Unlocking cross-border use of health data – lessons from a Nordic SPE pilot

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The case for VALO2 pilot

Why was this a Nordic study?

- Relevant patient populations are distributed across countries
- High quality EMR data across participating countries
- Access to multiple data sources broadens evidence generation
- The study provided an ideal opportunity to test cross-border research through SPEs building on VALO1 pilot study

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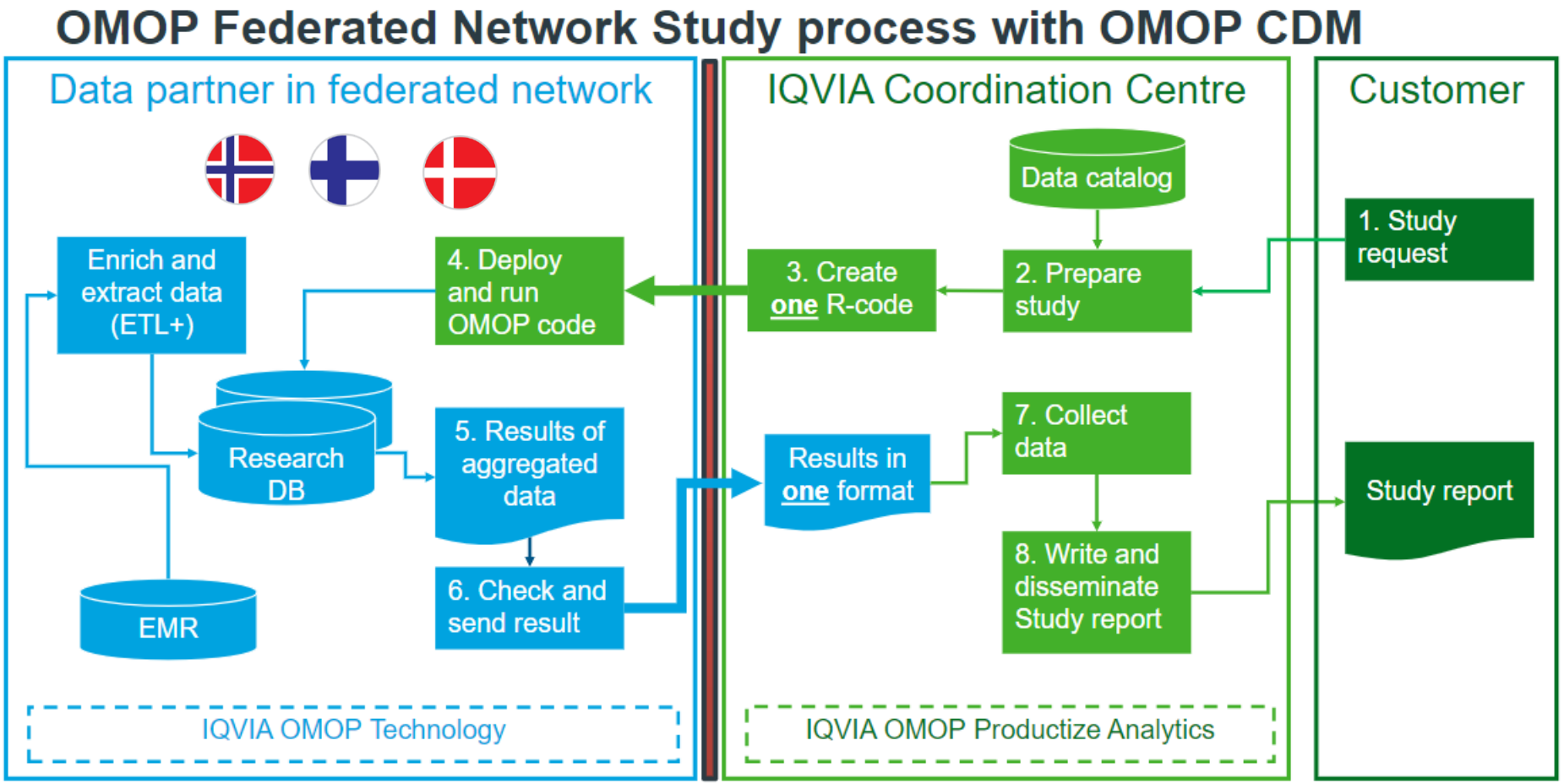
From VALO1 pilot to VALO2 pilot

