

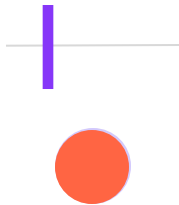


Modernizing Clinical Data Science

**Best practices for a unified,
governed SCE**

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PHUSE EU Connect 2025



Current State

Manual & disconnected

- Email for approvals
- Excel for tracking
- Manual validation
- Disconnected tools
- Limited traceability

Result: Chaos, rework, and audit anxiety



Ideal State

Unified & automated

- Smart planning (metadata)
- Embedded QC
- Policy-aware suggestions
- Automated validation
- Reproducible workflows

Result: Unified SCE with full visibility



LIVE POLL

How quickly can you reproduce any analysis with full traceability?

- Very confident | complete reproducibility, instant access
- Somewhat confident | Most analyses, with some effort
- Not confident | Significant investigation needed
- Unsure | Processes untested, unknown

The urgency of SCE modernization



**Intensifying
regulatory
scrutiny**



**Managing
explosion of data**



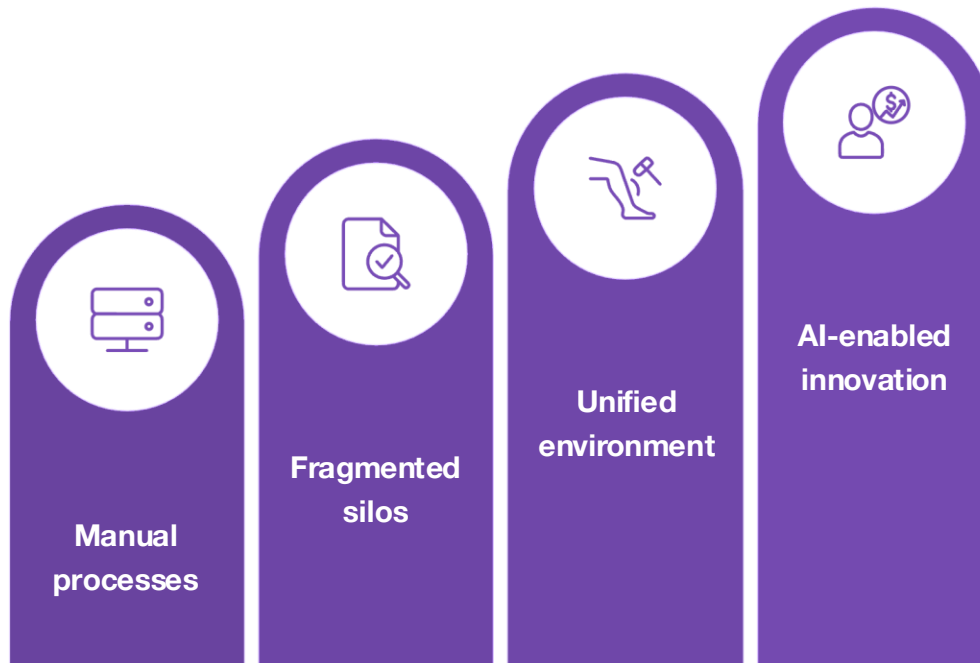
**Reducing
validation burden**



**Unified team
workflows**

Your SCE modernization path

Understand your current stage to strategically plan your SCE transformation





Best practices for SCE excellence

- 1 Centralize tools and teams
- 2 Embed quality and auditability
- 3 Reuse and scale workflows
- 4 Increase transparency and empower stakeholders
- 5 Future-proof architecture



#1: Centralize tools and teams

A single, governed environment eliminates friction

- One workspace for SAS, R, and Python
- Self-service compute scales to model needs
- Governed data access with appropriate permissions
- Direct connectors to raw data sources
- Metadata integration

