health data are used for research, innovation and public health across Europe. However, access to data alone will not be sufficient. The success of the EHDS should ultimately be measured by its ability to generate meaningful evidence across borders. To achieve this, Europe should not focus solely on governance and access mechanisms, but on practical foundations that make data interoperable, reusable and meaningful for research.

As organizations operating large-scale health data platforms, analytical infrastructure and research networks across Europe, we bring direct operational experience of data standardization, federated research and governed secondary use. We recognize the ambition of this work and the complexity of the challenges it addresses. We submit this statement because we know that the full potential of the EHDS for real-world-evidence can only be realized if its implementation is grounded in the operational realities of health data research and builds on the infrastructure, standards and communities that already exist and are utilized across Europe.

One mature avenue we want to highlight is the Observational Health Data Sciences and Informatics (OHDSI) community, whose open standards and tools, including the OMOP Common Data Model, have established a proven framework for standardized, reproducible large-scale observational research for secondary use. The European Health Data & Evidence Network (EHDEN) was the first initiative to bring large numbers of European data holders together to transform their data into OMOP, demonstrating that this harmonization is achievable at scale. The Data Analysis and Real World Interrogation Network (DARWIN EU®) built on this foundation to operate as a federated evidence network within the European regulatory system. This accumulated knowledge represents significant public investment that must be leveraged systematically. The current guidelines acknowledge this but provide no mechanism for how

engagement will be structured or how past experiences will influence political decisions. We therefore offer the following recommendations to further strengthen EHDS implementation:

- **Establishing interoperability as a foundational precondition**

Accessible data are not the same as usable data. Meaningful insights require shared standards, common vocabularies and harmonized data structures across institutions. Without semantic and structural interoperability, data may be accessible but cannot reliably be combined, compared or reused. The current guidelines acknowledge standardization but treat it as a preparation step rather than a foundational requirement shaping linkage quality, enrichment reusability and cross-border feasibility. Without deliberate action and leadership, there is a risk that data may become technically accessible while remaining difficult to reuse efficiently at scale. We therefore encourage to recognize interoperability as a foundational enabler and to draw on established open standards, such as the OMOP Common Data Model developed by the OHDSI community, as a proven reference for achieving it.

- **Trust requires transparent data quality**

Trust in secondary use depends on trust in data quality. Data quality assessment should be transparent, reproducible, standardized and supported by objective metrics. Shared quality frameworks and common reporting approaches can improve confidence in research outcomes and facilitate cross-border collaboration. Quality reporting that is optional, qualitative or inconsistently applied cannot provide the assurance that data users, Health Data Access Bodies and regulators need. The current guidelines define minimum quality outputs but frame them as recommendations, with no common metrics or mechanism for cross-border comparability. We advise designating a minimum set of quality reporting outputs as mandatory for all datasets released under a data permit, standardizing their format, and integrating these requirements into the EHDS quality-label framework. The Horizon Europe QUANTUM project has already developed a data quality and utility label. We recommend the guidelines reference its standards as a minimum baseline.

- **Creating reusable methods adds more value than single use analytics**

Knowledge generated through secondary use risks remaining locked within individual entities. A sustainable health data ecosystem supports the sharing of methods, analytical code and reusable artifacts in addition to data. When data are represented using common standards, analytical methods and code can be repurposed cross-organizationally without iterative development. This improves efficiency, transparency and reproducibility. The current guidelines describe method sharing pathways but frame them as optional, with no standardized outputs and no incentive structure. We therefore recommend creating explicit mechanisms for the documentation, sharing and reuse of analytical methods and derived knowledge, and recognizing method sharing as an expected output of secondary use.

In conclusion, the EHDS is a once-in-a-generation opportunity to turn Europe's health data into real-world-evidence that improves care and the TEHDAS2 guidelines have already done much of the hard work charting the way there. Drawing on our operational experience, we believe some of the named goals should be made more concrete and binding, while building on existing initiatives, standards and communities. Access is the prerequisite and robust, trustworthy evidence at scale is the engine, but the real goal is better care for patients. Building on what already works, engaging in existing communities as partners, and grounding implementation in operational reality should be the foundation for getting this right, together.

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Note: This statement is submitted in response to the TEHDAS2 third public consultation (5 May - 28 June 2026) and the draft guidelines. It reflects the views of the signatory organizations only and does not represent the position of any EU institution.