VALO1 pilot study operating model



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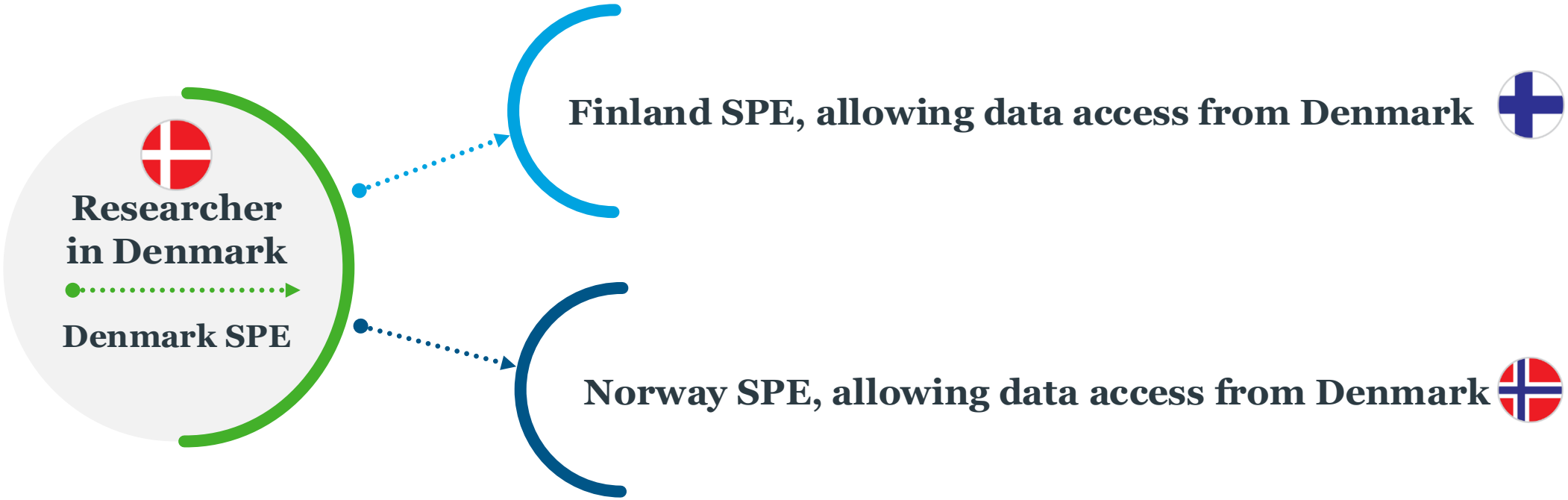
From VALO1 pilot to VALO2 pilot

