VALO2 pilot study lessons learned

Cross-border health data research through secure processing environments

Extended executive summary for the Nordic Health Data Summit 2026

Introduction

The European Health Data Space (EHDS) seeks to create a future in which health data can be reused securely and efficiently across Europe to support research, innovation, policymaking and public health. Achieving this ambition requires more than legislation, governance frameworks, and technical infrastructure. It requires practical evidence that researchers can successfully access, analyse and interpret health data across organisational and national boundaries while maintaining appropriate privacy, security, and governance controls.

The VALO2 pilot study was designed to contribute to that understanding. Building on the foundations established by the original VALO pilot (initiated in 2024, hereafter named VALO1, to separate from the VALO2 extension from November 2025), the project examined whether researchers from one Nordic country could directly access and analyse patient-level data held in another Nordic country through Secure Processing Environments (SPEs), while maintaining local control of patient data and compliance with relevant governance requirements.

Unlike many proof-of-concept exercises, VALO2 pilot study was conducted using a real-world oncology research study involving Danish, Finnish and Norwegian data. The pilot therefore provided a unique opportunity to move beyond theoretical discussions of interoperability and evaluate how cross-border research operates in practice when real researchers, real governance processes, and real data are involved.

Why VALO2 was needed

The VALO1 pilot study demonstrated that Nordic organisations could collaborate using a federated analytical model built around the OMOP Common Data Model. Under this operating model, the central coordinating team developed standardised analytical scripts which were distributed to participating sites. Local teams executed the analytical scripts within their own secure environments and returned aggregated outputs for central review and synthesis, while patient-level data remained under local control. The pilot successfully demonstrated that common data models and common analytical frameworks could support cross-border research while preserving local governance and data sovereignty.

However, the experience from the VALO1 pilot study also highlighted important limitations. The central coordinating team had limited visibility of local data structures, mappings, derivations, cohort-construction approaches, and analytical workflows. When unexpected findings emerged,

understanding the reasons often depended heavily on interactions with local teams. The central team could review the aggregated outputs but often had limited visibility of the operational and data context that produced them.

The VALO2 NSCLC pilot study was therefore designed to examine whether Secure Processing Environments could complement federated operating models by allowing authorised external researchers to work directly with patient-level data inside the environments operated by local data holders. Rather than sending analytical scripts to sites and receiving aggregated outputs in return, researchers could directly access the data, validate assumptions, explore cohort definitions, understand local mappings and perform analysis within the controlled environment itself.

The objective was not to replace local expertise or remove governance controls. Rather, it was to determine whether increased visibility could improve transparency, support validation of assumptions, facilitate analytical flexibility, and help researchers better understand the underlying data. This question remains highly relevant to EHDS implementation as policymakers, researchers and data holders continue to explore how Secure Processing Environments can support secure cross-border access while maintaining trust, accountability and data sovereignty.

What VALO2 demonstrated

The most important outcome of VALO2 is straightforward: cross-border health data research through Secure Processing Environments is feasible today. Danish researchers successfully analysed Finnish and Norwegian patient-level data within the secure environments operated by those organisations, while the corresponding Danish analysis was undertaken within Denmark's established analytical environment. Approved outputs were subsequently released through governed pathways and incorporated into the final study outputs.

This achievement is significant because it provides practical evidence that many of the technical and governance foundations required for EHDS-style research already exist within the Nordic region. The project demonstrated that researchers can access and analyse health data across borders without moving patient-level data to a central repository and while preserving local accountability and governance arrangements.

At the same time, the pilot revealed that successful cross-border research depends on far more than simply granting access to data. Researchers progressed through a complex sequence of activities involving approvals, onboarding, identity verification, analytical tooling, data preparation, workflow validation, output governance, and ongoing support. Each of these elements influenced the overall success of the project, and each became a potential point of delay or uncertainty.

A critical observation from the pilot was that access approval and successful authentication did not necessarily mean that researchers were ready to conduct analysis. Researchers required database connectivity, appropriate analytical tools, access permissions, workflow validation, and usable data before meaningful research could begin. This distinction between access and

analysis readiness emerged repeatedly throughout the project and became one of its most important operational findings.

What researchers learned from direct access

One of the strongest themes emerging from the VALO2 pilot study was the value of increased visibility.

Compared with the federated operating model tested in the VALO1 pilot study, researchers participating in the VALO2 pilot study were no longer limited to developing analytical scripts centrally and relying on local teams to execute them and return aggregated outputs. Instead, researchers could directly inspect data structures, explore cohort definitions, review mappings, investigate unexpected findings, and observe how analytical workflows operate within the Secure Processing Environments themselves.

This demonstrated one of the principal potential benefits of the Secure Processing Environment model. Direct access allowed researchers to move beyond simply receiving analytical outputs and instead understand how those outputs were generated. Researchers gained greater visibility of the analytical context, helping to expose issues relating to variable availability, mappings, derivations, cohort construction and workflow readiness that might otherwise have remained hidden within a purely federated operating model.

The pilot therefore demonstrated that Secure Processing Environments can improve transparency, increase researcher visibility, and provide greater analytical flexibility. These advantages address some of the challenges observed in the federated operating model used in the VALO1 pilot study, where understanding unexpected results frequently depended on indirect communication with local teams.

