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VALO2 non-small cell lung cancer (NSCLC) pilot: lessons learned

Cross-border Secure Processing Environment readiness and EHDS
implementation insights across the Nordics

Report 1.0 - Value from Nordic health data – VALO2 project

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Document info

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Executive summary

The European Health Data Space (EHDS) aims to make the secure secondary use of health data for research, innovation, policymaking and public health more efficient across Europe (Regulation (EU) 2025/327). Achieving this ambition requires more than legislation and technical infrastructure. The Value from Nordic health data (VALO) initiative was a Nordic collaboration established to explore and advance practical approaches for cross-border secondary use of health data. As part of this initiative, the VALO2 pilot study examined whether researchers could access and analyse cross-border patient-level health data using existing Nordic secure infrastructures.

Danish researchers analysed data held by Helsinki University Hospital in Finland and Oslo University Hospital in Norway within the Secure Processing Environments used by those organisations, while the corresponding Danish analysis was conducted within the research team's established local environment. Building on the foundations established through the initial VALO1 pilot study and adoption of the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), the VALO2 pilot study shifted the focus from locally executed federated analysis towards the practical realities of cross-border researcher access, generating insights into the operational, governance and service requirements needed to support future EHDS implementation.

The VALO2 pilot study demonstrated that cross-border analysis was operationally feasible through the Finnish and Norwegian Secure Processing Environments tested as external researcher-facing pathways, alongside local analysis in the Danish team's established environment. Analyses were completed using Danish, Finnish and Norwegian data. Outputs were released from all three environments, with Finland and Norway using defined review or approval pathways and Denmark operating under researcher and principal investigator responsibility. However, demonstrating feasibility does not automatically translate into scalable operational services. Approval, workspace entry, access to study data and readiness to perform analysis were separate milestones, each affected by governance, permissions, tooling, data preparation, documentation, local support and output release arrangements.

Three broader lessons emerged. First, differing interpretations of ethical and regulatory requirements at organisation and country level can materially change approval pathways and timelines. Second, adopting a common data model did not eliminate the need for protocol-specific feasibility assessment, local validation, and assessment of analytical comparability. Variables required by the study protocol were not always available at every site, consistently mapped and defined; included within approved data extractions; or sufficiently comparable across sites to support pooled analysis. Third, local data, clinical and institutional expertise remain essential to scientific validity, cohort validation and efficient study delivery.

The findings indicate that the EHDS readiness depends on technical, governance and service interoperability. Secure environments and lawful access must be complemented by transparent, sufficiently consistent researcher services and validated analytical workflows. Future readiness assessments should therefore distinguish between secure infrastructure, research-ready environments and operationally mature EHDS services.

Drawing on the findings of the VALO2 pilot study, the pilot team recommends a Nordic Secure Processing Environment maturity model, a common cross-border service profile, study-specific readiness packs, protocol-to-data feasibility checks, workflow readiness testing and common onboarding principles. The challenge is now to translate existing Nordic capabilities into transparent, repeatable and scalable services that make cross-border health data routine rather than exceptional.

Acronyms and abbreviations

Acronym	Meaning
CDM	Common Data Model
CRAN	Comprehensive R Archive Network
DGWG	Data Governance Working Group
ECOG	Eastern Cooperative Oncology Group
EHDS	European Health Data Space
FAQ	Frequently Asked Questions
HPC	High-Performance Computing
HUS	Helsinki University Hospital
ICI	Immune Checkpoint Inhibitor
ITSM	IT Service Management
MFA	Multi-Factor Authentication
NSCLC	Non-Small Cell Lung Cancer
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership
OUS	Oslo University Hospital
OTP	One-Time Password
PC	Personal Computer
PD-L1	Programmed Death-Ligand 1
PI	Principal Investigator
RBAC	Role-Based Access Control
REC	Regional Ethics Committee
SDC	Statistical Disclosure Control
SPE	Secure Processing Environment
THL	Finnish Institute for Health and Welfare
TRE	Trusted Research Environment
TSD	Services for Sensitive Data
TTAR	Time-to-Analysis-Ready
UiO	University of Oslo
VALO	Value from Nordic Health Data

VALO1	Initial phase of the Value from Nordic Health Data project
VALO2	Extension phase of the Value from Nordic Health Data project
VDI	Virtual Desktop Infrastructure

Glossary of definitions

Term	Definition
Dummy data	Artificially created placeholder data that does not represent real individuals or actual data distributions and is primarily used for testing access, workflows, interfaces or system functionality.
Mock data	Artificially created data used to test processes, tooling, environments and workflows. Mock data may resemble the structure of the real data but is not intended to accurately represent underlying data characteristics.
Synthetic data	Artificially generated data designed to preserve key statistical characteristics, relationships or distributions of a real dataset without containing real individuals.

1 Introduction and purpose

The VALO2 pilot study builds on the foundations established during the initial phase of the Value from Nordic Health Data (VALO) project, now referred to as the VALO1 pilot study. The VALO1 pilot study demonstrated that federated analysis using the Observational Medical Outcomes Partnership (OMOP) Common Data Model approach could support cross-border research across Nordic data partners. However, the lessons learned from the VALO1 pilot study highlighted that technical interoperability alone was not sufficient to support routine cross-border research. Important questions remained regarding researcher access, governance, approvals, secure analytical environments and operational delivery. The VALO2 pilot study therefore shifted the emphasis from multi-site federated analysis towards the practical feasibility of cross-border use of Secure Processing Environments (SPEs). The project examined whether Nordic health data can be accessed and analysed by researchers from another country within national or regional secure environments in a way that is feasible, auditable, privacy-preserving and suitable for real-world research.

In practical terms, the VALO2 pilot study was designed to enable the Danish research team to analyse patient-level health data held by Helsinki University Hospital (HUS) in Finland and Oslo University Hospital (OUS) in Norway through the secure environments used by those organisations. The Danish researchers also completed the corresponding analysis using Danish data within their established local Databricks-based analytics environment. This operating model enabled the project to examine both the practical experience of accessing data across national borders and the differences between external researcher-facing environments and a mature local analytical ecosystem, providing insight into the operational capabilities required to support routine cross-border research.

The lessons learned report therefore goes beyond documenting operational issues. It provides a structured assessment of current cross-border SPE readiness, considers the capabilities and operational requirements anticipated under European Health Data Space (EHDS) implementation, and identifies practical controls that could make future studies more consistent and scalable. This includes approval routes, user onboarding, identity management, tools, OMOP workflow readiness, pseudonymisation/data minimisation, data availability, output release, auditability, close-out and documentation quality.

Sitra specifically indicated interest in understanding how the SPEs operate in Finland, Norway and Denmark; what tools are available; what the end-to-end process to access data looks like; what legislation and standards are relevant; what the differences are between operating models; and how long it takes to gain access to data. This report responds to that requirement by combining project experience with structured discovery information and public documentation.

To support delivery of the cross-border research pilot and associated lessons learned activities, the VALO2 pilot study established a Data Governance Working Group comprising the Data Governance Workstream Lead, Data Governance Specialist, SPE Technical Expert, site Principal Investigators, Co-Principal Investigators, site data scientists, researchers and oncology specialists from participating countries. The group provided a forum for reviewing operational readiness, discussing approvals, researcher onboarding, data access arrangements, protocol feasibility, variable availability, governance considerations and emerging cross-border challenges. While not a formal decision-making body for local approvals, the Working Group played an important role in facilitating

shared understanding across participating organisations and enabled many of the practical lessons captured throughout this report to be identified, discussed and validated collaboratively.

1.1 How the VALO2 operating model differed from VALO1

The VALO2 pilot study built on the technical and collaborative foundations established through the VALO1 pilot study but tested a different researcher operating model. The VALO1 pilot study primarily used locally executed federated analysis, with aggregated outputs returned for central compilation. The VALO2 pilot study tested whether authorised researchers from one Nordic country could remotely access and analyse patient-level data within the SPEs used by data-holding organisations in other countries.

Table 1: VALO1 pilot study and VALO2 pilot study tested complementary operating models

Operating model dimension	VALO1 pilot study	VALO2 pilot study	Principal learning from the change
Primary model	Federated analysis using common scripts executed within participating sites.	Cross-border researcher access to patient-level data remotely within the Finnish and Norwegian secure environments, alongside local Danish analysis.	Common analytical code and common data structures remain important, but direct researcher access provides greater flexibility for exploratory and iterative analysis while introducing additional operational requirements around identity, onboarding, permissions, tooling, support and output release.
Location of patient-level data	Patient-level data remained within the participating organisations; aggregated results were shared for compilation.	Patient-level data continued to remain within the data-holding environments, but authorised Danish researchers could work with Finnish and Norwegian data inside those environments.	Cross-border access enables researchers to work directly within the data-holding secure environments improving visibility of cohort construction, data quality and analytical processes while allowing patient-level data to remain under local control.
Analytical execution	Local participating teams executed standardised analytical scripts.	Danish researchers developed standardised analytical scripts and localised them before execution within HUS Academic and TSD via remote access. The Danish analysis was undertaken by the local team in its established environment.	Direct researcher access can support more iterative investigation and reduce dependence on repeated local execution, but it does not remove the need for local data and clinical expertise.
Researcher relationship with the environment	The researcher journey into each local analytical environment was not the principal object of testing.	The end-to-end researcher journey became a core object of evaluation, including approvals, identity verification, workspace entry, software, data connectivity, workflow	Direct researcher access to external SPEs is feasible and provides greater visibility of data, analytical workflows and local operating practices; however, successful login or formal approval alone

Operating model dimension	VALO1 pilot study	VALO2 pilot study	Principal learning from the change
		readiness, support, output release and close-out.	does not guarantee analysis readiness.
Role of local teams	Local teams supported OMOP implementation, data preparation, execution of analysis scripts, returning results and interpretation.	Local teams remained responsible for institutional navigation, approvals, data preparation, local derivations, cohort validation, technical support and scientific interpretation.	Direct researcher access changes the division of analytical work and provides greater visibility of data and analytical processes while local teams remain essential for institutional navigation, cohort validation, governance, technical support and scientific interpretation.
Main readiness question	Can participating sites standardise data to OMOP and execute a common analytical package through a federated model?	Can authorised foreign researchers progress from approval-to-analysis and governed output release inside different national or regional secure environments?	The VALO2 pilot study moved the focus from technical interoperability alone towards the operational readiness and interoperability of SPEs, including researcher access, approvals, onboarding and support services.
Principal evidence generated	Evidence on OMOP implementation, data readiness, federated package execution, vocabulary alignment and multi-site coordination.	Evidence on cross-border SPE usability, researcher onboarding, workflow readiness, support, data provenance, cohort-construction, correction/re-extraction and output governance.	The two pilots provide complementary evidence rather than representing competing models.

Abbreviations: HUS, Helsinki University Hospital; OMOP, Observational Medical Outcomes Partnership; SPE, Secure Processing Environment; TSD, Services for Sensitive Data.

Interpretation

VALO1 pilot study established that a common data model and federated analytical approach could support multi-site Nordic research while data remained locally controlled. The VALO2 pilot study built on this foundation by testing whether authorised researchers could work directly within the secure environments used by cross-border data holders, without transferring patient-level data. This approach increased researcher visibility of data and analytical processes and supported more direct interaction with the research environment, while also exposing service-level dependencies that were less visible in a locally executed federated model, including onboarding, workspace permissions, tooling configuration, workflow validation, support and governed output release.

2 Methods and source materials

This report uses a mixed evidence base, combining structured discovery, project lesson capture, project meeting records, site correspondence, researcher feedback, Sitra update materials, Ethical Expert Group report, and public documentation. The approach is qualitative and operational rather than statistical; its purpose is to identify repeatable patterns, current readiness gaps, and practical recommendations for future cross-border research using SPEs.

The Non-Small Cell Lung Cancer (NSCLC) use case also provided a demanding test of cross-border analytical readiness. Oncology research may depend on information drawn from multiple clinical and administrative sources, including diagnoses, pathology, biomarkers, treatments, performance status and disease progression. The VALO2 pilot study experience therefore provided an opportunity to assess not only whether OMOP-formatted data could be accessed, but whether protocol-specific variables distributed across different source systems and data domains could be made available and used consistently for analysis.

Table 2: Multiple evidence sources were combined to assess cross-border researcher readiness and EHDS implementation

Evidence source	Purpose
VALO1 lessons learned report	Used as a structural and operating model comparator. VALO1 pilot study primarily examined OMOP implementation and locally executed federated analysis, whereas the VALO2 pilot study examined cross-border researcher access, SPE workflow readiness and governed analysis within cross-border data-holding secure environments.
Data Governance Lessons Learned Log	Used as the primary structured source for lesson descriptions, impacts, root causes, and recommendations.
VALO2 pilot study protocol extract	Used to anchor the report to the formal deliverable requirement on SPE feasibility and process outcomes.
Data Governance SPE Discovery Tracker	Used as the core structured source for site/SPE access processes, approvals, tools, RBAC, audit, revocation and output-control gaps.
Danish Researchers Questionnaire Response	Used as primary first-hand evidence of researcher experience across HUS Academic, Databricks and TSD, including onboarding, documentation, permissions, tooling, OMOP connectivity, workflow execution, workarounds, mock data, variables and output export.
Data Governance Working Group (DGWG) and Sitra meeting notes	Used to evidence evolving risks, decisions, site updates and client expectations.

Evidence source	Purpose
Researcher/site emails and Teams discussion	Used to capture practical access, tooling, language, mock data, and output release experiences.
Public SPE/user documentation	Used to supplement HUS Acamedic and TSD public process information and generic Databricks platform capability context.
TEHDAS2 and EHDS public references	Used to benchmark the VALO2 pilot study experience against emerging European guidance on SPE use and EHDS secondary use objectives.
VALO2 Ethical Expert Group Final Report (2026c): Ethical Governance of Secondary Use of Health Data in the Nordic Countries	Used to contextualise national ethical review requirements, Quality Assurance (QA) versus Research interpretation, Nordic harmonisation challenges and EHDS implementation considerations.

Abbreviations: DGWG, Data Governance Working Group; EHDS, European Health Data Space; HUS, Helsinki University Hospital; OMOP, Observational Medical Outcomes Partnership; QA, Quality Assurance; RBAC, Role-Based Access Control; SPE, Secure Processing Environment; TSD, Services for Sensitive Data; VALO1, Initial phase of the Value from Nordic Health Data project; VALO2, Extension phase of the Value from Nordic Health Data project.