VALO2 pilot study operating model



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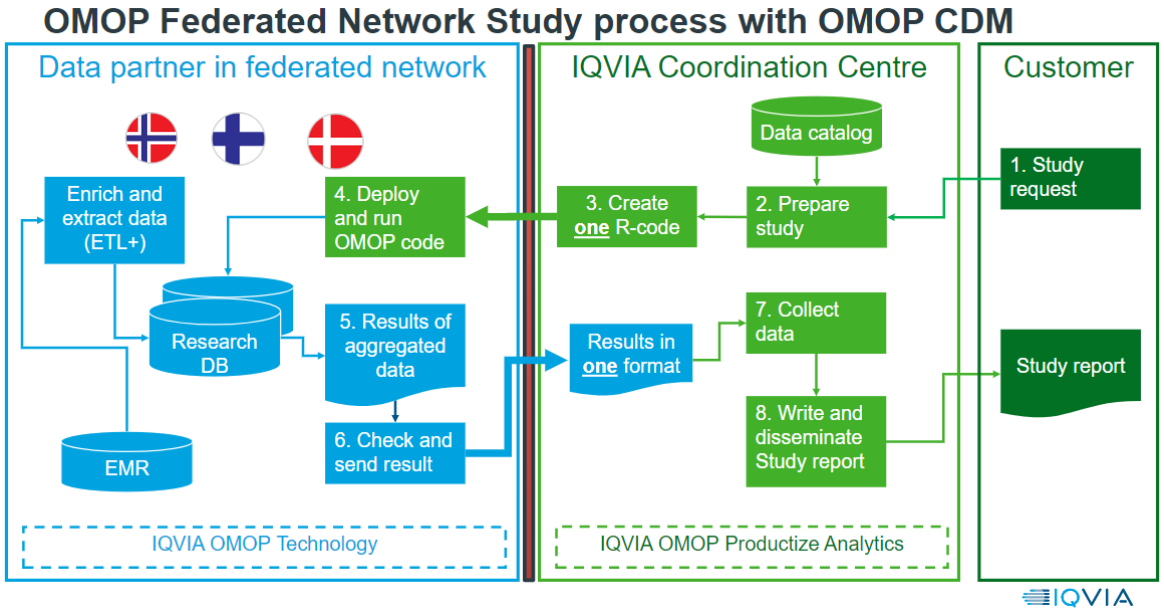
From VALO1 pilot to VALO2 pilot

Different operating models

VALO1 Pilot Study



VALO2 Pilot Study

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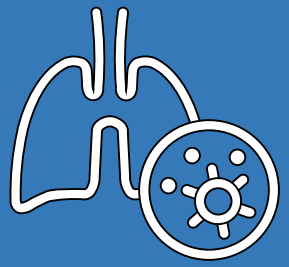
The science and benefits of VALO2 pilot study

Nordic Multicentre Retrospective Cohort Study in Metastatic Non-Small Cell Lung Cancer



Primary objective

Compare treatment outcomes in patients with advanced lung cancer receiving first-line immunotherapy with pembrolizumab, atezolizumab or cemiplimab

Secondary objective

Describe patient characteristics and treatment outcomes, including differences by performance status and comorbidity burden

Exploratory objective

Investigate prognostic scores (LIPI, LIPS-3), and whether they can improve risk adjustment between treatment groups

