

The Clinical Data Science Conference

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Shilpa Sood
Customer Success Manager, Services
shilpa.sood@sycamoreinformatics.com

Kala Shivali
Director, Services
kala.shivali@sycamoreinformatics.com

The introduction of a new, GxP-compliant environment for statistical programming and data sciences marks a significant advancement in efficiency and compliance within organizations. This poster examines how well-defined use cases, aligned with customer SOPs, can facilitate a smooth transition to the new system. Emphasizing a short learning curve, streamlined training, and accelerated adoption, we discuss strategies to ensure that teams quickly embrace the new system, achieving both operational excellence and regulatory compliance.

SPA MDR CDR SCE
PROTOCOL METADATA DATA COMPUTING

Why does your organization need a new SCE?

- Latest regulatory requirements
- Increase efficiency & reduce overhead
- Consolidate disparate legacy systems
- Need for more robust programming setup
- Workflow integration
- Stay current with the latest in technology

Finding the best SCE for your organization

What does business want?

- Support for multiple languages (R, Python & SAS)
- In-built version control
- Effective data handling including unblinded data
- Seamless integration with third-party tools (P21 etc.)
- Optimized programming workflows

What does your IT want?

- Support for large number of concurrent users
- Reliable, secure system with audit & access control
- Quickly scalable system
- Meets performance needs
- Meets budget constraints

What does regulatory want?

- Auditability
- Data Lineage & Traceability
- Reproducibility
- Validated System (21CFR Part 11)
- Data integrity & security

Potential Challenges

- Business continuity
- User adoption & new system training
- Change management related to new processes & systems
- Migration of inactive/legacy studies
- Resistance to new technology

Strategies for smoother implementation

Sprint-driven Product Understanding

Parallel Synergistic Streams

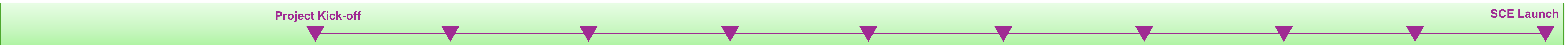
Enthusiastic Change Champions

Continuous End-user Engagement

End-user Training

Process Optimization

Robust Support Pathways



Project Management Stream

Oversees overall SCE implementation, coordinates with other workstreams and the vendor; Manages issues, mitigates risks; Ensures timelines and budgets are met

Schedule meetings for stand-ups, operations, governance, and strategy alignment.

Builds excitement within organization for upcoming SCE launch (Newsletters/Road-shows/Open House)

Validation Stream

Develops a validation & User Acceptance Testing (UAT) strategy

Track User Acceptance Testing (UAT)

Conducts validation to verify system functionality, security, and compliance

Finalize documentation to confirm system validation

Change Management Stream

Works with business to identify process optimizations & removal of obsolete processes; Works to identify changes needed to SOPs, work instructions & job aids

New user on-site training

New user LMS training

Works with vendor to develop training materials, including videos, user guides, and FAQs to deploy to organizational Learning Management System (LMS)

Technical Stream

Ensures technical architecture and info security teams aligns with processes

Identify integrations with existing tools used by programming teams

Tests and fine-tunes integrations for seamless operations post-launch

Plans annual capacity & performance capability

Plans and works with vendor for disaster recovery planning

Finalizes migration strategies for legacy studies

Business Stream

Aligns business requirements with the internal stakeholders & product capabilities

Present representative use cases to vendor to optimize product usage

Gets a sign off from business users to convey product acceptance

Establishes robust support channels for users, including helpdesk and escalation pathways

Identify change champions

Works with vendor to employs a sprint-based approach to explore and understand product functionalities

Conducts UAT to validate system readiness and adaptability

Expand end-user engagement in SCE launch and usage by promoting SCE, addressing queries for a seamless transition to the new SCE

Problem Statement

Different standards, Operational delays, Inefficiencies

Cost overruns: Multiple licenses

Compliance inconsistencies

Complex Clinical Trials Data Ecosystem

Solution Approach

Identify an SCE that meets regulatory and business needs.

Develop a standard workflow and process framework.

Ensure the SCE application performance requirements are met

Ensure a smooth migration with minimal disruption to ongoing work.

Implementation Process

Step 1

Understand business & technical requirements. Map to SCE functionalities

Step 2

Initial system configuration
Identify Change champions

Step 3

Conduct Sprints
Develop standard processes and workflows like standard folder structure

Step 4

Process optimization
Study adaptation process
Training documentation
Train the trainer

Step 5

GO-LIVE!

Post Go-Live

Phase 1

• New Analysis: Bring in new studies

Phase 2

• Active Analysis: Identify schedule to migrate active studies with no deliverables in nearby future

Phase 3

• Closed & Archived Analysis: Bring in closed and archived studies

Business & Technical Benefits

Unified System

Stable & Efficient

Cost Savings

Regulatory Compliance

SCE