No single source was sufficient to understand the researcher journey. The findings combine project records, researcher experience, operational evidence, public SPE documentation and emerging EHDS guidance to provide a comprehensive assessment of cross-border research-readiness.

A structured questionnaire response from the Danish research team has been incorporated to ensure that the report reflects the researchers' first-hand operational experience of working within or connecting to each environment. This evidence is particularly important because it distinguishes formal platform capability from practical research usability, including the steps required to make OMOP workflows executable in practice.

2.1 Analytical approach

This report is not intended to provide a formal evaluation of the participating SPEs or a comparative assessment of national performance. Instead, the evidence was analysed to identify factors that influenced the ability of researchers to navigate the end-to-end cross-border research journey.

Findings were interpreted through the VALO2 pilot study researcher journey framework, which builds on the user journey concepts developed through the TEHDAS and TEHDAS2 Joint Actions and examines the sequence of activities required to undertake cross-border secondary use of health data. The framework follows the researcher experience from approvals and onboarding through workspace access, analysis, output release and project close-out, providing a structured lens through which operational readiness, service interoperability and researcher experience can be assessed.

Evidence from project records, researcher feedback, site discussions, public documentation and governance activities was reviewed and triangulated to identify recurring themes, operational

dependencies, barriers and enabling factors. Particular attention was given to understanding where governance processes, onboarding arrangements, tooling, data availability, researcher support or service delivery influenced study delivery.

Throughout the report, distinctions are made between documented platform capability, functionality that was directly tested through the VALO2 pilot study activities and areas requiring further validation. This approach supports a balanced assessment of current capabilities while identifying practical considerations relevant to future EHDS implementation.

3 VALO2 as an operational test of EHDS readiness

EHDS establishes an ambition for health data to be reused securely for research, innovation, policy and public health, with access mediated through defined governance routes and controlled processing environments (Regulation (EU) 2025/327). The VALO2 pilot study is valuable because it tests the operational layer beneath that ambition: whether the practical steps required to access and analyse data across borders are sufficiently consistent, transparent and executable by real researchers, using real data and real analytical tools, under different national constraints.

Table 3: Current Nordic capabilities provide important EHDS foundations but require greater operational maturity for routine cross-border research

Readiness dimension	Current-state evidence from VALO2	Operational capability needed for greater EHDS readiness
Approval pathway visibility	Country pathways differed materially. Finland required a dedicated VALO2 study approval. Subsequent amendments were approved by the HUS Chief Medical Officer on 11 March 2026. Denmark used an existing study-specific approval covering comparisons of immune checkpoint inhibitor efficacy together with additional hospital legal office approval before study replication and result sharing with IQVIA could proceed. Norway required Regional Ethics Committee approval followed by patient notification and opt-out arrangements for living patients.	Each site provides a validated approval pathway map with submission cut-offs, expected review windows, permit evidence, post-approval conditions and escalation routes before protocol finalisation and built into the baseline plan.
SPE service and access information	HUS Acamedic, the Secure Processing Environment (SPE) used by Helsinki University Hospital for the Finnish VALO2 pilot study pathway, and TSD, the Services for Sensitive Data environment used for the Norwegian pathway, have public service and user documentation. Denmark's Databricks-based process was described by the local team, but internal process documentation was not available for review.	Every participating SPE provides a standardised service description and user guidance covering access requirements, approval processes, onboarding, supported tools, technical capabilities, costs, support arrangements, output-release procedures and information available to external researchers.

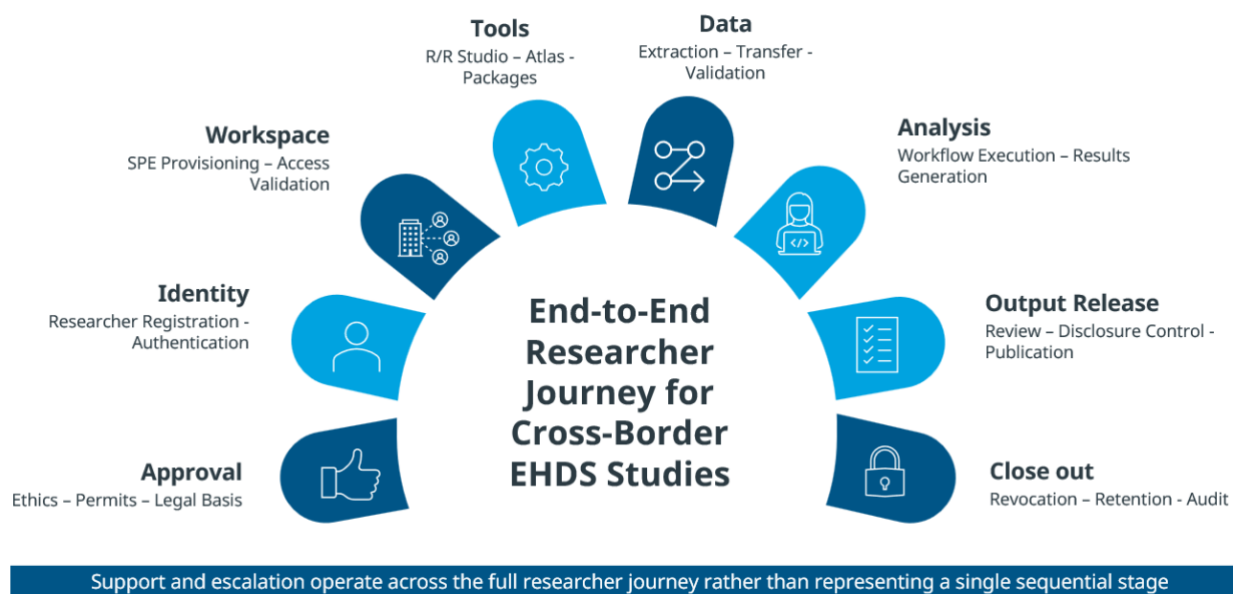
Readiness dimension	Current-state evidence from VALO2	Operational capability needed for greater EHDS readiness
Researcher onboarding	Foreign researchers required local support, translated guidance, and practical troubleshooting. TSD showed that authentication succeeded before full research-space access or permissions were ready.	Named users complete a validated access workflow supported by multilingual or dynamically translated documentation. The workflow should cover identity proofing, access approval, workspace entry, tool launch and data connectivity, with role-based permissions and day-zero testing completed before the analysis begins.
Analytical tooling	The analytical tooling required for OMOP/OHDSI studies was available across participating environments but differed in implementation, configuration and permissions. Successful execution depended on access to appropriate analytical tools (for example R/RStudio and ATLAS equivalent workflows) database connectivity, schema behaviour, package availability, write permissions and local technical support.	For studies using a common data model, SPEs publish a standard analytical tool profile describing available tools, programming environments, package installation arrangements, database access, permissions and data-storage capabilities. The study team's selected analytical workflow should be validated through successful execution of a representative test before analysis begins. For OMOP/OHDSI studies, this should include the relevant database, vocabulary, concept-set, intermediate storage and results-writing workflow.
Research data readiness	Protocol-critical variables such as PD-L1 and metastatic status were not consistently present in available OMOP extractions, even where related data existed or had been used in prior work.	Protocol-critical variables are assessed before protocol lock or data-request submission across source availability, structured extractability, common data model representation, standard-concept mapping, approved-delivery inclusion, completeness and analytical usability.
Cohort construction and data-minimisation approach	Norway provided the approved cohort after local application of inclusion and exclusion criteria, whereas the Finnish and Danish pathways required greater researcher involvement in cohort-	The location, ownership and validation of cohort construction are agreed before data access. Researchers receive sufficient documentation of inclusion and

Readiness dimension	Current-state evidence from VALO2	Operational capability needed for greater EHDS readiness
	construction using broader datasets, local rules and derived variables. The project did not establish that one model is universally preferable; each approach created different implications for data minimisation, transparency, researcher flexibility, local expert involvement and delivery time.	exclusion logic, derived variables, concept sets, source-data limitations and local validation, whether the cohort is constructed locally or within the researcher environment.
Output release	HUS Academic in Finland has a defined output release route: export requests are initiated through an automated website inside Academic, users receive an email link and log in using HUS credentials. Outputs must be anonymous and handled in accordance with Findata guidance. Depending on the disclosure risk assessment performed by the responsible reviewer during the output review process, outputs may require notification to Findata or formal anonymity review before release. VALO2 pilot study outputs were submitted for review as a precaution because some outputs were considered potentially higher risk. VALO2 pilot study output export request was submitted on 5 August 2026 and approval received on 8 August 2026. Denmark relied on researcher and PI responsibility for export governance. The Norwegian TSD pathway requires the designated approver acting on behalf of the project owner or responsible authority to review and approve the export, allowing the researcher to export results.	Each SPE has a published output release process specifying permitted output types, anonymisation and disclosure control criteria, the party responsible for disclosure-risk assessment and approval, notification or review requirements, expected turnaround times, and associated audit trail. Where national guidance applies, such as Findata guidance in Finland, this should be linked directly to the SPE user workflow.
Close-out and revocation	Documented revocation and close-out arrangements exist across the participating environments, although the evidence is not equivalent in scope. Public TSD documentation	Close-out checklist covers user removal, data deletion/retention, audit-log retention, and approved output archiving.

Readiness dimension	Current-state evidence from VALO2	Operational capability needed for greater EHDS readiness
	describes time-limited projects, termination of resource access at the project end date and subsequent deletion of project resources after a defined retention period unless archival arrangements apply. Final VALO2 pilot study close-out roles, evidence, data retention decisions and artefact ownership remain to be validated across sites.	

Abbreviations: EHDS, European Health Data Space; HUS, Helsinki University Hospital; OHDSI, Observational Health Data Sciences and Informatics; OMOP, Observational Medical Outcomes Partnership; PD-L1, Programmed Death-Ligand 1; PI, Principal Investigator; RBAC, Role-Based Access Control; SPE, Secure Processing Environment; TSD, Services for Sensitive Data.

Figure 1: Cross-border research depends on progression through a complete researcher journey rather than a single access process



Source: VALO2 Pilot Study Data Governance Workstream analysis.

The VALO2 pilot study can be understood as a practical test of the complete researcher journey required for future EHDS-style studies. While individual governance routes, operational models and technologies differed between participating countries, researchers ultimately needed to progress through a common sequence of activities:

Approval → Identity → Workspace → Tools → Data → Analysis → Output → Close-out

Support and escalation operate across the full researcher journey, from approval and onboarding through tooling, data access, analysis, output release and close-out, rather than representing a single sequential stage.

At each stage researchers needed to answer six operational questions:

- What do I need to do?
- Who owns this step?
- What information or approval is required?
- How long should it normally take?
- How do I know it is complete?
- Where do I escalate if it fails?

This journey provides a useful organising framework for interpreting the operational lessons identified throughout the project.

Interpretation

The VALO2 pilot study shows that successful EHDS implementation will depend not only on legal frameworks and technical infrastructure, but also on the quality of operational execution across the end-to-end researcher journey. Researcher-ready environments and associated researcher-access services require documented service models, validated workflows, clear support arrangements, transparent output release processes and reusable readiness evidence.

A further observation from the VALO2 pilot study is that approval pathways cannot be viewed solely as procedural differences. Finland, Denmark and Norway each apply different triggers for ethics review and secondary use approvals, creating materially different operational pathways for broadly similar research objectives. Finland generally does not require separate ethics review for register-based secondary use studies, whereas Norway typically requires ethical review where the purpose is to generate new knowledge about health and disease. Denmark applies a narrower ethics review requirement focused primarily on specific categories of sensitive bioinformatic data. The project therefore demonstrated that EHDS implementation will occur within diverse national governance frameworks, even where common European objectives exist.

3.1 What the VALO2 pilot study demonstrated

The VALO2 pilot study demonstrated that Danish researchers could access and analyse Finnish and Norwegian patient-level data within the secure environments used by those organisations, alongside analysis of Danish data in the team's established local environment. Governed output release pathways were completed for the Finnish and Norwegian results. The pilot nevertheless showed that operational readiness, onboarding, workflow validation, local expertise, protocol-variable availability,

cohort-definition methods and output governance materially influence study delivery. The project did not demonstrate equivalent maturity or fully harmonised pathways across all participating environments; rather, it identified the operational capabilities that require further development before cross-border research can be delivered through sufficiently consistent, scalable and routine services.

4 Cross-site comparison: current-state

The comparison below is intentionally practical: the purpose is to evaluate what a future cross-border study group would need to know before committing timelines. In addition to differences in tooling and operating models, the participating countries operate under substantially different regulatory and ethics review frameworks. These differences directly influenced mobilisation timelines, researcher onboarding, data access sequencing, and project risk exposure. The comparison therefore reflects both technical maturity and the broader governance environment in which each SPE operates.

Table 4: Participating environments offered different operating models and levels of evidence across the researcher journey

Capability dimension	Finland: HUS Acamedic	Denmark: Databricks TRE/SPE	Norway: TSD
Process ownership	HUS Acamedic team provisioned project-specific environment; HUS/site contacts coordinated access and user licensing. Public HUS Acamedic pages describe ordering routes and pricing.	Central Data Organisation and Central IT organisation enabled access; central platform team reviewed request and generated a deployment task/story in ITSM.	TSD project administrators appointed by the Norwegian local PI managed membership and roles via Selfservice; TSD staff provisioned users and support users without Norwegian eID.
Access request route	The principal investigator (PI) secured the appropriate study permit before a HUS Acamedic environment was ordered. Where a HUS study permit exists, HUS Acamedic is ordered through the Researcher's Desktop; otherwise, an alternative ordering route exists for research outside HUS. New users must register or be added by the study administrator.	The study was conducted under an existing study-specific approval covering comparisons of ICI efficacy. Additional approval from the hospital legal office was required before study replication and result sharing with IQVIA could proceed. The Danish pathway therefore focused primarily on operational study execution and analytical environment readiness. Based on information provided during the VALO2 pilot study, the process for internal/local researcher access was described as an	PI applies for project using Nettskjema; users apply for membership in TSD Selfservice and project administrators approve. International users can be invited where needed.