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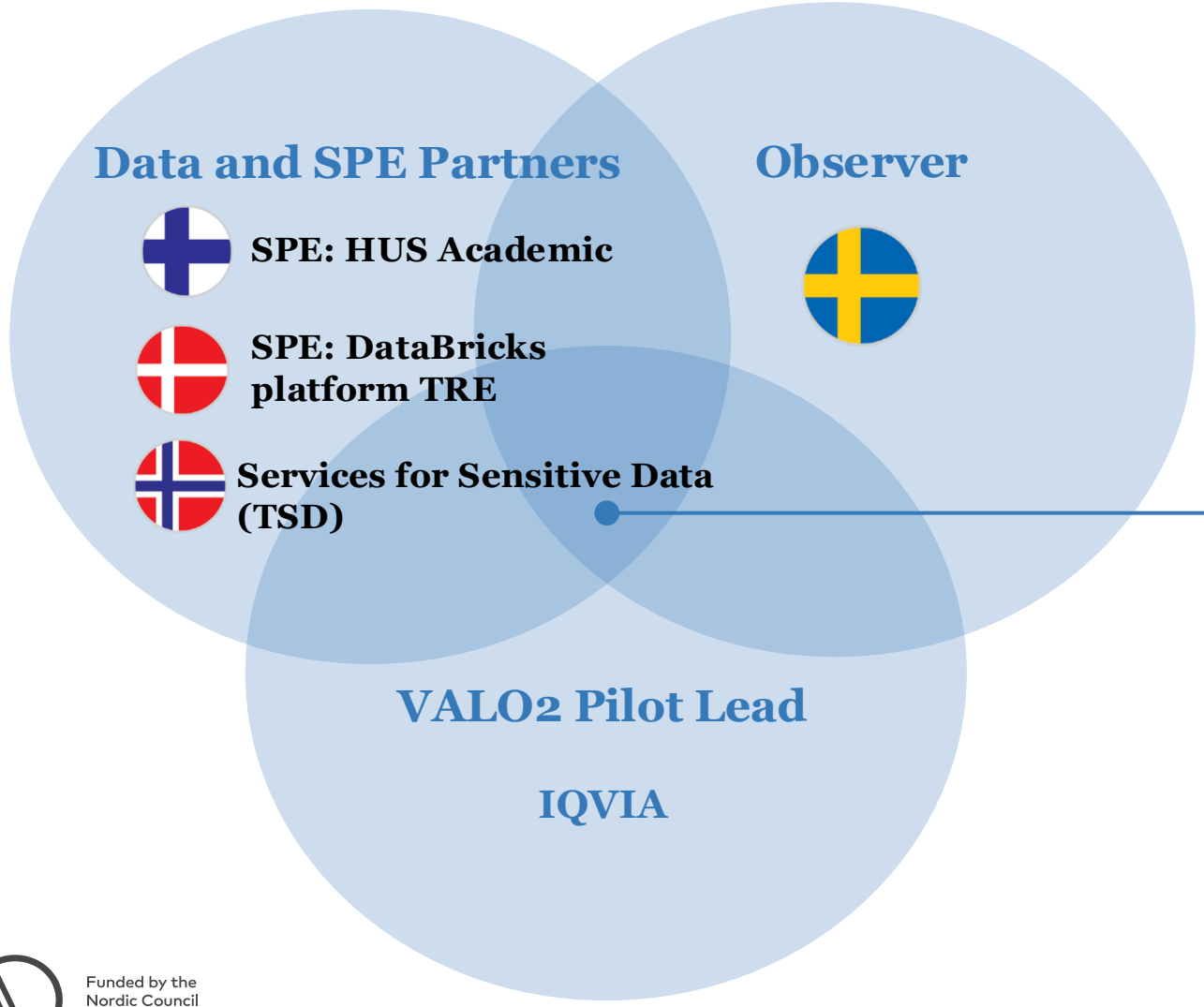
VALO2 pilot partners



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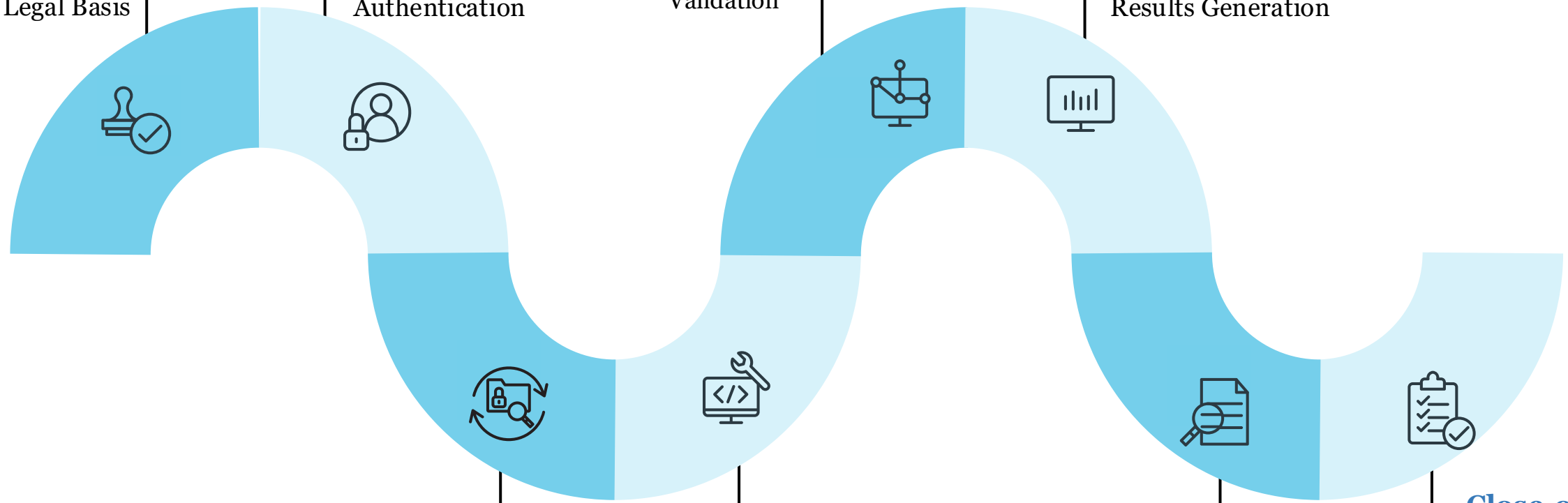
The researcher journey through an SPE