However, the experience also demonstrated that visibility alone does not eliminate all barriers. Researchers repeatedly relied on local clinical experts, data specialists and institutional contacts to explain data provenance, validate cohort definitions, interpret unexpected findings, understand local derivations, and navigate organisational processes. Access to data did not remove the need for local knowledge.

The project therefore produced an important balanced conclusion. Secure Processing Environments can increase researcher visibility, transparency and analytical autonomy, but they do not eliminate the need for local expertise. Common data models support structural interoperability and portability of analytical frameworks, but they do not automatically resolve semantic interoperability challenges or remove the need for contextual understanding of how data are captured, transformed and interpreted within individual organisations.

This experience suggests that future EHDS-style operating models are likely to benefit from combining the advantages of researcher access, common data models and Secure Processing Environments with continued involvement of local experts who can provide scientific validation, operational guidance and contextual interpretation of the data.

What VALO2 revealed about EHDS implementation

VALO2 can be understood as an operational readiness assessment for future EHDS-based research.

The project highlighted that technical interoperability alone is insufficient to support scalable cross-border research. Although participating environments provided secure infrastructure and technical access routes, operational and organisational factors frequently became the more significant determinants of project success.

The pilot identified three forms of interoperability that must work together:

- Technical interoperability, enabling data and analytical systems to function together.
- Governance interoperability, enabling approvals, identities and access rights to be reconciled.
- Service interoperability, enabling researchers to navigate operational processes in a transparent and predictable manner.

Among these, service interoperability emerged as one of the most important and least visible requirements. Future researchers need to understand not only how to access data but also who provides support, how long activities will take, where approvals are required, how outputs are released, and what happens when problems arise. The quality of these services is likely to become increasingly important as cross-border health data access becomes more commonplace.

The project also revealed that regulatory interpretation can be as significant as regulation itself. Differences in how similar activities were categorised by review bodies materially affected study timelines and delivery. These observations suggest that operational variation may continue to exist even within a common European regulatory framework unless accompanied by greater harmonisation of implementation practices.

Implications for a future Nordic Health Data Space

Perhaps the most encouraging message from VALO2 is that the Nordic countries already possess many of the building blocks required to create a future Nordic Health Data Space.

The pilot demonstrated mature technical environments, experienced researchers, strong governance practices, and a willingness among participating organisations to collaborate across borders. These are important assets for future development.

At the same time, the project suggests that future progress should focus less on creating entirely new infrastructure and more on improving the consistency, transparency, and usability of the services that surround that infrastructure. Researcher onboarding, approval pathways, analytical readiness, data understanding and support arrangements all emerged as areas where harmonisation could deliver substantial benefits.

Importantly, the pilot also reinforced the value of Nordic collaboration itself. Many of the lessons captured during VALO2 emerged not from technical testing alone but from discussions between researchers, governance experts, ethical reviewers, and data holders. These conversations helped expose implementation challenges, clarify assumptions, and generate practical recommendations that will benefit future initiatives.

For this reason, the value of VALO2 extends beyond the results of a single study. The project provides a practical foundation from which future Nordic and European health data initiatives can continue to evolve.

Strategic recommendations

The findings from the VALO2 pilot study suggest five priority areas for future development.

1. Establish a Nordic secure processing environment maturity model

Develop a common framework that allows organisations to describe their operational and technical capabilities consistently

2. Define a common cross-border service profile

Enable researchers to understand the services available within each environment before access is requested.

3. Require protocol-to-data feasibility assessment

Validate protocol-critical variables, cohort assumptions, and analytical requirements before timelines and commitments are established.

4. Create a Nordic cross-border researcher onboarding framework

Provide consistent guidance for identity management, onboarding, researcher support, and workflow readiness.

5. Strengthen ethical governance collaboration

Support more consistent interpretation of ethical and governance requirements through continued Nordic collaboration.

Conclusion

The VALO2 pilot study demonstrates that cross-border health data research through Secure Processing Environments is achievable today.

The pilot successfully showed that authorised researchers can access and analyse patient-level data across Nordic borders while preserving local governance controls, privacy protections, and data sovereignty.

Perhaps most importantly, the project demonstrated both the opportunities and the challenges associated with future EHDS implementation. Direct researcher access can improve visibility, transparency, and analytical flexibility. At the same time, successful cross-border research

continues to depend on local expertise, semantic interoperability, operational maturity, and effective governance.

The central lesson from the pilot is therefore not simply that access is possible. It is that sustainable cross-border research requires technical capability, governance interoperability, service interoperability, and human expertise working together.

The experience generated through the VALO2 pilot study also demonstrates the value of practical implementation testing. By moving beyond theoretical frameworks and testing cross-border research using real researchers, real governance processes and real-world data, the pilot exposed operational challenges, implementation gaps and improvement opportunities that would have been difficult to identify through policy development or technical planning alone. The findings therefore provide practical evidence not only for future Nordic collaboration, but also for organisations across Europe preparing for EHDS implementation.

The Nordic countries now have an opportunity to build on this experience and transform successful pilot projects into predictable, scalable and researcher-friendly services capable of supporting the next generation of health-data research under both Nordic collaboration frameworks and the European Health Data Space.

The experience generated through the VALO2 NSCLC pilot study demonstrates that the future challenge is no longer proving that cross-border research is possible. The challenge now is translating the capabilities demonstrated through the pilot into predictable, scalable and operationally mature services that can support routine cross-border research across the Nordic region and, ultimately, within the European Health Data Space.