Capability dimension	Finland: HUS Acamedic	Denmark: Databricks TRE/SPE	Norway: TSD
		ITSM-driven request to create a project workspace. If Lakehouse data was required, relevant permits were included. Provisioning was described as automated through infrastructure-as-code. The equivalent pathway for foreign or non-Region H researchers remains to be validated.	
Approvals and permit traceability	A dedicated VALO2 study approval was initially obtained on 26 January 2026 and subsequent amendments approved by the HUS Chief Medical Officer on 11 March 2026. Access remained dependent on the applicable HUS permit arrangements, project setup and user licensing. External collaborators were required to complete a Confidential Disclosure Agreement (CDA).	Workspace/data access is linked to permits where applicable; traceability between the data permit and workspace is established if the approval contains a data permit.	Ethical/legal approvals are required by controllers; project creation requires approval evidence and membership approval by PI/project administrator.
Identity and login	Browser/Citrix VDI access; user licences per processing environment. The VALO2 pilot study showed that foreign users need translated guidance and local support. Researcher feedback indicates that login to HUS Acamedic did not by itself provide data access; a further login within the SPE and	Access is from approved regional infrastructure in the organisational domain, using SSO and MFA. Non-employees require organisational identity management provisioning. The VALO2 pilot study did not evaluate an external researcher access route. Any future access model	TSD Selfservice, password and One-Time Password (OTP) setup; ID-porten where available; magic-link route possible for users without Norwegian eID; login to Windows/Linux VMs via Unified Access Gateways. Researcher feedback indicates that initial TSD login resulted in a permissions error, and that R/RStudio

Capability dimension	Finland: HUS Acamedic	Denmark: Databricks TRE/SPE	Norway: TSD
	database configuration was required.	for researchers outside Region H would require separate validation.	installation required support from the Norwegian team.
Tools and compute	Windows/Linux virtual desktops including GPU options; tools include R, RStudio, Python, SPSS, Excel, Power BI and VS Code; Azure ML/DevOps options and private PyPI are referenced. For the VALO2 pilot study, R and RStudio were available, and ATLAS was available to some extent, although the researchers did not get ATLAS fully working because vocabulary data and patient data were delivered in separate batches. Packages could be installed directly from CRAN once configuration issues were resolved, and RStudio ran locally on the VDI.	SQL, R, Python and Scala supported; platform includes data engineering, data governance, data science, visualisation capabilities, approved AI models and Enterprise GitHub integration. For the VALO2 pilot study, Databricks notebooks and compute power were available within the Danish environment. Researchers were provided with personal Databricks workspaces and approved datasets through a Delta Sharing Catalogue. Data could be copied into Unity Catalogue for local enrichment and transformation. Analysis was performed through an RStudio environment hosted within Region H infrastructure and connected to Databricks via ODBC, rather than through native Databricks notebooks. Researchers reported that notebooks were technically capable but less suitable for large analytical workflows.	Tracker lists R, RStudio, Python, internal CRAN/Bioconductor/PyPI mirrors, HPC CPU/GPU and containers; packages needing admin rights installed by TSD staff on request. For the VALO2 pilot study, after installation requested by the Norwegian team, researchers had access to R and RStudio. Danish researcher feedback described the available compute as broadly comparable to HUS Acamedic.

Capability dimension	Finland: HUS Acaademic	Denmark: Databricks TRE/SPE	Norway: TSD
RBAC and audit	Project-specific isolated environments and per-environment user licensing; public source describes isolated processing environments.	Comprehensive RBAC across control plane and data plane, including identities, workspaces, compute, jobs and data via Unity Catalogue. Workspace and data access audit logs are in place.	Role-based PI/PA/PM/AM model, IAM groups/grants, network isolation and audit logs for file/API and notification events.
Data ingress and availability	Data extracted from HUS Data Lake or other permitted sources and loaded into a project-specific HUS Acaademic environment. Public material indicates projects can process data from HUS Data Lake, Findata or other permitted sources. In practice, the researchers needed to request missing vocabulary data, combine patient and vocabulary data into a local OMOP database and correct missing observation period data before analysis could proceed.	Dedicated people provide data to the project based on the data permit; interaction with researchers may be needed to align actual data delivery. The Danish analysis required local preparation work, including importing data into the SPE, merging pathology data into the OMOP database and extracting ECOG performance status from clinical notes using rule-based extraction. Additional concept mapping was also required because some pathology-related variables existed in the OMOP output but had not been mapped to the standard concepts required for analysis.	Data transfer routes include File API, S3 wrapper or encrypted disc import in tracker. The VALO2 pilot study real data availability depended on REC approval, patient notification, and transfer steps. Initial Norwegian mock data were provided as CSV files, requiring the researchers to assemble their own OMOP database; a later PostgreSQL dump could not be restored in TSD with the available tooling, while the current DuckDB file format did not present the same issue. The final Norwegian data comprised the locally defined approved cohort after inclusion and exclusion criteria had been applied. This reduced the cohort-construction work required within TSD, although it also meant that the Danish researchers had less direct visibility of the broader source

Capability dimension	Finland: HUS Acamedic	Denmark: Databricks TRE/SPE	Norway: TSD
			population and locally applied selection logic.
Output release and SDC	HUS Acamedic has a clearly described output release process: outputs must be anonymous and aligned with Findata guidance; exports are initiated through an automated Acamedic website; and, depending on assessed disclosure risk, the process may require notification to Findata or formal anonymity review. The VALO2 pilot study outputs were submitted for review as a precaution because some were considered potentially higher risk. Where formal review applies, the HUS description states that results may be published if no response is received within seven working days. Project experience subsequently demonstrated that the process can be completed in practice. The VALO2 pilot study output export request was submitted to Findata on 5 August 2026 and approval for release was received on 8 August 2026.	Aggregated results, figures and plots can be exported. According to the Danish research team, exports are currently governed through researcher and PI responsibility. No formal output review, approval or SDC process was identified within the validated project evidence.	Required outputs are aggregated results, figures and plots. Public TSD documentation describes role-based export controls. For the VALO2 pilot study, the designated Norwegian approver reviewed and approved the export request and confirmed the Danish researcher's export rights, after which the Norwegian results were released from TSD. The VALO2 pilot study provides practical evidence that this project-specific export pathway could be completed. Further documentation of the applicable review criteria, permitted output formats and expected turnaround would improve transparency and support more reliable planning for future external researchers.
Revocation and close-out	User licences/access removed via environment management; HUS terms state client	Access automatically revoked when the specified project time has passed.	Project administrators can disable users through TSD Selfservice. TSD projects have defined

Capability dimension	Finland: HUS Acamedic	Denmark: Databricks TRE/SPE	Norway: TSD
	material must be copied out where legally possible, after which HUS destroys client data unless legally required to retain it.		end dates; access to project resources ceases at termination; and project resources are deleted 90 days after the end date unless archival arrangements have been requested.
Documentation and training	Public website provides product, pricing and features; user materials and videos were described as coming soon; the VALO2 pilot study showed Finnish-language access pages and user guide currency issues.	Internal process documentation exists but was not provided because it is not public; training refers researchers to public Databricks materials.	Public UiO TSD user guide includes sections for project members, project admins, virtual machines, software, files/import/export and HPC.

Abbreviations: AI, Artificial Intelligence; API, Application Programming Interface; CDA, Confidential Disclosure Agreement; CRAN, Comprehensive R Archive Network; CSV, Comma-Separated Values; eID, Electronic Identification; ECOG, Eastern Cooperative Oncology Group; EHDS, European Health Data Space; GPU, Graphics Processing Unit; HPC, High-Performance Computing; HUS, Helsinki University Hospital; HUS Acamedic, Helsinki University Hospital Secure Processing Environment; ICI, Immune Checkpoint Inhibitor; IAM, Identity and Access Management; ITSM, IT Service Management; MFA, Multi-Factor Authentication; OHDSI, Observational Health Data Sciences and Informatics; OMOP, Observational Medical Outcomes Partnership; ODBC, Open Database Connectivity; OTP, One-Time Password; PI, Principal Investigator; PyPI, Python Package Index; R/RStudio, R statistical programming language and RStudio integrated development environment; RBAC, Role-Based Access Control; SDC, Statistical Disclosure Control; SPE, Secure Processing Environment; SSO, Single Sign-On; TSD, Services for Sensitive Data; UiO, University of Oslo; VDI, Virtual Desktop Infrastructure; VM, Virtual Machine.

4.1 Comparative researcher journey and service-level analysis

The VALO2 pilot study demonstrated that approval, onboarding, access, workflow readiness and output release should be treated as separate operational milestones rather than a single access journey. Future EHDS implementation, and wider Nordic efforts towards harmonised cross-border research services, would benefit from measuring not only whether processes and infrastructure exist, but whether they are delivered through consistent, understandable and effective operational services. This includes monitoring how services are experienced and delivered in practice, rather than simply confirming that the required capabilities are available.

The comparison below therefore considers both progression through the researcher journey and the operational dependencies associated with each milestone.

Table 5: Approval, access and analysis readiness milestones occurred asynchronously across participating environments

Milestone	Finland (HUS Acamedic)	Denmark (Databricks)	Norway (TSD)
Approval received	Initial approval 26 January 2026 Amendments approved 11 March 2026 by Chief Medical Officer	The study was conducted under an existing study-specific approval covering comparisons of ICI efficacy. Additional approval from the hospital legal office was required before study replication and result sharing with IQVIA could proceed	Conditional REC Approval 8 May 2026
Workspace provisioned	3 March 2026	Utilised an existing empty workspace	Evidence not available for validation
First user login	9 April 2026	Not applicable to operating model	14 April 2026
Study data available	31 March 2026	12 April 2026	Data for deceased patients 24 June 2026 Data for living patients 10 August 2026
First database connection	26 May 2026	12 April 2026	Evidence not available for validation
Required software/tools available	23 June 2026	Continuously	Evidence not available for validation
Analysis completed	30 July 2026	10 July 2026	7 September 2026
First output submitted	5 August 2026	Not separately recorded; export operated under researcher and PI responsibility	7 September 2026
First output released	8 August 2026	Completed; exact date not available in validated project evidence	9 September 2026

Abbreviations: HUS, Helsinki University Hospital; ICI, Immune Checkpoint Inhibitor; PI, Principal Investigator; REC, Regional Ethics Committee.

Where validation evidence was not available at the time of publication, entries reflect the best available project evidence and should not be interpreted as confirmation that the activity was incomplete or did not occur.

Project experience suggested that approval, onboarding, workflow readiness, analysis execution and output release should be considered distinct milestones rather than a single access journey. The participating countries reached analytical milestones at different times because approval, onboarding, data availability and workflow readiness dependencies did not progress in parallel. Although all three analyses and output pathways were ultimately completed, the experience demonstrates the need to plan multi-country delivery as an asynchronous process with phased reporting and explicit dependencies. The timeline comparison illustrates where milestones occurred at different points in the researcher journey and where approval, onboarding, data availability, tooling and workflow readiness became critical-path dependencies.

Future studies should capture these milestones prospectively using common definitions to support clearer comparison of approval-to-access and Time-to-Analysis-Ready performance across participating environments.

4.2 Operational impact analysis

While the individual issues identified in the VALO2 pilot study may appear minor when viewed in isolation, their cumulative effect was significant. Delays associated with ethical review, onboarding, permissions, tooling configuration, data preparation and workflow validation repeatedly affected mobilisation and analysis timelines. Importantly, many of these delays occurred after formal access had been granted, demonstrating that access approval alone is not an adequate indicator of study readiness.

The protocol included an infrastructure evaluation objective that considered the time required to progress from approval to data access. Project experience suggests that this measure provides a useful indication of infrastructure readiness but may not fully capture the point at which researchers can begin productive analytical work. Researchers frequently completed additional onboarding, configuration, tooling, data preparation and workflow validation activities after access had formally been granted.

The VALO2 pilot study therefore suggests that future EHDS readiness assessments may benefit from extending this concept beyond approval-to-access timelines through a broader Time-to-Analysis-Ready (TTAR) measure. TTAR could be defined as the elapsed period between completion of approvals required to initiate a study and successful execution of a representative analytical workflow against the approved dataset.

Unlike measures such as account creation, environment provisioning or first login, TTAR reflects the point at which a researcher can actually begin productive analysis. The project evidence is not yet sufficiently complete to propose TTAR as a formal performance standard, but the concept warrants further evaluation in future cross-border studies.

Researcher effort should be considered alongside elapsed time

The VALO2 pilot study also suggests that service performance should not be assessed solely through elapsed time measures. A process may appear operationally efficient because experienced local researchers perform substantial work independently, resolve issues through established local networks, or navigate institutional processes using prior knowledge and experience.

Future assessments should therefore consider indicators of researcher effort alongside elapsed time, including:

- number of manual transfers of work or information between teams, organisations or systems
- number and type of support interventions required, including helpdesk, technical, data, clinical and local expert support
- local specialist involvement required
- manual configuration activities
- workaround dependence
- repeat troubleshooting activities

Such measures may provide a more accurate indication of the scalability of future EHDS operating models. A service that appears fast because expert local researchers compensate for process complexity may not be equally effective when used by unfamiliar external researchers.

4.3 Infrastructure evaluation outcomes

In addition to the scientific objectives, the VALO2 pilot study included a formal infrastructure evaluation objective intended to assess the feasibility of accessing Nordic health data through SPEs. The protocol identified three evaluation dimensions:

- Time from ethics approval to data access
- Proportion of protocol-specified variables successfully extracted
- Cross-site data quality concordance metrics

The VALO2 pilot study experience indicates that all three measures are potentially useful indicators of operational readiness, although they were not captured with equivalent completeness across participating sites. Although the available measures were not captured with equivalent completeness across all sites, project experience demonstrated considerable variation between sites in the elapsed time between approvals, researcher onboarding, data availability and analysis readiness. The study also demonstrated that successful protocol execution depends not only on the existence of OMOP datasets but on the availability, extractability and analytical usability of protocol-specific variables. Finally, the project highlighted the importance of local validation, analytical quality review and contextual interpretation when comparing results generated from independently maintained OMOP implementations.