Approval
Ethics – Permits – Legal Basis

Identity
Researcher Registration - Authentication

Data
Extraction – Transfer - Validation

Analysis
Workflow Execution – Results Generation



Workspace
SPE Provisioning – Access Validation

Tools
R/R Studio – Atlas - Packages

Output release
Review – Disclosure Control - Publication

Close-out
Revocation – Retention - Audit

Support and escalation operate across the full researcher journey rather than representing a single sequential stage.

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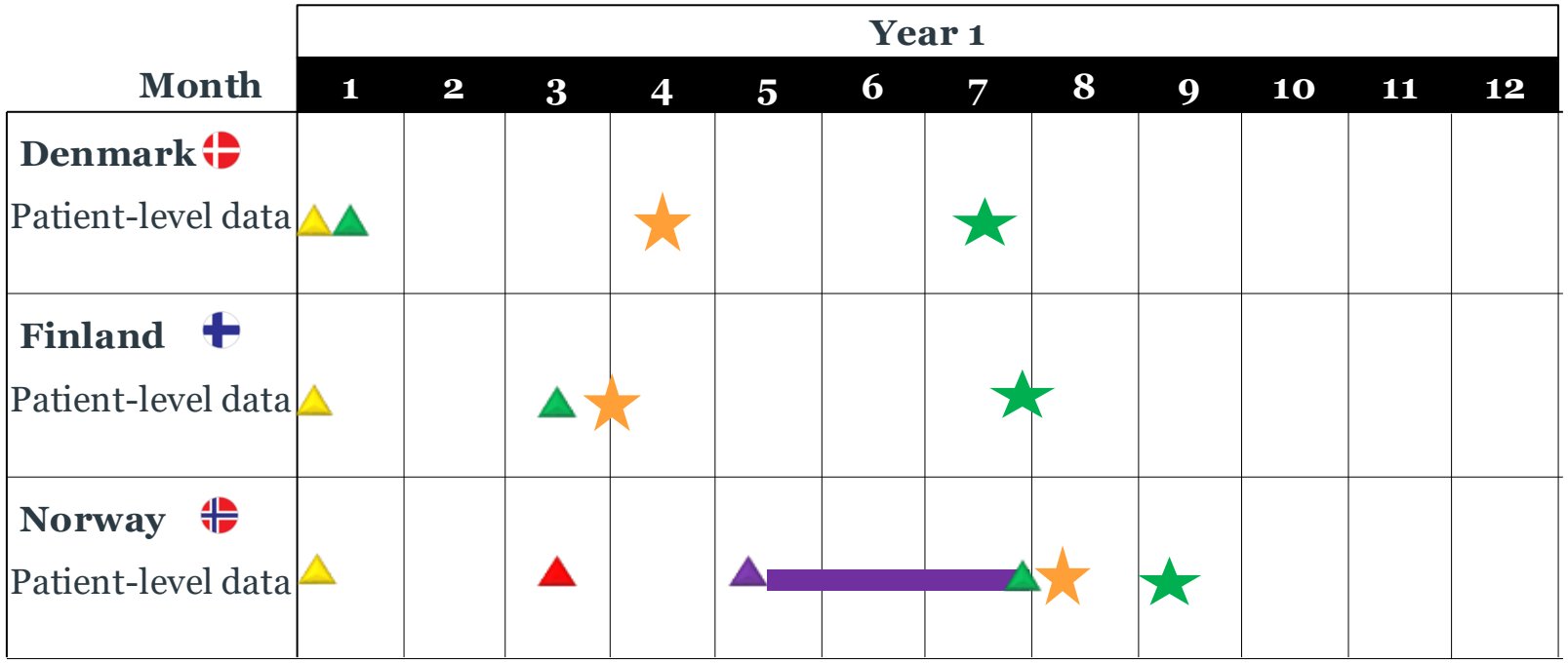
VALO2 Pilot Timeline