Eliminate rework

No rebuilding environments
or recreating data pipelines

Reduce silos

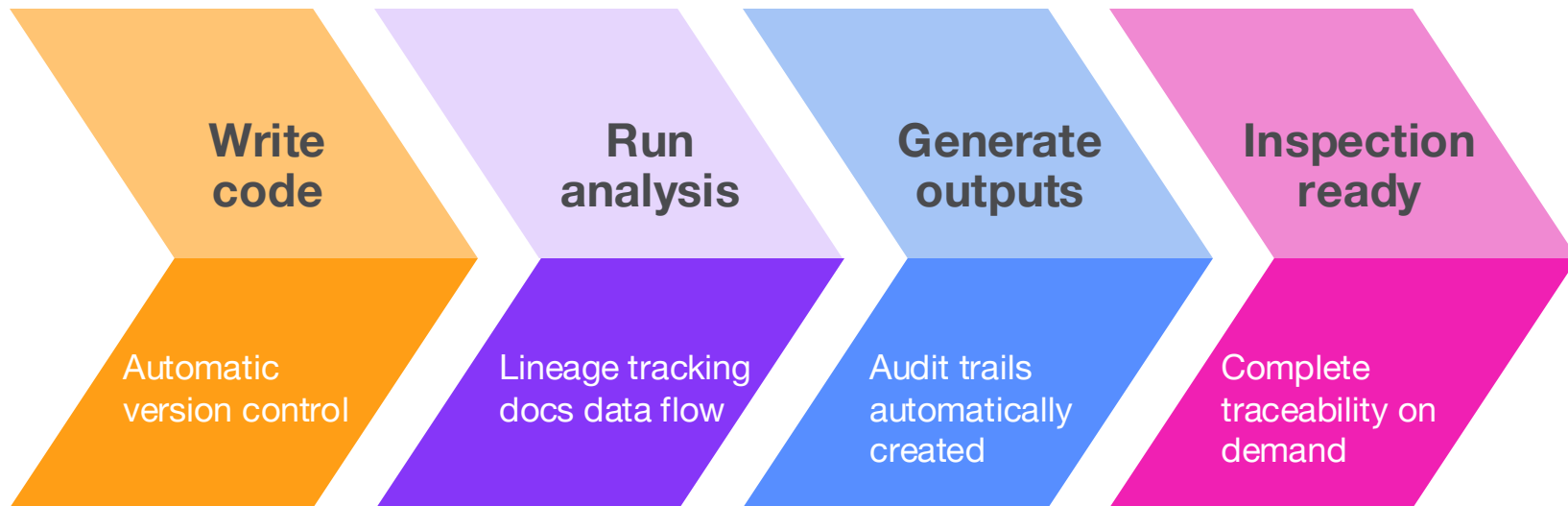
Teams collaborate in shared
workspaces

Free up Time

Analysts focus on insights,
not infrastructure

#2: Embed quality and auditability

Quality isn't an afterthought; it's built into every workflow from the start





LIVE POLL

Which best describes how your SCE
QC process works today

- Mostly manual | spreadsheets & email tracking
- Partially automated | inconsistent automation across teams
- Fully embedded | complete lineage & audit trails
- Other | unsure of current state

#3: Scale quality through reusable workflows

Standardize what works; reuse patterns to deliver quality at scale

Focus on reusability and reproducibility

- **Risk-based policies**
- **Metadata-driven templates** - e.g. Automate SDTM->ADaM-> TLF
- **Reusable derivation macros** - e.g. Shared logic for durations, flags, endpoints
- **Validated packages** - Focused on R usage
- **Cross-study pipelines** - e.g. Enable reproducible QC and reporting

Governance meets flexibility

- **Version-controlled libraries** - Preserve validation history as code evolves
- **Stage-based reviews** - Enforce independent QC and approvals
- **Configurable workflows** - Adapt QC depth to study complexity
- **Central Audit Evidence** - Auto-capture reviewer notes and findings



Organizations that implement reusable workflows report 30–50 % faster analysis cycles while maintaining validation integrity.



#4: Increase transparency and empower stakeholders

Transparency builds trust and accelerates decision-making. Stakeholders become partners, not gatekeepers.

Real-time data lineage

- Source-to-output trace maps
- Column-level lineage views showing dependencies
- Automated refreshes when upstream data changes

Live QC status

- Validation completion % by deliverable
- QC in-progress vs signed off trend
- Failed vs passed outputs
- Avg QC turnaround per deliverable

Self-service insights

- Macro adoption
- Common root causes of failures
- High-risk outputs pending secondary validation
- Defect density trends

Actionable Transparency means making validated results visible through governed, interactive applications

Your Path Forward: 5 Key Actions

Transform Your SCE

1

Assess Maturity

Understand your starting point. Evaluate your current SCE: Manual? Fragmented? Unified? This guides prioritization.

2

Start with Centralization

Unite tools and teams in one governed environment. This foundation enables quality, reuse, and efficiency.

3

Embed Quality

Build lineage, version control, and audit trails from day one. Don't bolt on validation at the end.

4

Design Cross-Functionally

Bring all teams together. Shared workflows require shared design, avoiding siloed decisions.

5

Build for Tomorrow, Today

Implement architecture for current needs and future AI. Thoughtful implementation now ensures future-proofing.



Remember: SCE transformation delivers **faster submissions, higher quality, greater trust, and energized teams**. Every step compounds.

The question is not if you should modernize your SCE, but how quickly you will achieve unified, AI-enabled excellence.



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Thank you.

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