The final results also demonstrated that technical access and common-model representation do not necessarily create analytical comparability. Participating sites differed in cohort-selection methods, treatment definitions, variable availability, concept mapping, data completeness, follow-up and the local derivation of clinically important variables. These differences were considered sufficiently material that the researchers decided not to pool the site results or proceed with the planned meta-analysis. Future infrastructure and data readiness assessments should therefore evaluate not only whether a common analytical script can run, but whether the resulting cohorts, variables and outcome definitions are sufficiently comparable to support valid cross-site synthesis.

The findings suggest that approval-to-analysis timelines, protocol-variable availability and confirmed semantic interoperability should be considered core readiness indicators for future cross-border studies rather than secondary evaluation measures.

5 Site narratives: Finland, Denmark, Norway

The country narratives presented below are not intended to rank participating environments. The VALO2 pilot study tested different operating models under different legal, organisational and technical conditions. Denmark was not tested as an external researcher-facing SPE in the same way as Finland and Norway. The purpose of the comparison is therefore to understand which characteristics increased or reduced friction within the end-to-end researcher journey and to identify lessons relevant to future EHDS implementation.

The value of the VALO2 pilot study lies precisely in the fact that different operating models were tested. Finland, Denmark and Norway each provided insights that would not have emerged had only a single operational approach been examined. The objective is therefore not to identify a preferred national model, but to understand how differing governance arrangements, researcher support models, service designs and approval pathways influence the researcher experience and operational readiness for future EHDS-style studies, while identifying areas where greater Nordic harmonisation could improve the efficiency, transparency and scalability of cross-border research.

5.1 Finland – HUS Acamedic

Finland provides the most complete tested example within the VALO2 pilot study of a functioning external cross-border researcher access route, while also demonstrating that mature infrastructure still requires careful operational planning. HUS Acamedic allowed Danish researchers to access Finnish OMOP data remotely, with support from the HUS team. The research permit and data extraction pathway were progressed early, and HUS provided a useful end-to-end date sequence showing how commitment, permit, environment order, extraction, data import and first researcher access unfolded over time.

The public HUS Acamedic materials allow the Finnish environment to be described more concretely as a project-specific, isolated, browser-accessed SPE (HUS, n.d.). HUS Acamedic is ordered either through the HUS Researcher's Desktop where a HUS study permit exists, or via the external HUS Acamedic ordering route. Each project receives its own processing environment; access is managed through user licences, and the platform is cloud-based on Microsoft Azure (HUS, n.d.). This gives Finland a comparatively visible published service model, including pricing/order and feature information.

The Finnish process shows several strengths: an established SPE, experienced local collaborators, clear engagement from HUS contacts, and a pseudonymisation process that applies a HUS Data Lake pseudonym and a scope-specific research pseudonym before data enters the secure research environment. The project also benefited materially from an embedded HUS principal investigator (PI) and local technical/clinical support who could escalate, interpret and validate issues.

The HUS Acamedic output release process is initiated through an automated website inside the Acamedic environment. Researchers receive an email link and must log in using HUS credentials. Outputs leaving the environment must be anonymous and handled in accordance with Findata guidance (Findata, n.d.-a). The applicable route depends on the assessed disclosure risk: lower-risk outputs require notification, while outputs requiring additional assurance may be submitted to Findata for anonymity review (Findata, n.d.-b). Where formal review applies, the HUS description states that results may be published if no response is received within seven working days. This provides a useful example of an SPE output model where the export route is integrated into the environment

and explicitly linked to national anonymisation guidance. For the VALO2 pilot study, the research team was uncertain whether some outputs would be considered higher risk and therefore submitted them for review as a precaution. The request was submitted on 5 August 2026, and approval was received on 8 August 2026. This provides a useful project-specific example of risk-based output governance but should not be interpreted as meaning that every export requires prior Findata review or as establishing a general service-level commitment. Future studies would benefit from systematically capturing review turnaround times, query rates and publication impacts to better understand how output governance processes affect overall study delivery.

However, the VALO2 pilot study also showed that published environment capability does not remove the need for study-specific workflow validation. External researcher onboarding depended on Finnish-language guidance and translated instructions. The HUS Acamedic user guide was helpful overall but not up-to-date or sufficiently signposted for OMOP users, leading researchers to search for data in non-OMOP locations. Technical setup issues included outdated Comprehensive R Archive Network (CRAN) mirror instructions and authentication guidance not aligned with multi-factor authentication (MFA) enabled workflows. A subsequent system update also required the researchers to troubleshoot and reconfigure the CRAN mirrors during the analysis period, creating additional delay. This reinforces the need for change control, user notification and regression testing where secure-environment updates may affect an active analytical workflow. OMOP workflow issues also emerged around `write_schema` command, which prohibited the use of certain OHDSI functions, showing that read access to data is not enough to support standard Observational Health Data Sciences and Informatics (OHDSI) workflows.

Danish researcher feedback provides a more granular view of the Finnish researcher journey (VALO2 Lessons Learned Questionnaire Danish Response, 2026). Before analysis could start, the Danish team had to sign the collaboration agreement, register as users, read the HUS Acamedic instruction manual, create an account, set up authentication, configure RStudio for data access, request and obtain missing vocabulary data, combine patient and vocabulary data into a local OMOP database, and correct missing observation period data. This shows that HUS Acamedic was usable for cross-border OMOP analysis, but only after several study-specific configuration and data preparation steps had been completed.

The HUS Acamedic instruction manual, once translated into English, was described as covering most areas required by researchers and the account setup process generally worked when followed carefully. However, parts of the registration process were available only in Finnish, RStudio package installation guidance was outdated, code examples no longer reflected the current system configuration, and OMOP-specific workflow guidance appeared late in the manual. These findings highlight the importance of maintaining current, language-accessible and workflow-specific documentation for external researchers.

The Finnish data experience is important for future policy. Danish researchers identified Eastern Cooperative Oncology Group (ECOG) performance status, PD-L1 score, smoking status and biomarkers as missing or unexpectedly difficult to use. These issues were not simply data quality problems; they reflected the gap between what may exist in source systems or prior study logic, what is represented in OMOP, and what is actually included in the approved extraction. In several cases, it had been assumed that issues identified during the VALO1 pilot study had subsequently been addressed, but the VALO2 pilot study experience demonstrated that such assumptions cannot be relied upon without verification. One of the Danish researchers confirmed that issues were resolved either through local support, workarounds such as proxy markers, or omission of variables that could

not be incorporated. Future studies therefore need variable-level confirmation before extraction submission and a clear distinction between source availability, OMOP availability, extraction inclusion, and analytical usability. Although the final Finnish cohort was smaller than originally anticipated, the broader lessons relating to variable-level readiness, cohort construction, local validation and analytical comparability remain valid irrespective of the final explanation for the cohort size.

Cohort-construction in Finland also required significant interaction between the Danish researchers and Finnish experts. The Danish team applied the cohort logic within a broader dataset, but the rules depended on local interpretation of treatment pathways, derived variables and clinical documentation developed through repeated meetings and correspondence with the Finnish team. This provided researchers with visibility and flexibility, but also increased the effort required to reach a validated analytical cohort. The experience reinforces the need to agree cohort-construction ownership, document local derivation logic and include formal local validation before analysis is finalised.

The completion of the Finnish analysis provides important evidence that the HUS Academic pathway can support cross-border analytical execution in practice, provided that local expertise, variable-level validation and output release governance are available. However, the experience should not be interpreted simply as evidence that the environment was “ready” from the outset. The analysis was completed after study-specific configuration, local support, vocabulary/data resolution and output governance steps had been navigated. The policy lesson is therefore that a mature SPE can enable cross-border analysis, but only where the operational workflow from access through to export is actively managed and validated.

The Finnish experience also highlights broader EHDS implementation considerations beyond the VALO2 pilot study itself. Public analyses of the Finnish SPE ecosystem have identified fragmented information sources, differing service models, varying pricing approaches and interoperability challenges across audited environments (Vilpponen, et al., 2026). While Finland has established a mature national framework for secondary use of health data, cross-border researchers may still face difficulties comparing environments, understanding service capabilities and navigating differing access models. These observations are consistent with lessons identified during the VALO2 pilot study and reinforce the need for transparent capability statements and standardised onboarding approaches.

Overall, Finland provided practical evidence that an external researcher pathway can support cross-border analysis and governed output release, while demonstrating the continuing importance of study-specific configuration, local support and workflow validation.

5.2 Denmark – Databricks Trusted Research Environment (TRE) and researcher experience

Denmark occupies a different position from Finland and Norway in the VALO2 pilot study. It is both a participating site and the home analytical environment for the Danish research team, who also accessed the Finnish and Norwegian SPEs. This makes the Danish team’s perspective central to the final report: they can describe the practical researcher journey across all three environments and compare differences in tooling, documentation, permissions, data availability and output workflows. However, the VALO2 pilot study tested Denmark primarily as the home analytical environment for the Danish research team, rather than as an externally accessed researcher-facing SPE equivalent to HUS Academic or Services for Sensitive Data (TSD).

The Danish study used an existing study-specific approval covering comparisons of immune checkpoint inhibitor (ICI) efficacy that had previously been applied in a non-OMOP project. Additional approval from the hospital legal office was required before the study could be repeated for the VALO2 pilot study and results shared with IQVIA.

In the VALO2 pilot study operating model, Databricks functioned as the governed data and analytics platform used by the experienced local analytical team rather than as a complete externally accessed researcher environment. The Danish Databricks TRE access model was described by the local team as an IT Service Management (ITSM) driven process in which a researcher requests creation of a project workspace and attaches relevant permits if data from the central Lakehouse is required. The central platform team reviews the submission and, where approved, creates a deployment story in ITSM. Provisioning is automated using infrastructure-as-code, including creation of the required Active Directory group and related artefacts (SPE Discovery Tracker; Danish Researcher Questionnaire Response). This provides useful evidence of internal process maturity.

A project supporter then reviews permits and ensures the required data are made available in the workspace, after which researchers are added to the relevant Azure AD group. This indicates that Denmark has an established internal process for creating project workspaces, linking access to permit conditions where applicable, and enabling researchers to work within a governed Databricks-based analytics environment. The available evidence supports the conclusion that the Danish environment is mature and effective for authorised local analytical teams.

Danish researchers confirmed that the Danish environment was the most familiar and operationally straightforward for their team, largely because they already had prior experience with the tools, data structures, local processes and technical constraints (VALO2 Lessons Learned Questionnaire Danish Response, 2026). This familiarity materially reduced friction. However, the Danish analytical workflow was not simple or fully pre-packaged. Before analysis could begin, the team still needed to request data import into the SPE, merge pathology data into the OMOP database because pathology is not part of the default OMOP implementation in the Capital Region of Denmark, extract ECOG performance status from clinical notes using automatic rule-based extraction and set up their RStudio connection to Databricks. A limited amount of concept mapping was also required because some pathology-related variables were present in the OMOP output but were not mapped to the standard concepts required for the analysis.

The Danish experience is therefore valuable, but the lesson should be framed around local analytical autonomy and researcher productivity rather than cross-border SPE access readiness. The Danish researchers indicated that they did not rely on formal guides, that support was available for data extraction and that many issues were resolved directly by the team using established local knowledge. Within Databricks, researchers were provided with personal workspaces where approved datasets were made available through a Delta Sharing Catalogue. Researchers could then copy data into their own Unity Catalogue where additional transformations, enrichment activities and derived variables could be created. Compute resources were provisioned using a usage-based model. While analyses could technically be performed using native Databricks notebooks, the Danish researchers considered notebooks less suitable for larger analytical workflows and therefore connected an RStudio environment hosted within Region H infrastructure to Databricks via ODBC. This provided a more familiar and efficient analytical experience and enabled the researchers to retain flexibility within their workflow.

The Danish experience therefore provides evidence of how an experienced local team can operate productively within a mature Databricks-based analytics ecosystem. Its principal lessons concern

researcher autonomy, tooling flexibility, data preparation, OMOP adaptation and integration with familiar analytical workflows. It does not, on its own, validate a repeatable external cross-border access route; any future researcher-facing model would require dedicated validation of its governance, onboarding, support and technical arrangements.

The Danish team's practical experience is also a major source of project learning. They developed code on Danish data, reused/adapted the Danish analytical framework for Finland, and helped identify environment-specific barriers in both HUS Academic and TSD.

The Danish questionnaire response remains an important source of evidence because it captures the same research team's practical experience across the three operating environments, including differences in onboarding, documentation, permissions, tooling, data preparation and workflow execution.

5.3 Norway – TSD

The Norwegian pathway illustrates how regulatory interpretation and post-approval conditions can materially affect cross-border study delivery. The project initially expected the local governance pathway to be comparable to that used for the VALO1 pilot study and other relevant OMOP-based real-world evidence activities. However, unlike the VALO1 pilot study, which proceeded through a local governance pathway, the local assessment determined that the VALO2 pilot study constituted new research requiring Regional Ethics Committee (REC) approval. This determination was received only a few days after the REC monthly submission deadline and highlighted that governance assumptions based on previous studies should not be relied upon without formal confirmation. This created an initial delay of approximately four weeks before the next submission deadline could be met. The REC website indicated a six-to-eight-week lead time for review and decision; in practice, the project waited nearly ten weeks before conditional approval was received. The classification of the VALO2 pilot study as research rather than quality assurance therefore became a major schedule driver. Conditional approval required patients whose data were to be used to receive a study-specific information sheet and be given a four-week period in which to opt-out. This condition applied to living patients. Data relating to deceased patients were not subject to the same notification requirement and could therefore be progressed earlier, while use of data relating to living patients remained dependent on completion of the notification and opt-out process.

The consortium's discussions with Norwegian stakeholders highlighted that the categorisation of a project as research or quality assurance may not always be straightforward. Similar activities had previously been considered quality assurance in some contexts, whereas the VALO2 pilot study was classified as research requiring REC approval. This illustrates how interpretation of regulatory requirements can become a significant project risk in cross-border studies.