- Study permit application submission
- Submission for ethical application
- Study permit conditional approval
- Study permit fully approved
- Data available for researcher
- Alive Patient identified, informed and 4 week Opt Out period
- Analysis complete

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What the cross-boarder SPE approach enabled and challenged

Enabled

- **Patient-level data remained** within local environments
- **Cross-border analysis** without moving patient-level data
- **Shared analytical approach** across countries
- **Local control** over governance and output release
- **Direct researcher access** to Nordic datasets
- **First-hand understanding** of future EHDS-style SPE

Challenged

- **Different onboarding processes** across sites
- **Access involved more** than obtaining login credentials
- **Workspace, tools and permissions** needed to align before analysis could begin
- **Output review and release processes** varied between sites
- **Researcher onboarding** differed between environments
- **Local expertise remained essential** for interpreting data and resolving issues

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Challenges and learnings

Governance and ethical approvals were less aligned than expected
The Norwegian REC requirement differed from the approach used in VALO1 pilot and became a critical dependency for study timelines.

Approval did not equal researcher readiness
Access involved onboarding, workspaces, tools, permissions, data and output processes.

Data access did not guarantee study readiness
Researchers still needed to confirm that the required protocol variables were available, usable and fit for purpose.

Technology did not replace local validation
Local clinical and data experts remained essential to interpret variables, validate assumptions and contextualise findings.

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Recommendations to the next research project

Create predictable approval pathways
Align governance, ethics, permits and researcher access early.

Treat the SPE as a service, not only a technology
Research success depends on support, expertise and governance as much as the platform itself.

Confirm protocol-to-data feasibility at variable level
Study requirements must be validated against the available data before timelines are committed.

Validate the complete researcher journey before the study starts
Not just approvals, logins or access.

Plan for interoperability, not uniformity
Countries can use different environments if the researcher experience is predictable and transparent.

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What the study found - results

