

Final Cross-Border Research Lessons from VALO2 Pilot

Mobilisation & Governance

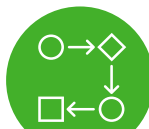


Mobilisation Readiness is Critical to Delivery

- Delays in identifying country representatives, SPE access coordinators, and data governance contacts prevented early initiation of site assessment, access validation, and onboarding activities. Without these roles in place, cross-border coordination could not begin as planned.

Lesson

Cross-border studies require formal mobilisation readiness: named site roles, clear responsibilities, and confirmed points of contact must be established before execution begins.



Approval Pathways Must Be Validated Early and Managed as Schedule Drivers

- Approval requirements varied significantly by country and, in some cases, differed from expectations based on previous projects. Late identification of the correct approval route introduced avoidable delays and impacted the overall delivery timeline.

Lesson

Approval pathways are not transferable between countries and must be validated at mobilisation. Regulatory processes and submission timelines should be treated as critical schedule drivers.



Ethics Approval Does Not Equate to Operational Readiness

- Even after formal approval was granted, additional requirements (e.g. patient notification periods, conditional approvals, environment provisioning and data preparation) delayed the ability to begin analysis. Approval decisions did not translate directly into immediate analytical readiness.

Lesson

Viewing approval as a milestone rather than an endpoint helps ensure that downstream access, onboarding, tooling and data-readiness activities are actively managed.

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Technical & SPE



SPE Access Must Be Validated End-to-End for Analytical Workflows

- Successful login did not guarantee researchers being able to perform analysis.
- Workflow readiness depended on workspace access, tool availability, package installation, database connectivity, intermediate storage and output export.
- Researcher experiences in Finland and Norway showed that multiple stages remained between initial access and analytical execution.

Lesson

Access validation should be based on successful completion of a representative analytical workflow rather than account creation alone.



OMOP Readiness Must Be Validated at Variable Level

- Availability of an OMOP database did not guarantee protocol-critical variables being available, included in approved extracts, or analytically usable.
- Variable availability, extraction methods and completeness differed across countries.
- Protocol execution depended on local validation and understanding of data provenance.

Lesson

Future studies should validate protocol variables against source systems, OMOP representation, approved extraction and analytical usability before analysis begins.



Local SMEs and Site Knowledge Are Essential for Cross-Border Execution

- Danish researchers relied on local SMEs to navigate data structures, variable availability and site-specific processes.
- Local support accelerated issue resolution and improved interpretation of findings.
- Common data models supported interoperability but did not remove dependence on local knowledge.

Lesson

Named local SMEs should be embedded throughout mobilisation, onboarding, analysis and interpretation activities.

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Execution & Delivery



Synthetic Data Is Valuable But Must Be Planned and Fit-for-Purpose

- Mock data supported onboarding, familiarisation and early technical setup.
- It was less useful for analytical validation because it did not sufficiently reflect the structure and characteristics of real study data.
- The purpose of mock data must be clearly defined.

Lesson

Synthetic data should be planned and budgeted from the outset, with a clear purpose, shared definition, and inclusion in study permits where required. Its use should be carefully justified, balancing benefits against the additional cost and effort introduced.



Cross-Country Studies Require Phased Delivery and Flexible Planning

- Sites progressed through approvals, onboarding, data access and analysis at different speeds.
- Completion of analysis and output release occurred asynchronously across countries.
- Phased reporting allowed study activities to continue whilst outstanding work remained in other countries.

Lesson

Cross-border studies should plan for asynchronous site readiness and downstream data validation issues. Phased delivery and built-in flexibility are essential to maintain progress while accommodating site-specific challenges and emerging risks..



Standardisation Enables Reuse but Not Automatic Comparability

- A common analytical framework was successfully reused across Denmark, Finland and Norway.
- However, cohort-selection methods, variable availability and data completeness differed between countries.
- The project team concluded that a pooled meta-analysis would introduce considerable uncertainty and was unlikely to provide meaningful additional value.

Lesson

Reusable analytical code supports efficiency, but cross-site comparability should be demonstrated before undertaking pooled analyses. Clear visibility of cohort definitions, extraction logic, and data completeness is essential to ensure reliable and interpretable outcomes.