The TSD discovery evidence and public University of Oslo (UiO) user guidance show that TSD has a well-documented access and project administration model (du Toit, 2025; University of Oslo, n.d.). Researchers apply for project membership through TSD Selfservice, project administrators approve membership, users set a TSD password and one-time password, and access is then provided through TSD virtual machines. The documentation also records that users without Norwegian eID follow a dedicated access pathway. The process includes invitation by a project administrator, provision and review of identity information, issuance of a time-limited authentication link and completion of account creation by the user. This provides evidence that TSD has established procedures to support international collaboration beyond users possessing Norwegian electronic identities, which is important for cross-border researcher access. TSD supports role-based project

administration, internal package mirrors for R/Python ecosystems, high-performance computing, and container options (du Toit, 2025; University of Oslo, n.d.).

Project experience showed that documented platform capability still needs to be configured for the specific study workspace. Danish researchers were able to authenticate but initially could not enter the research environment due to permissions. Later, access to the environment and visibility of mock data were achieved while deployment of R/RStudio remained a further dependency. These issues reinforce the distinction between platform access, project workspace access, and analytical workflow readiness. Future projects should require an end-to-end TSD access validation checklist that covers login, workspace entry, tool launch, package availability, data visibility, write permissions, and output handling.

Because access to real Norwegian patient data remained dependent on completion of the REC conditions, patient notification and associated data preparation activities, mock data were introduced as an interim mitigation. The intention was to allow the Danish researchers to become familiar with the TSD environment, complete initial technical setup and begin preparing the analytical workflow without waiting for access to the final study dataset.

Danish researcher feedback provides a more detailed view of the TSD user journey (VALO2 Lessons Learned Questionnaire Danish Response, 2026). Before analysis could start, the Danish researchers needed to sign the collaboration agreement, create a user account with the Norwegian team, set up authentication, read the TSD Frequently Asked Questions (FAQ) on data handling in the SPE, and request installation of R and RStudio. The TSD FAQ was described as helpful, intuitive, and easier to navigate than the longer HUS Acomedic documentation. However, TSD access was not immediately analysis-ready: initial login produced a permissions error, access to the virtual Personal Computer (PC) had to be resolved by TSD administrators, and researchers were not permitted to install required software themselves.

The mock data created by the OUS team enabled the Danish researchers to familiarise themselves with TSD, resolve some initial environment issues and align data formats with the Norwegian team. However, they were not sufficiently representative for meaningful script validation. In parallel, access to data relating to deceased patients provided a phased route for progressing part of the analysis while data relating to living patients remained subject to the notification and opt-out process. The experience suggests that SPEs benefit from providing representative test datasets before live data become available. Even fully synthetic or dummy datasets can support onboarding, environment validation and workflow testing, while more representative synthetic datasets can provide additional value for analytical preparation and script validation.

The distinction between environment familiarisation and analytical validation is important. Relatively simple synthetic or mock data may be sufficient to test access, file transfer and basic software configuration. Data intended for analytical workflow validation must instead be purpose-designed to reproduce the necessary schema, concept coverage, variable relationships, date logic, missingness patterns and technical formats while maintaining appropriate privacy protection and avoiding disclosure of real patient information. The Norwegian experience therefore illustrates that synthetic-data design should be governed by the intended validation use case rather than by a general objective of resembling the final dataset. The final Norwegian data delivery differed from the Finnish workflow because the Norwegian team applied the inclusion and exclusion criteria locally and provided the approved cohort to the Danish researchers. As a result, the Danish team had less need to use ATLAS for cohort-construction within TSD, although cohort and concept-set documentation remained important for transparency and interpretation. This approach reduced the time required

between access to the final dataset and completion of analysis, but it also placed greater responsibility on the local team to document and validate the cohort-selection logic.

While the Norwegian experience created significant schedule impact, it also provided some of the most valuable policy insights within the VALO2 pilot study. The project highlighted how differences in ethics classification, patient notification requirements and regulatory interpretation can fundamentally alter study design and delivery. These findings are directly relevant to EHDS implementation because they demonstrate that harmonised legislation alone will not remove operational variability. National and regional governance processes, including the role of ethics committees where they form part of standard approval pathways, can continue to influence study timelines, access decisions and operational delivery. Greater consistency in interpretation and implementation will therefore remain important for enabling efficient cross-border research.

The Norwegian experience demonstrated that EHDS implementation challenges may arise not only from differences in legislation, but from differences in how broadly similar studies are interpreted and operationalised by local governance bodies. This represents a material operational challenge for future cross-border research because approval requirements and timelines may differ even where study objectives appear broadly comparable.

Public TSD documentation describes a formal, role-based export-control model. Project administrators can manage export privileges, authorised project members may submit outputs for export and activity can be reviewed through TSD Selfservice (University of Oslo, n.d.; Services for Sensitive Data, 2026). In the VALO2 pilot study, the designated Norwegian approver reviewed and approved the export request and confirmed the Danish researcher's export rights. The Norwegian results were subsequently released from TSD and incorporated into the study reporting. This provides practical project evidence that the export pathway could be completed, while more explicit documentation of applicable review criteria, permitted formats and expected turnaround would improve transparency and support more reliable planning for future external researchers. The public documentation also provides a clearer account of the TSD project lifecycle. TSD projects are time and purpose-limited, with an end date defined in accordance with the project's ethical approval. The principal investigator is notified before project termination; access to project resources ceases at the end date; and project resources are subsequently deleted after a defined retention period unless archival arrangements have been requested (University of Oslo, n.d.; Services for Sensitive Data, 2026). At the time of finalising this report, equivalent evidence of project-specific close-out responsibilities, retention decisions and access revocation had not been confirmed across all participating sites.

6 Cross-cutting lessons learned

6.1 Cross-border research through the tested Nordic SPE pathways is feasible

The VALO2 pilot study demonstrated that authorised researchers could access and analyse patient-level data within externally hosted secure environments in Finland and Norway and release approved outputs without transferring patient-level data outside the data-holding organisation. Alongside the Danish local analysis, this provides practical evidence that the tested operating model is feasible.

6.2 Analysis completion does not necessarily mean investigation completion

The VALO2 pilot study demonstrated that analyses could be completed across all participating environments, but successful delivery depended on approvals, onboarding, data readiness, tooling, researcher support and output release processes. The project also demonstrated that access to data and analysis readiness can occur much later than formal study approval. Delays associated with approvals, onboarding, workspace readiness and data availability reduced the time available for follow-up investigation of emerging findings. This limited the opportunity to fully explore issues such as the unexpectedly small Finnish cohort, the final Norwegian cohort composition, and the analytical comparability of site results before project close-out. Future cross-border studies should therefore plan sufficient contingency not only to complete analysis, but also to investigate and resolve unexpected findings that emerge during execution.

6.3 Mobilisation readiness must be treated as a gated activity

The VALO2 pilot study began with delays because Data Governance Working Group contacts, SPE contacts and country-specific access coordinators were not fully available at mobilisation. Future projects should not treat stakeholder identification as an early workstream task; it should be a mobilisation gate before timelines are baseline approved.

6.4 Approval pathways are schedule drivers, not background assumptions

Norway showed that local, regional and national approval routes can materially shift the critical path. Approval pathways, submission deadlines, review windows, study categorisation risk, and possible post-approval conditions should be validated during protocol development. The VALO2 pilot study demonstrated that approval risk is not limited to review timelines. Regulatory interpretation itself can become a major delivery risk. The Norwegian experience showed that projects which appear similar on paper may be classified differently by ethics committees depending on how objectives, data access arrangements and cross-border researcher involvement are interpreted. Future studies should therefore assess not only approval routes and timelines but also the likelihood of differing research versus quality assurance classifications.

6.5 SPE discovery should be a signed-off readiness deliverable

The SPE Discovery Tracker was valuable because it asked operational questions about who enables access, how users are approved, what identity controls are used, what tools are available, whether role-based access control (RBAC)/audit logs exist, whether training materials can be shared and how access is revoked. Future projects should make this a signed-off deliverable before analysis timelines are committed.

6.6 Access validation must mean workflow readiness

A user account or successful login is not a sufficient milestone. Danish researcher feedback shows that access maturity should be assessed across several layers: account creation, workspace access, data access, tool availability, package installation, database connectivity, ability to create and store intermediate analytical outputs, workflow execution and output export. Finland demonstrated that login did not equal data access and that additional database configuration was required. Norway demonstrated that login did not initially equal virtual PC or tool access. Denmark demonstrated that a familiar local environment can be efficient, but still requires data import, data transformation and RStudio-to-Databricks connectivity. Future studies should therefore define a formal “analysis-ready” milestone based on completion of a representative test workflow rather than account provision alone.

6.7 Access problems require a common triage and escalation model

The VALO2 pilot study demonstrated that operational issues initially described as “access problems” frequently had different underlying causes. Some were related to governance approvals, some to permissions, some to tooling, and others to data configuration or workflow readiness.

Future cross-border studies should classify issues consistently across categories such as:

- Regulatory and approval
- Identity and onboarding
- Permissions and RBAC
- Workspace and tooling
- Data provisioning
- OMOP readiness and data quality
- Output release

Public TSD documentation provides an example of a tiered support arrangement in which cases move from first-line helpdesk support to trained TSD superusers, then to the specialist TSD support team and relevant technical specialists where required. This illustrates how a visible escalation model can connect general user support with platform-specific expertise. For cross-border studies, the researcher-facing guidance should make clear how this organisational support pathway connects to the project’s own PI, local study navigator, data specialists and analytical leads.

Each category should have a clearly defined owner and escalation pathway. Early categorisation reduces unnecessary escalation and supports more efficient problem resolution.

6.8 OMOP readiness is variable-level, not database-level

An OMOP database can exist and still not be analysis-ready or analytically comparable with another OMOP database. Danish researcher feedback shows that readiness must be assessed at variable, vocabulary, concept mapping, schema, cohort-definition and workflow levels. In Finland, the team had to request missing vocabulary data, combine patient and vocabulary data into a local OMOP database, correct missing observation period data, and work around missing or difficult variables including ECOG performance status, PD-L1 score, smoking status and biomarkers. In Denmark,

pathology data and ECOG performance status required local enrichment, extraction or mapping because they were not fully available through the default OMOP implementation, and a limited amount of additional concept mapping was required for pathology-related variables before analysis could proceed. In Norway, early data formats required the researchers to assemble or adapt the database before it could be used, while the final delivery comprised a locally constructed approved study cohort. Future studies should therefore treat OMOP readiness as a tested analytical state, not as a binary statement that OMOP data exists.

The VALO2 pilot study demonstrated that the following states should be considered separately:

- Data exist in source systems
- Data have been extracted
- Data are represented within OMOP
- Variables are mapped to the standard concepts required for the analysis
- Data are included in the approved extraction
- Cohort-selection and derivation logic are documented and locally validated
- Data are analytically usable for the protocol
- Results are sufficiently comparable across sites for valid synthesis

The decision not to proceed with the planned meta-analysis provides direct evidence of the distinction between structural interoperability and analytical comparability. The sites differed substantially in cohort-selection methods, treatment definitions, variable availability and data completeness. Pooling the results was therefore considered likely to introduce considerable uncertainty without providing meaningful additional value. OMOP supported a common analytical framework, but it did not remove the need to assess whether the resulting cohorts and variables were comparable enough to combine. The experience demonstrates that a common analytical script and a common data model can support reproducible analytical execution without necessarily producing directly comparable analytical populations. Future EHDS-style studies should therefore distinguish between script portability, structural interoperability and analytical comparability.

Future studies would benefit from maintaining detailed and regularly updated metadata catalogues describing variable availability, OMOP representation, standard concept mappings, inclusion within approved extracts and known limitations. Such catalogues can improve transparency and reduce uncertainty during study design and feasibility assessment. However, metadata alone cannot ensure analytical comparability. Variable-level semantic review and documented mapping decisions remain necessary to establish whether apparently equivalent variables can be used consistently across sites.

6.9 Cohort-construction requires defined ownership, transparent logic and local validation

The VALO2 pilot study demonstrated that cohort-construction is not a purely technical implementation step. It requires decisions about where inclusion and exclusion criteria are applied,

who interprets locally derived variables, what data are made available to researchers and how the resulting cohort is validated.

Different approaches were used across the participating sites. In Norway, the local team applied the approved inclusion and exclusion criteria before providing the final cohort to the Danish researchers. This reduced the cohort-construction work required within TSD and supported faster progression from final data access to analysis. In Finland and Denmark, researchers had greater involvement in constructing or refining the cohort within broader datasets, supported by local expertise and locally developed derivation rules.

Neither approach should be treated as universally preferable. Local construction may support data minimisation, reduce researcher burden and make greater use of source-data expertise. Researcher-led construction may provide greater flexibility and direct visibility of attrition and sensitivity to alternative definitions. The appropriate model depends on the quality of the data catalogue, documentation of available variables, complexity of local derivations, governance constraints and the capability of the research team.

Future cross-border studies should therefore agree the cohort-construction model before data extraction. The agreed approach should define:

- ownership of inclusion and exclusion logic
- responsibility for local clinical and data interpretation
- documentation of concept sets and derived variables
- visibility of cohort-attrition
- local validation and sign-off
- the data context made available to researchers
- the process for resolving changes or discrepancies

The consortium discussions also highlighted the importance of iterative feasibility assessment. Initial estimates based on broad disease populations may differ substantially from final analytical cohorts once protocol criteria, local derivations, approved extraction rules and variable availability are applied. Future studies should therefore treat feasibility assessment as an iterative process supported by documented cohort-attrition analysis rather than as a single pre-study estimation exercise.

For EHDS implementation, scalable cohort feasibility will require better data catalogues and documentation so that researchers can understand available populations and variables before submitting a request. Local clinical and data expertise will nevertheless remain necessary where electronic health-record data require institution-specific interpretation.

6.10 Data provisioning must support change, not only initial delivery

Research data provision should not be treated as a one-time event. During the VALO2 pilot study, analytical activities identified situations where variables, mappings, extraction logic or dataset content required clarification, correction or amendment.

An environment should therefore not be considered fully research-ready simply because it can deliver an initial extract. Research-ready services should also provide a transparent and proportionate process for approved correction and re-extraction requests.

Future study mobilisation should therefore assess:

- correction pathways
- re-extraction processes
- expected lead times
- escalation routes
- governance requirements.

6.11 Researcher confidence depends on extraction provenance

The VALO2 pilot study demonstrated that researchers require more than access to an approved dataset. They also need sufficient understanding of how that dataset was created. Questions regarding whether variables originated from source systems, OMOP transformations, manual derivations, enrichment processes or extraction-specific logic arose repeatedly during analytical activities.