2 of 3 countries

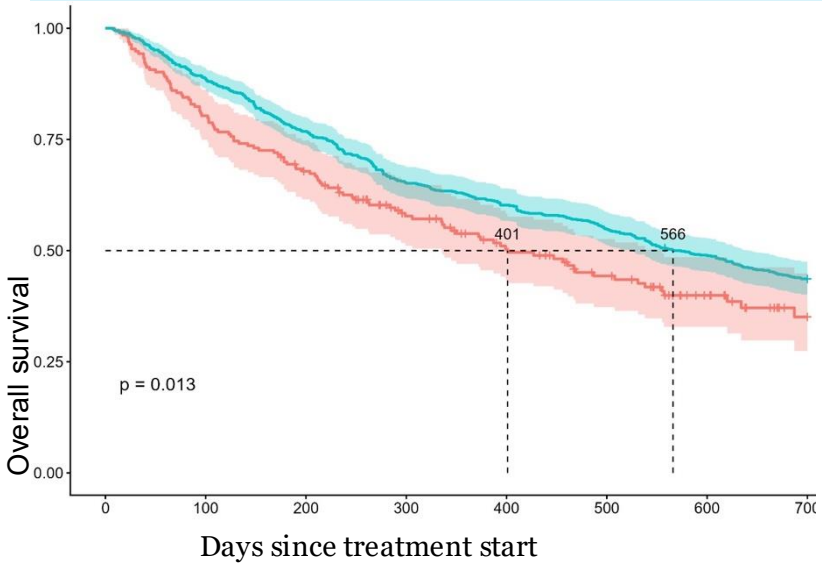
showed a significant difference between the treatments

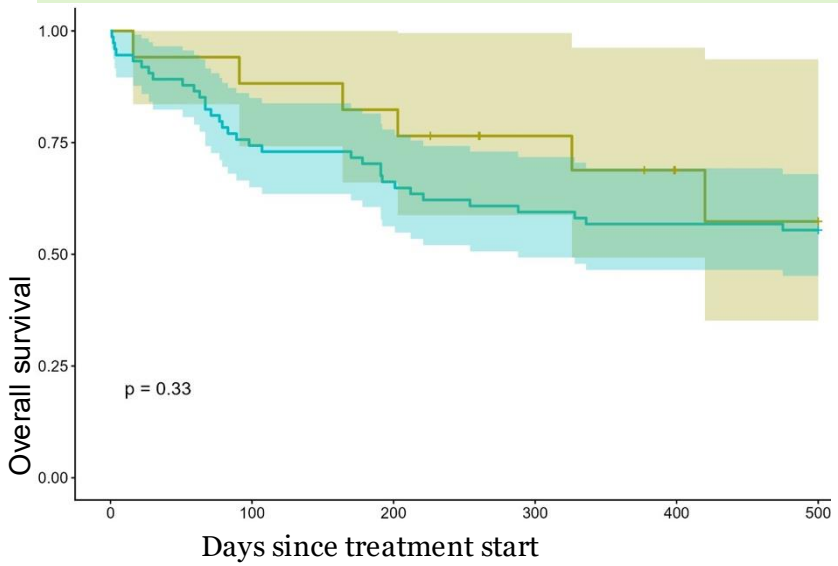
Data availability varied

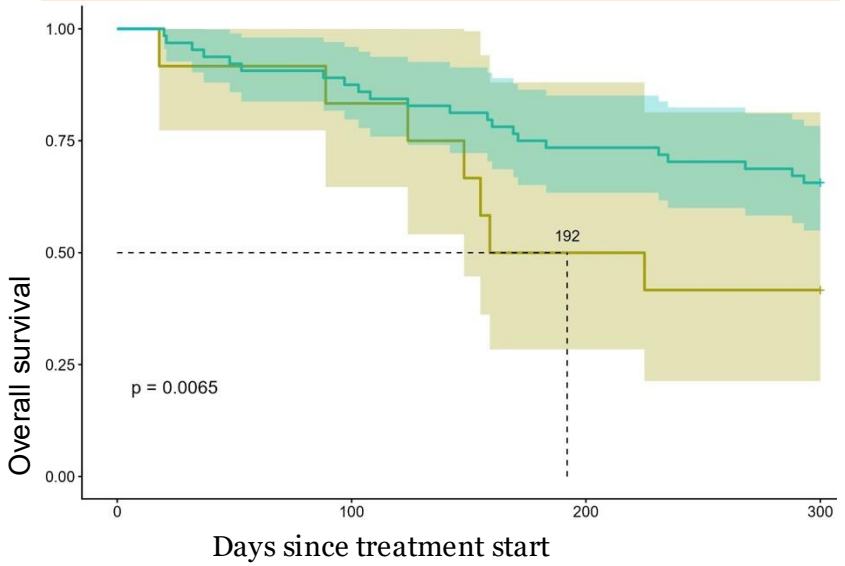
between countries, challenging inclusion of patients

Patient characteristics

were largely similar between countries and treatment groups







— Pembrolizumab — Atezolizumab — Cemiplimab

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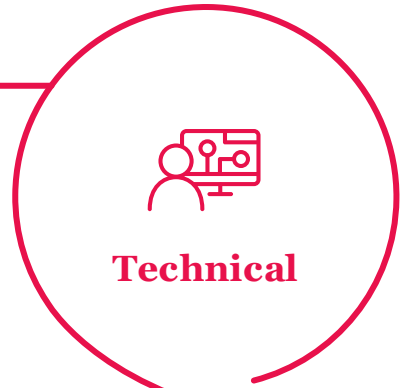
What VALO2 pilot revealed about running an SPE study in the Nordics today?

Technical interoperability

What proved feasible

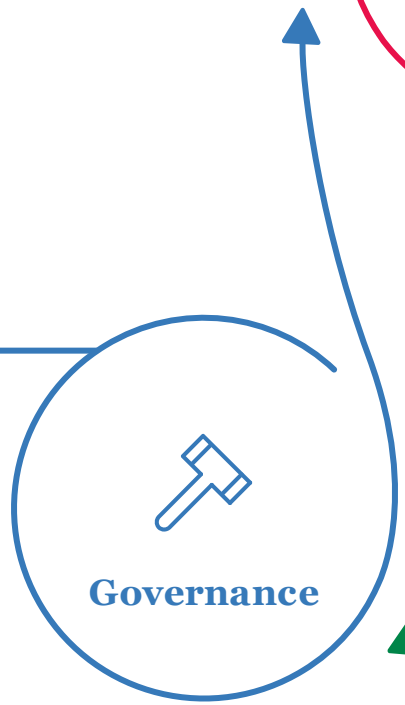
- ✓ Researchers accessed multiple SPEs
- ✓ Analysis could be conducted without moving patient-level data
- ✓ Common analytical approaches could be applied



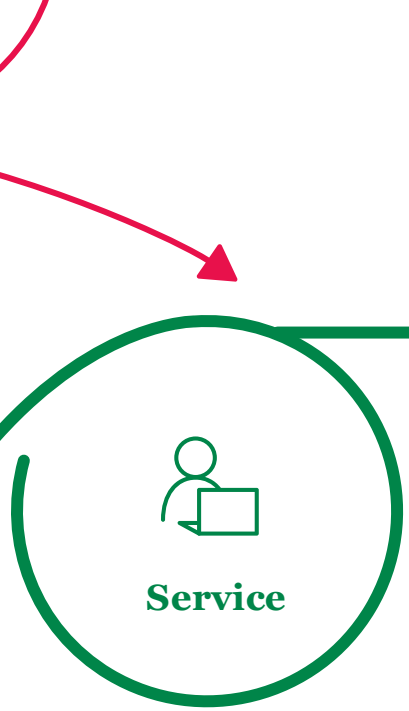
Governance interoperability

Still requires standardisation

- ! Approval pathways differed
- ! Research access processes varied
- ! Timelines were not always predictable



Critical to Success



Service interoperability

Largest scaling challenge

- ! Researcher experience varied
- ! Support models differed
- ! Analysis readiness was not consistently achieved after access was granted

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Question to the panel and audience

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What is currently the greatest obstacle to routine cross-border health-data research?

- Governance
- Technology
- Data readiness
- Researcher service

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Key takeaway

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What did the VALO2 pilot reveal about running an SPE study in the Nordics today?

Researchers crossed borders, Patient-level data did not.

Scaling it requires interoperable researcher services, governance and data readiness.

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