Future cross-border studies should ensure that researchers can access proportionate information regarding:

- source systems used
- key transformation logic
- inclusion and exclusion decisions
- variable derivations
- OMOP mapping assumptions
- known extraction limitations
- quality-control activities performed

The VALO2 pilot study experience also demonstrated that stronger extraction provenance can help researchers understand unexpected differences between anticipated and delivered study populations, including situations where final cohorts are substantially smaller than originally expected. Extraction provenance improves analytical transparency, reduces duplicate investigation and helps researchers interpret study findings more confidently. The project suggests that extraction provenance should be considered a research-readiness capability rather than simply a technical implementation detail.

6.12 Local SMEs are indispensable for scientific validity

Cross-border studies require more than secure access mechanisms, documented processes and technical platforms. The VALO2 pilot study demonstrated that local expertise remains essential for transforming data access into scientifically valid research.

A common assumption within international data-sharing initiatives is that common data models and standardised analytical approaches reduce dependency on local knowledge. While the VALO2 pilot study demonstrated the significant benefits of OMOP standardisation, the project also showed that local expertise remained critical to understanding data provenance, variable availability, clinical context, institutional processes and analytical feasibility.

Importantly, the VALO2 pilot study highlighted that two distinct forms of local expertise contributed to successful progression of the study.

Local data and clinical subject matter experts

Local data and clinical SMEs were required to:

1. explain coding practices and local data structures;
2. validate protocol feasibility against available data;
3. interpret differences in variable completeness and availability;
4. advise on derivations, transformations and mappings;
5. explain treatment pathways and clinical context;
6. support interpretation of unexpected findings;
7. identify scientifically appropriate workarounds where variables were unavailable.

Several challenges encountered during the study, including interpretation of variables such as PD-L1 status, ECOG performance status, smoking status and metastatic disease, required detailed local knowledge that could not be inferred from OMOP structures alone. The project demonstrated that common data models improve structural interoperability but do not eliminate the need for local scientific interpretation.

Local institutional navigators

The VALO2 pilot study also highlighted a second role that was equally important but different in nature: the local institutional navigator.

These individuals were required to:

1. navigate organisational structures;
2. coordinate approval and permit processes;
3. identify the correct operational contacts;
4. progress data extraction and provisioning activities;
5. escalate issues through local governance channels;

6. coordinate interactions between researchers, platform teams and data holders;
7. provide continuity across multiple institutional processes.

The project experience demonstrated that progression through complex organisational and governance activities was often accelerated where a knowledgeable local contact could coordinate stakeholders and navigate internal processes. While this was also evident during the VALO1 pilot study, the VALO2 pilot study demonstrated that the role remained equally important under a cross-border researcher access model and expanded to include onboarding, environment access, permissions, provisioning, operational troubleshooting and output release activities. This was particularly important during mobilisation, onboarding, data provisioning and issue resolution activities.

EHDS implementation implications

An important lesson emerging from the VALO2 pilot study is that successful cross-border research currently depends upon both types of expertise. Data and clinical SMEs provide scientific validity. Local navigators provide operational continuity.

Future EHDS implementation should aim to reduce dependence on informal personal relationships by improving documentation, process transparency and service maturity. However, for the foreseeable future, cross-border studies would benefit from identifying a named local study navigator alongside technical, data and clinical SMEs during mobilisation.

The project therefore suggests that local expertise should be considered a core component of EHDS operational readiness rather than an optional support function. Common governance frameworks and common data models improve interoperability, but local knowledge remains essential for both scientific and operational success.

6.13 Cross-border collaboration accelerated learning

The VALO2 pilot study demonstrated that the value of cross-border research extends beyond access to health data. The project created opportunities for researchers, platform teams, governance experts, ethical experts and data custodians from different Nordic countries to exchange practical experience regarding approvals, onboarding, pseudonymisation approaches, OMOP implementation, analytical workflows, output governance and researcher support models. The collaboration enabled participating organisations to compare operating models, identify common challenges and share practical solutions that might not have emerged through isolated national initiatives.

Several lessons captured during the VALO2 pilot study emerged through collaborative discussion between participating countries rather than through formal platform documentation alone. Experiences from Finland, Denmark and Norway helped contextualise local challenges, challenge assumptions regarding readiness, and identify opportunities for future harmonisation. The parallel Ethical Expert Group activities similarly provided valuable insights into how different countries interpret and operationalise ethical governance requirements for secondary use of health data. (VALO2 Ethical Expert Group, 2026a; VALO2 Data Governance Working Group Meeting Notes, 2026).

Future EHDS implementation should recognise structured knowledge exchange as a strategic capability rather than an incidental project benefit. Pilot studies such as the VALO2 pilot study

generate value not only through the research findings themselves but also through the practical learning created between participating organisations. Supporting mechanisms for systematic knowledge sharing may therefore accelerate EHDS readiness and reduce duplication of effort across future Nordic initiatives. This may be particularly valuable in a Nordic context, where participating countries share many common characteristics in healthcare organisation, data infrastructure and governance models. In a Nordic context, structured collaboration may help participating countries identify areas where shared terminology, processes or minimum service expectations are achievable, while recognising continuing national and organisational differences.

6.14 The transition from VALO1 to VALO2 required both knowledge transfer and operating model adaptation

The VALO2 pilot study demonstrated that moving from a locally executed federated model to cross-border researcher access required more than reusing the common data model, analytical code or lessons from the original pilot. Previous knowledge needed to be transferred and revalidated, while the project also had to address a different set of operational requirements associated with researcher identity, onboarding, workspace access, permissions, analytical tooling, support and output release. Several issues encountered during the VALO2 pilot study had been identified, investigated or partially resolved during earlier VALO1 pilot study work (VALO project, 2026; Data Governance Lessons Learned Log, 2026). Relevant knowledge relating to variable definitions, local derivations, data limitations, analytical decisions and workarounds was not always readily available at the VALO2 pilot study mobilisation. However, repeated investigation did not result solely from incomplete knowledge transfer. OMOP implementations and local extraction processes continued to evolve between the pilots. For example, the Danish OMOP extract, transform and load (ETL) process was substantially rewritten and became an established option for data delivery between the VALO1 pilot study and VALO2 pilot study. Previous issues might therefore have been resolved, altered or superseded. Future projects need both effective transfer of prior knowledge and explicit revalidation of that knowledge against the current production implementation.

Compared with the original VALO1 pilot study, the VALO2 pilot study gave the Danish researchers substantially greater direct visibility of the Finnish and Norwegian data, analytical environments and workflow execution processes. Researchers could undertake cohort review, analytical validation, troubleshooting and workflow execution within the SPEs rather than depending solely on local teams to run common analytical scripts and return aggregated outputs. This supported more iterative investigation of data availability, mappings and workflow constraints. However, it did not eliminate dependence on local teams for approvals, data preparation, local derivations, cohort validation, technical support, clinical interpretation and output governance.

This finding highlights an important distinction between data interoperability and knowledge interoperability.

Data interoperability enables datasets to be exchanged, analysed and interpreted using common structures and standards. Knowledge interoperability ensures that the contextual understanding required to use those datasets effectively is preserved between studies.

The VALO2 pilot study demonstrated that valuable knowledge may exist in multiple forms, including:

- variable definitions and business rules;
- local derivations and transformation logic;

- OMOP mapping assumptions;
- known data quality limitations;
- protocol-specific feasibility assessments;
- successful mitigations and workarounds;
- unresolved analytical questions;
- lessons from previous researcher experiences;
- relationships with key local experts and support teams.

Without deliberate transfer mechanisms, this knowledge may remain embedded within previous project documentation or retained only by individuals involved in earlier studies.

The project experience suggests that a common data model alone is insufficient to preserve operational and scientific knowledge. Information regarding variables, mappings and population characteristics may remain highly dependent on local context and historical project experience. Consequently, future studies may invest significant effort rediscovering information that is already known within participating organisations.

Recommended future approach

Future studies should therefore preserve reusable knowledge from both operating models: federated execution assets such as validated code, concept sets and site-specific adaptations, and researcher access assets such as onboarding guides, workspace acceptance tests, support pathways and output release procedures. Where appropriate, non-confidential elements of this knowledge should be captured in reusable appendices or companion materials so that future studies can build on previous experience rather than rediscover known issues and solutions.

A study knowledge pack should include:

- protocol-critical variables assessed in previous studies;
- data availability findings and known limitations;
- local derivations and mapping approaches;
- prior analytical decisions and rationale;
- unresolved gaps and future considerations;
- named data, technical and clinical experts;
- lessons learned from previous researcher journeys;
- confirmation of whether previous corrections or mappings have subsequently been incorporated into production OMOP implementations.

Several components of such a study knowledge pack are already captured across the VALO1 pilot study and the VALO2 pilot study lessons learned reports; however, future initiatives may benefit from

consolidating these artefacts into a reusable knowledge package that reduces duplication of effort and accelerates mobilisation for subsequent cross-border studies.

EHDS implementation implications

The lesson extends beyond the VALO2 pilot study. Future EHDS implementation will require not only interoperability of systems, governance frameworks and data models, but also mechanisms for preserving and sharing operational experience between studies.

The project therefore suggests that data interoperability and knowledge interoperability should be viewed as complementary capabilities. Reusable knowledge assets may ultimately become as important to successful cross-border research as reusable technical infrastructure.

6.15 Synthetic/mock data needs a defined purpose and acceptance criteria

Synthetic or mock data should be designed against an explicit use case. In TSD, generated mock data supported environmental familiarisation, completing initial setup activities and aligning data file formats with the Norwegian team. However, the mock data were not sufficient for meaningful script validation because their schema, concept coverage and variable relationships did not reproduce the requirements of the planned analytical workflow (VALO2 Lessons Learned Questionnaire Danish Response, 2026). This demonstrates that synthetic/mock data can be valuable, but only if its purpose is clear. If the purpose is onboarding, simple mock data may be sufficient. If the purpose is analytical validation, the synthetic dataset should be purpose-designed to reproduce the necessary structures, relationships, date logic, missingness patterns and technical formats while ensuring that the resulting dataset does not contain identifiable records or disclose information about real individuals.

6.16 Documentation must be live, workflow-specific and language-accessible

Documentation must be maintained as a live operational asset, not a static onboarding document. Danish researcher feedback shows that the HUS Academic English instruction manual covered almost all areas, but parts of the registration process were available only in Finnish, the RStudio package installation section was outdated, code examples did not work because backend parameters had changed, and OMOP-specific workflows were described too late in the manual. The Finnish experience also demonstrated that documentation management must be connected to technical change control. A system update during active analysis required reconfiguration and troubleshooting of CRAN mirrors. Future SPE operating models should notify active users of changes that may affect analytical workflows, test representative workflows following material updates and provide current recovery guidance. In contrast, the TSD FAQ was described as sufficient, helpful, and easier to navigate. Cross-border readiness will therefore require current master documentation, clear version control, workflow-specific quick-start routes for OMOP studies, and easy-to-update FAQ-style guidance for common setup issues (VALO2 Lessons Learned Questionnaire Danish Response, 2026).

6.17 Data minimisation and research usability need explicit design choices

The VALO2 pilot study demonstrated that data minimisation and research usability must be designed together. Providing only a locally constructed approved cohort can reduce exposure and researcher workload but requires transparent cohort logic and strong local validation. Providing a broader dataset can support researcher-led cohort-definition, attrition analysis and sensitivity testing, but may increase data exposure and place greater demands on governance and analytical support. Future

studies should document the rationale for the selected model and demonstrate that the data made available are proportionate to the approved purpose while sufficient for scientifically valid analysis.

6.18 Output release must be designed before analysis starts

The VALO2 pilot study demonstrated that output release is not simply a study close-out activity but an integral part of the end-to-end research workflow. Different participating environments applied different approaches to publication review, anonymisation assurance, disclosure control and export governance. These differences influenced planning assumptions, researcher responsibilities and reporting timelines. Future studies should therefore establish output release requirements during project mobilisation, including permitted output formats, anonymisation requirements, review responsibilities, expected turnaround times and publication conditions. Output release should be validated in the same way as onboarding and workflow readiness, rather than being treated as a final administrative step.

Researchers should be able to understand:

- what outputs may be released
- who reviews them
- how review decisions are made
- expected operational timeframes
- escalation routes
- publication conditions

6.19 Phased delivery should be planned, not improvised

The VALO2 pilot study demonstrated that multi-country studies are unlikely to progress at a uniform pace. Variations in approval pathways, onboarding requirements, data preparation activities, and operational dependencies resulted in different countries reaching analytical milestones at different times. The ability to progress reporting and synthesis activities using available results while awaiting completion of remaining workstreams proved an important project mitigation strategy. Future studies should therefore build phased delivery, modular reporting structures, and staged review cycles into project design from the outset rather than introducing these approaches reactively when delays occur.

6.20 Regulatory interpretation can be as significant as regulation itself

The VALO2 pilot study highlighted that delays may arise not because regulations change, but because similar studies can be interpreted differently by different reviewing bodies. In Norway, a project that was initially expected to follow a pathway similar to previous work was instead categorised as research requiring REC approval and additional patient notification measures. Future cross-border studies should identify potential classification risks early, engage local regulatory experts during study design and document assumptions regarding ethical review requirements before timelines are baselined. This challenge is not unique to the VALO2 pilot study and has been recognised within wider Nordic ethics review discussions, where differences in interpretation

regarding research versus quality assurance have been identified as a recurring source of variation (VALO2 Ethical Expert Group, 2026a).

Findings from the VALO2 Ethical Expert Group mapping suggest this issue is present across multiple Nordic countries and is not limited to Norway (VALO2 Ethical Expert Group, 2026a; VALO2 Ethical Expert Group, 2026b). Differences in interpretation may arise both between countries and, in some cases, between individual ethics committees or competent authorities, creating uncertainty for cross-border applicants.

6.21 Common data model-ready SPEs need analyst-centred design

Danish comparative feedback provides one example of an effective environment for researchers conducting OMOP/OHDSI analysis using an R-based workflow. For this research team, the preferred baseline included a virtual desktop infrastructure (VDI) with the R programming language, and RStudio integrated development environment preinstalled, straightforward read and write access to an appropriate database and stable configuration throughout the analysis period. Preferred features include a Windows-based virtual desktop, a local CDMConnector-compatible database such as DuckDB stored directly on the VDI, access to ATLAS connected to the local database and vocabularies, reliable access to CRAN mirrors, documentation with executable code examples available within the environment, and no material environment updates during active analysis unless appropriately notified, assessed and supported (VALO2 Lessons Learned Questionnaire Danish Response, 2026). This feedback shows that the analyst experience depends less on the number of available platform features and more on whether the core analytical path is stable, obvious and performant.

These preferences should not be interpreted as universal technical requirements. Other researchers may use Python, native notebooks or alternative analytical frameworks and may not require RStudio, CDMConnector or ATLAS. The broader requirement is that an SPE should declare its supported analytical patterns and demonstrate that the study team's selected workflow can run reliably from data connection through intermediate result creation and approved output release.

The VALO2 pilot study demonstrated that analyst productivity may depend as much on integration with researchers preferred analytical tools as on capabilities provided natively within the secure platform itself. The Danish team deliberately chose an RStudio-to-Databricks workflow rather than relying on native Databricks notebooks, highlighting the importance of supporting established analytical workflows alongside secure platform capabilities.

Table 6: Cross-cutting lessons translate into practical controls for future EHDS-style studies

Lesson theme	Implication for EHDS implementation	Recommended control
Mobilisation	Readiness cannot be assumed from consortium participation.	Pre-kick-off readiness checklist with named contacts and site sign-off.
Approval pathways	EU-level harmonisation will not remove local implementation variability immediately.	Country approval pathway map and schedule-risk register.
SPE usability	Infrastructure must support real analytical workflows, not just secure login.	Day-zero end-to-end SPE readiness test.

Lesson theme	Implication for EHDS implementation	Recommended control
Data availability	Common data models do not remove variable-level data gaps.	Protocol-to-variable-to-source-to-OMOP mapping review.
Local expertise	Cross-border access still needs local interpretive accountability.	Named clinical and data SMEs per site with planned review checkpoints.
Output release	Research timelines depend on export review certainty.	Published output review criteria and target turnaround times.
Analyst-centred SPE design	EHDS-ready environments must support the practical analytical path, not only secure access.	Define a study-specific workspace acceptance test covering the research team's chosen programming environment, database connectivity, concept-set or cohort tooling where required, package management, writable intermediate storage, representative workflow execution and the approved output release route.
Data correction and re-extraction	The first data delivery may not be the final one. Analysis can reveal missing variables, extraction errors or other issues that need to be corrected without creating unnecessary delay.	Agree the correction and re-extraction process before analysis starts, including who approves changes, expected turnaround times and the escalation route if delivery is delayed.
Data provenance	Researchers need to understand how the dataset they receive was created so they can interpret it correctly and distinguish source-data from mapped, derived or transformed data.	Provide a clear record with each dataset showing its source, key extraction and mapping rules, important derivations, exclusions, known limitations and quality checks.

Abbreviations: EHDS, European Health Data Space; OMOP, Observational Medical Outcomes Partnership; SPE, Secure Processing Environment.

7 EHDS and TEHDAS2 alignment assessment

The EHDS Regulation creates a framework for the primary and secondary use of electronic health data (Regulation (EU) 2025/327). TEHDAS2 guidance on using data in SPEs reinforces the need for early planning, clear user responsibilities, access modalities, security requirements, result export and data deletion (TEHDAS2 Joint Action, 2025; TEHDAS2 Joint Action, 2026). The VALO2 pilot study is therefore directly relevant because it demonstrates what these requirements mean in practice.

A significant theme emerging from the Norwegian experience was the challenge of determining whether a project should be classified as quality assurance or research. During the VALO2 pilot study, a project that was initially expected to follow a pathway similar to previous initiatives was instead categorised as research requiring REC review and additional participant notification measures. This aligns with broader Nordic discussions on EHDS implementation, where differences in interpretation regarding whether a project constitutes quality assurance or research have been identified as a potential source of variability between ethics committees and approval pathways. The resulting classification can significantly affect ethics review requirements, timelines and project feasibility, suggesting that future EHDS implementation may benefit from greater harmonisation or clearer decision frameworks across participating countries.

The VALO2 Ethical Expert Group mapping demonstrated that Finland, Sweden, Norway, Denmark and Iceland apply substantially different triggers for ethical review, territorial applicability rules and interpretations of quality assurance versus scientific research (VALO2 Ethical Expert Group, 2026a). While there is broad conceptual alignment across the Nordic countries, the practical implementation of ethical review requirements remains heterogeneous. The VALO2 pilot study experience demonstrates that these differences are not merely theoretical but can materially affect project planning, approval timelines, and cross-border collaboration.

Service interoperability

The VALO2 pilot study experience suggests that a third dimension of interoperability deserves consideration alongside technical and governance interoperability.

Technical interoperability considers whether systems, platforms, analytical tools and data models can operate together.

Governance interoperability considers whether permits, ethics processes, user identities and access conditions can be reconciled.

Service interoperability considers whether researchers can experience sufficiently consistent and understandable operational services across different SPEs.

Cross-border research depends not only on systems and governance arrangements being compatible, but on researchers being able to navigate operational pathways that are sufficiently transparent, consistent and scalable.

The VALO2 pilot study also provided practical evidence of the value of researcher access to data within SPEs. Compared with the initial VALO1 pilot, researchers had substantially greater visibility of the data, analytical environment and workflow execution process within participating sites. This improved transparency, supported iterative validation of data and cohort assumptions, and reduced dependence on local teams for routine analytical execution. At the same time, researcher access

did not remove the need for local expertise, onboarding support, workflow validation or governance controls. The findings therefore suggest that SPEs can improve researcher autonomy and transparency while maintaining local governance and security requirements.

Table 7: VALO2 pilot study shows that service interoperability remains a key EHDS readiness challenge

EHDS / TEHDAS2 theme	VALO2 pilot study observation	Readiness assessment	Action for future studies
SPE as controlled workspace	Finland and Norway used researcher-facing SPE/TRE environments for controlled analysis. Denmark used a governed Databricks-based analytical environment operated by the local team, rather than an equivalent externally accessed SPE model.	Aligned in principle; operational maturity and transparency vary.	Document workspace isolation, access controls, audit features and published/internal documentation status.
Early secure-environment planning	SPE Discovery conversations were captured in the tracker, but several practical issues still emerged during execution.	Partially aligned; needs stronger gating and sign-off.	Make SPE discovery a formal mobilisation deliverable.
Access modalities and security	Identity/login methods differed across environments: HUS browser/Citrix, Denmark SSO/MFA, TSD Selfservice/password/OTP/gat away.	Partially aligned; needs clearer cross-border user pathways.	Document internal, external and international user journeys.
Data-user responsibilities	Researchers needed clarity on what they could do inside each workspace, especially tooling, package installation, write permissions, and outputs.	Needs strengthening.	Create a researcher quick start guide per SPE.
OMOP/OHDSI workflow execution	Researcher feedback showed that OMOP workflows depended on practical configuration details including vocabulary availability, ATLAS usability, RStudio connectivity, write permissions, database location, package installation and copy/paste constraints.	Partial readiness; capability existed, but execution required workarounds and local support.	Define an OMOP/OHDSI-ready SPE acceptance test before analysis begins, including a representative cohort-definition and results-writing workflow.

EHDS / TEHDAS2 theme	VALO2 pilot study observation	Readiness assessment	Action for future studies
Analytical comparability and cross-site synthesis	Common-model representation supported reuse of an analytical framework, but differences in cohort-construction, treatment definitions, variable availability, mapping and data completeness prevented robust pooling or meta- analysis.	Structural interoperability demonstrated; analytical comparability not established.	Define comparability criteria before analysis, including harmonised cohort definitions, concept sets, variable provenance, completeness thresholds, follow- up and outcome definitions. Where possible, data holders should also provide up- to-date variable- level metadata catalogues describing variable availability, OMOP representation, mappings and known limitations to support assessment of semantic interoperability and analytical comparability.
Output release and disclosure control	HUS Acamedic has a clearly described output release process: outputs must be anonymous and aligned with Findata guidance; exports are initiated through an automated Acamedic website; and, depending on assessed disclosure risk, the process may require notification to Findata or formal anonymity review. VALO2 pilot study outputs were submitted for review as a precaution	Finland/HUS Acamedic provided completed The VALO2 pilot study evidence of output release governance. Denmark's project-level approach is evidenced through the researcher and PI workflow. For Norway, TSD has a documented and confirmed operational export pathway that was successfully executed	Require each SPE to publish or provide a clear output release profile covering permitted output types, risk- assessment, notification or approval requirements, decision ownership, expected

EHDS / TEHDAS2 theme	VALO2 pilot study observation	Readiness assessment	Action for future studies
	because some were considered potentially higher risk. Denmark permits export of aggregated results, tables, figures and plots under researcher and PI responsibility. No formal output review or statistical disclosure control process was identified within the validated project evidence. In Norway, TSD provided a role-controlled export pathway. The designated approver approved the VALO2 pilot study export request, the Danish researcher's export rights were confirmed, and the Norwegian study results were released from TSD.	following approval by the designated project approver.	turnaround and retained evidence.
Result export and deletion/close-out	Output release and close-out requirements were not fully defined across all operating environments at mobilisation. Finland and Norway subsequently demonstrated completed output-release pathways. Public TSD documentation provides a formal lifecycle model, but final VALO2 pilot study close-out responsibilities, retention decisions, access revocation and evidence remain to be confirmed across sites.	Output release was operationally evidenced, while project close-out remains partially evidenced.	Include output release, account revocation, data retention or deletion, output retention and audit-log responsibilities in the Minimum SPE Capability Profile and study readiness pack.
Interoperability and reuse	Danish code was reused/adapted for Finland, but environment-specific differences still created friction.	Partial readiness.	Define an OMOP/OHDSI-ready workspace specification before study start.

Abbreviations: EHDS, European Health Data Space; HUS, Helsinki University Hospital; ICI, Immune Checkpoint Inhibitor; MFA, Multi-Factor Authentication; OHDSI, Observational Health Data Sciences and Informatics; OMOP, Observational Medical Outcomes Partnership; PI, Principal Investigator; SDC, Statistical Disclosure Control; SPE, Secure Processing Environment; SSO,

Single Sign-On; TEHDAS2, Towards the European Health Data Space Joint Action 2; TRE, Trusted Research Environment; TSD, Services for Sensitive Data.

Policy relevance

The VALO2 pilot study shows that EHDS guidance is necessary but not sufficient unless it is translated into operational service standards. A future Nordic model should specify what a researcher can expect from an SPE before the study starts: approval pathway, access lead time, permitted users, tools, data formats, support route, output controls, translation support, audit logs and close-out process.

What an EHDS-ready researcher journey should look like

The findings from the VALO2 pilot study suggest that future EHDS implementation should be evaluated not only against legal, governance or technical requirements, but also against the practical experience of the researcher.

An EHDS-ready researcher should be able to:

1. understand the approval pathway before protocol finalisation
2. understand likely timelines and critical dependencies
3. complete onboarding through a documented and repeatable process
4. know when access is genuinely analysis-ready rather than simply available
5. access required tools and study data without significant additional configuration
6. receive data supported by sufficient provenance and quality information
7. access clearly defined support and escalation pathways
8. obtain corrections or re-extractions through a defined process where justified
9. execute validated analytical workflows
10. submit outputs through a transparent review process
11. complete close-out activities through a documented route

The objective should not necessarily be identical operating models, but sufficiently transparent, repeatable and interoperable researcher journeys that allow cross-border studies to be planned and executed with confidence.

8 Recommendations for Nordic collaboration and future EHDS implementation

The recommendations below represent the principal actions emerging from the VALO2 pilot study. They are intended to support Nordic data holders, SPE operators, Health Data Access Bodies, research organisations and future EHDS stakeholders in improving operational readiness, researcher experience and service interoperability. Their implementation would benefit from continued Nordic coordination and collaboration.

The recommendations operate at three levels. Nordic-level actions should establish common terminology, ethical-governance dialogue and minimum service expectations. SPE operators and data holders should improve standing researcher services, documentation and feedback mechanisms. Individual studies should implement readiness packs, protocol-to-data feasibility assessment, workflow acceptance testing and defined output-release arrangements before committing analytical timelines.

8.1 Establish a Nordic SPE maturity model

A practical Nordic SPE maturity model should be developed to enable health data holders, Secure Processing Environment operators and future Health Data Access Bodies to describe capability consistently. The model should not be used to rank individual platforms. Instead, it should provide a transparent capability profile that supports study planning, service improvement and future EHDS implementation.

The five-level model proposed below was developed from the operational observations and researcher experiences captured during the VALO2 pilot study. It is presented as a discussion framework for further Nordic development and validation, rather than as an existing published or formally endorsed standard.

Table 8: A five-level maturity model can help distinguish secure infrastructure from operational EHDS readiness

Maturity level	Description	Indicative criteria
Level 1 – Secure workspace available	Environment exists and supports controlled access to sensitive data.	MFA/strong authentication; user logging; project isolation; basic support.
Level 2 – Cross-border access enabled	Foreign researchers can be onboarded through a documented and repeatable process.	External identity route; documented approval and onboarding pathway; language-accessible guidance; named support model; and target access timeframe
Level 3 – Research workflow ready	Environment supports common research tools and output workflows.	R/Python or equivalent; package management; compute profile; read/write workspace; result export process.
Level 4 – Common Data Model Ready (including	Environment supports analysis using an applicable common data model. For OMOP studies, it supports	A researcher should be able to connect to the common data model, access the required vocabularies, execute representative cohort construction and

Maturity level	Description	Indicative criteria
OMOP/OHDSI where applicable)	OHDSI workflows without dependence on ad hoc workarounds.	analytical workflows, write intermediate outputs and complete a validated test script without requiring environment-specific fixes or manual intervention from platform administrators. Published database connection guidance; required vocabularies or terminology assets available within the analytical path; reliable package management; writable intermediate storage and validated workflow-testing evidence should be available. For OMOP/OHDSI studies, relevant capabilities may include ATLAS or equivalent cohort tooling, CDMConnector, R/RStudio, Python or other agreed analytical tools.
Level 5 – EHDS operationally mature	Environment operates as part of a repeatable and scalable multi-site secondary use ecosystem.	Published capability profile; output review expectations; evidence of audit/certification; Health Data Access Body (HDAB) interoperability; continuous improvement metrics.

Abbreviations: ATLAS, OHDSI web-based cohort definition and analytics tool; CDM, Common Data Model; CDMConnector, Common Data Model Connector package; EHDS, European Health Data Space; HDAB, Health Data Access Body; MFA, Multi-Factor Authentication; OHDSI, Observational Health Data Sciences and Informatics; OMOP, Observational Medical Outcomes Partnership.

Future Nordic studies should consider piloting TTAR as an operational maturity metric. TTAR would measure the elapsed period between completion of the approvals required to initiate the study and successful execution of a representative analytical workflow against the approved dataset. Such a measure may provide a more meaningful indication of practical researcher readiness than account creation, environment provisioning or first successful login alone.

8.2 Define a Nordic cross-border SPE minimum service profile

The VALO2 pilot study demonstrated that future researchers require not only access to SPEs, but also clarity regarding the operational services that support successful study delivery.

A Nordic Cross-Border SPE Minimum Service Profile should be developed to improve transparency regarding the operational services available to cross-border researchers. The profile would not impose an identical service-level across all environments. Instead, it would require participating environments to describe researcher-facing services using a common structure.

At a minimum, participating environments should document:

1. researcher onboarding
2. workspace provisioning
3. data provisioning

4. correction and re-extraction processes
5. software and package requests
6. support arrangements
7. output review and release
8. project close-out

For each service, environments should identify:

- service owner
- prerequisites
- expected timeframe
- escalation route
- evidence of completion

This would provide future researchers, Health Data Access Bodies and project sponsors with a common way of understanding how different environments operate without requiring those environments to become identical.

8.3 Define a minimum cross-border SPE readiness pack

The Minimum Service Profile describes how an SPE operates as a standing service; the readiness pack applies that information to the requirements of a specific cross-border study.

- **Site contact map:** PI, SPE/access coordinator, technical support, data SME, clinical SME and output release approver.
- **Approval pathway map:** local/regional/national ethics and data permit steps, expected review periods and post-approval conditions.
- **Researcher onboarding guide:** foreign user access route, identity proofing, MFA/OTP, workspace access, tool access, data access, common error messages, training materials, language support and escalation route.
- **Technical readiness checklist:** tools, package installation, database connection, write permissions, compute, storage and export route.
- **Common Data Model workflow acceptance test:** confirm that the team's selected analytical workflow can connect to the study database, access required vocabularies or concept sets, use the chosen analytical tools, create and store intermediate results and release a permitted aggregated output. For OMOP/OHDSI studies, this may include R/RStudio, Python, ATLAS, CDMConnector or equivalent tools according to the agreed study workflow.
- **Data readiness matrix:** all protocol variables mapped to source system availability, OMOP availability, extraction inclusion and known limitations.

- **Cohort-construction and comparability plan:** identify who applies inclusion and exclusion criteria, how local derivations and concept sets are documented, how attrition is reviewed, who provides clinical validation and what criteria must be met before results may be compared or combined across sites.
- **Output release guide:** permitted output formats, anonymisation or statistical disclosure control (SDC) criteria, risk-assessment requirements, notification or review authority, expected turnaround, publication conditions, escalation route and links to applicable national guidance, such as Findata anonymisation and results-export guidance where relevant (Findata, n.d.-a; Findata, n.d.-b).
- **Close-out process:** data deletion, account removal, audit-log retention and publication review obligations.

8.4 Require protocol-to-data feasibility before extraction

Future studies should not rely on high-level assertions that a site has OMOP, or that variables exist somewhere in source systems. Each protocol-critical variable should be validated across source availability, structured extractability, OMOP representation, standard-concept mapping, inclusion in the approved extract, local derivation logic, completeness and analytical usability. Feasibility should also assess whether cohort definitions, treatment definitions, follow-up and outcome measures are sufficiently aligned to support the intended cross-site comparison or synthesis. Variable-level metadata catalogues should be available to support feasibility assessment by documenting variable availability, OMOP representation, standard-concept mappings, derivations and known limitations. These catalogues support assessment of semantic interoperability and analytical comparability, but do not replace the need for expert review and harmonisation across participating sites. This should happen before finalising the extraction request and before analysis timelines are committed.

Protocol-to-data feasibility should also explicitly define the cohort-construction model. Studies should agree whether inclusion and exclusion criteria will be applied locally by data and clinical experts, by researchers within the analytical environment, or through a hybrid approach. The agreed model should identify ownership of cohort logic, local derivations, validation activities, clinical sign-off and cohort-attrition reporting before data extraction begins. Responsibility for protocol-to-data feasibility should be jointly owned by the study sponsor or coordinating organisation, participating data holders, local data and clinical subject-matter experts, and analytical leads. Feasibility should be formally completed and documented before extraction requests are submitted and before analytical timelines are committed.

8.5 Establish a Nordic cross-border researcher onboarding framework

Future EHDS-style studies would benefit from a common Nordic onboarding framework covering terminology, identity verification routes, ethics pathways, access processes, language support and minimum researcher guidance expectations. While technical platforms may remain locally managed, a shared onboarding model would reduce researcher burden, improve transparency and support a more consistent cross-border user experience.

8.6 Establish a Nordic ethical governance community of practice

A continuing Nordic community of practice for ethical governance should be established, building on the structured dialogue initiated through the VALO2 Ethical Expert Group. Such a forum could enable ethical experts to exchange experiences, discuss borderline cases, improve consistency of interpretation and identify implementation challenges before they affect cross-border research projects.

8.7 Govern synthetic and mock data according to their intended use

Synthetic or mock data should be included in study design only where its intended use is clearly defined. If the use case is environment familiarisation, simple mock data may be sufficient. If the use case is analytical workflow validation, the data should be purpose-designed to reproduce the required schema, concept coverage, relationships, date logic, missingness patterns and technical formats while ensuring that the resulting dataset does not contain identifiable records or disclose information about real individuals. The research plan should specify the intended use, generation method, acceptance criteria, ownership and limitations of the synthetic dataset.

8.8 Make documentation translation sustainable

Maintaining multiple manual language versions creates an update risk. A pragmatic future approach would be to maintain a single validated master document and provide controlled translation-on-demand for foreign researchers. However, this should be supported by version control, clear warnings on automated translation, and a named owner for the master guidance. The bigger risk is not translation imperfection; it is researchers using outdated or incomplete guidance.

8.9 Build researcher feedback into SPE continuous improvement

The Danish researcher questionnaire demonstrates the value of structured user feedback. It provided specific evidence on what was clear, what required local support, where documentation was outdated, which permissions were missing, how workarounds were created, which variables were difficult to use, and what the Danish research team considered an effective analytical configuration for its OMOP/OHDSI workflow. Future SPE operators should gather this type of feedback after onboarding, first database connection, first workflow execution, and first output export. This would convert individual troubleshooting into reusable service improvement and would help data holders distinguish between general platform capability and actual researcher usability.

9 Strategic conclusion

The VALO2 pilot study demonstrates that cross-border secondary use of health data is achievable today. However, the study also shows that successful implementation depends on more than legal access or secure infrastructure. It requires approval pathways, onboarding processes, analytical tools, data provision, researcher support and output governance arrangements to operate together as an understandable and reliable end-to-end service.

The project suggests a progression that is directly relevant to future EHDS implementation:

Secure data access enables cross-border research.

Operational readiness makes the conduct of research practicable.

Transparent, repeatable and scalable researcher services can make cross-border research routine.

The VALO2 pilot study demonstrated the feasibility of the tested operating model, with analyses completed using Danish, Finnish and Norwegian data and outputs released from all three environments. It did not demonstrate a uniformly mature or scalable cross-border service. Scalability will require more consistent onboarding, reusable documentation, transparent support, validated analytical workflows and sustainable operational delivery.

The final analyses also demonstrated that technical access and common-model implementation do not automatically establish analytical comparability. Differences in cohort-construction, treatment definitions, concept mapping, variable availability and data completeness meant that pooling results through a meta-analysis was not considered scientifically robust. Future EHDS implementation must therefore address not only whether data can be accessed and analysed, but whether the resulting cohorts and measures are sufficiently transparent, consistently defined and comparable to support valid cross-border synthesis.

The value of the VALO2 pilot study extends beyond the countries directly participating in the pilot. The operational experience generated through the study provides practical implementation insights for the wider Nordic community and other organisations across Europe preparing for EHDS implementation and demonstrates how pilot programmes can accelerate collective EHDS readiness. Continued Nordic collaboration, knowledge exchange and shared learning will be important as countries develop future cross-border health data access models.

Overall, the VALO2 pilot study indicates that future EHDS success will depend on three complementary forms of interoperability: technical interoperability, governance interoperability and service interoperability. The first two create the conditions for lawful and secure access. The third determines whether researchers can translate that access into efficient, scientifically valid and scalable research.

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Annex 1: Minimum SPE capability profile template

Dimension	Question to site/SPE lead	Evidence requested
Access owner	Who owns and enables access, and who can escalate access issues?	Named role/contact; support route; escalation path.
Access process	How is a project workspace requested, approved and provisioned?	Process map or written workflow.
Service levels and operational expectations	What operational timeframes apply to onboarding, workspace provisioning, data delivery or re-extraction, support requests and output release, and what escalation route applies where those expectations are not met?	Published, contractual or internal service targets; service catalogue; escalation route; and available performance information.
Approval evidence	What permits/approvals must be attached or referenced?	Permit route, traceability mechanism, legal basis.
Identity and login	How are internal, external, and international users authenticated?	Identity proofing, SSO/MFA/OTP, account process.
Tools and compute	What tools, programming languages, packages and compute are available?	Software list, package install procedure, compute profile.
OMOP/OHDSI readiness	Can common OHDSI workflows run end-to-end?	Test script result, ATLAS availability, write schema/intermediate storage status.
Data ingress	How is data moved into the workspace and transformed?	Data flow diagram, transfer process, pseudonymisation stage.
Output release	What outputs may leave and how are they reviewed?	Permitted output formats; anonymisation or SDC rules; risk-assessment form or equivalent; notification/review authority; reviewer or approving body; expected turnaround; publication conditions; escalation route; links to applicable national guidance.
Audit and logging	What access/data activity is logged?	Audit-log scope, retention, and availability for review.

Dimension	Question to site/SPE lead	Evidence requested
Revocation/close-out	How are users removed and data deleted/retained?	End-of-project checklist, retention/deletion policy.
Documentation/training	What user guides can be shared or cited?	Public/internal user guides, training links, quick-start guide.

Abbreviations: ATLAS, OHDSI web-based cohort definition and analytics tool; MFA, Multi-Factor Authentication; OHDSI, Observational Health Data Sciences and Informatics; OMOP, Observational Medical Outcomes Partnership; OTP, One-Time Password; SDC, Statistical Disclosure Control; SPE, Secure Processing Environment; SSO, Single Sign-On.

This capability profile template was developed from evidence gathered through the VALO2 pilot study SPE Discovery Tracker, Data Governance Lessons Learned Log, Danish researcher feedback, public HUS Academic and TSD documentation, and relevant EHDS and TEHDAS2 guidance. It is presented as a practical readiness tool derived from the VALO2 pilot study operational experience rather than a formally published standard.

Annex 2: Danish researcher feedback instrument and summary themes

The questions below were shared with the Danish research team to capture first-hand experience of working across the Danish, Finnish and Norwegian environments. A key member of the Danish research team provided structured responses in spreadsheet format, covering the researcher journey, onboarding and documentation, access and permissions, tooling, data connectivity, workflow execution, mock data, data quality, output export and comparative SPE design. These responses have been incorporated into the main report narrative and should be retained as supporting evidence for the researcher experience findings.

Theme	Questions
Researcher journey	What did you need to do before you could start analysis in each environment? What steps were clear, unclear or dependent on local support?
Onboarding and documentation	Which guides were helpful? Where were they outdated, untranslated or not specific to OMOP workflows? What would a good quick-start guide contain?
Access and permissions	Did login equal workspace access? Which permissions were missing? How quickly were issues resolved and who resolved them?
Tooling	Which tools were available in each environment? R/RStudio, Python, ATLAS, CDMConnector, database clients, package installation, version control, compute?
Data connectivity	How did you connect to OMOP data? Which credentials, authentication methods, database names or drivers caused issues?
Workflow execution	Could you run standard OHDSI workflows? Could you write intermediate tables and store results? What workarounds were needed?
Synthetic/mock data	What did the mock data help with? What was missing for script validation? What minimum criteria would make synthetic-data useful?
Data quality and variables	Which variables were missing or unexpectedly hard to use? How did local experts help interpret or resolve issues?
Output export	What outputs did you need to extract? What was the process? Did it affect timelines?
Comparative view	If you were designing an EHDS-ready SPE from scratch, what features would be mandatory, desirable or unnecessary?

Theme	Summary from Danish researcher response
Finland	Usable but required careful setup, local support, vocabulary/data workarounds, RStudio configuration and OMOP-specific documentation improvements.
Denmark	Most straightforward for local Danish researchers, but relied on prior familiarity, local technical autonomy, data preparation, pathology/ECOG enrichment and RStudio-to-Databricks connectivity. Valuable as evidence of researcher productivity within a mature local analytics ecosystem, but not yet evidence of a repeatable external cross-border SPE access model.
Norway	TSD was intuitive once access and permissions were resolved. Software installation and early data-format issues delayed workflow readiness, but the final locally constructed cohort reduced the cohort-development work required within the researcher environment and the governed export pathway was completed successfully.
Cross-cutting	Researcher-ready SPEs should support the study team's selected analytical workflow through stable tools, reliable package management, writable database or intermediate storage, appropriate cohort and concept-set tooling, current documentation and a tested output release route. The specific preferred tools may vary between research teams.

Abbreviations: ATLAS, OHDSI web-based cohort definition and analytics tool; CDMConnector, Common Data Model Connector package; EHDS, European Health Data Space; OHDSI, Observational Health Data Sciences and Informatics; OMOP, Observational Medical Outcomes Partnership; RStudio, Integrated Development Environment for the R programming language; SPE, Secure Processing Environment; TSD, Services for Sensitive Data.