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Implementing a Modern Open-Source SCE Without Disruption

TONI AUENE TUXEN, CLAUS OXVIG STENBERG AND KALA SHIVALI



Agenda

- **What is a modern Statistical Computing Environment (SCE)?**
- **Why did we need to change?**
  - Practical lessons learned from implementing a modern SCE that supports open-source technologies
  - Strategies for transitioning from traditional SCE platforms to a scalable and compliant environment
  - Stakeholder alignment, migration planning, validation strategies, infrastructure readiness, user adoption, governance, and support operating models
  - A practical implementation framework, key success factors, and lessons learned
- **Conclusion**

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What is a modern Statistical Computing Environment (SCE)?

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What Should a Modern Statistical Computing Environment (SCE) Have?

1. Single Comprehensive Application

Built-in version control, access control, compute management, traceability, reproducibility, and comprehensive audit trails.

2. Polyglot Programming

Seamless integration and execution of **SAS**, **R**, **Python**, **RShiny**, and **Agentic AI apps** within the same GxP compliant ecosystem.

3. Automated Governance

Built-in **21 CFR Part 11**, **GxP**, and **EU Annex 11** compliance.

4. End-to-End Traceability

Complete visibility from data acquisition to submission, including data provenance, blinding/unblinding, and chain of custody.

5. Reproducibility & Transparency

Every dataset, program, and output can be reproduced with a full audit trail for verification and regulatory compliance.

6. Integrated AI & Automation

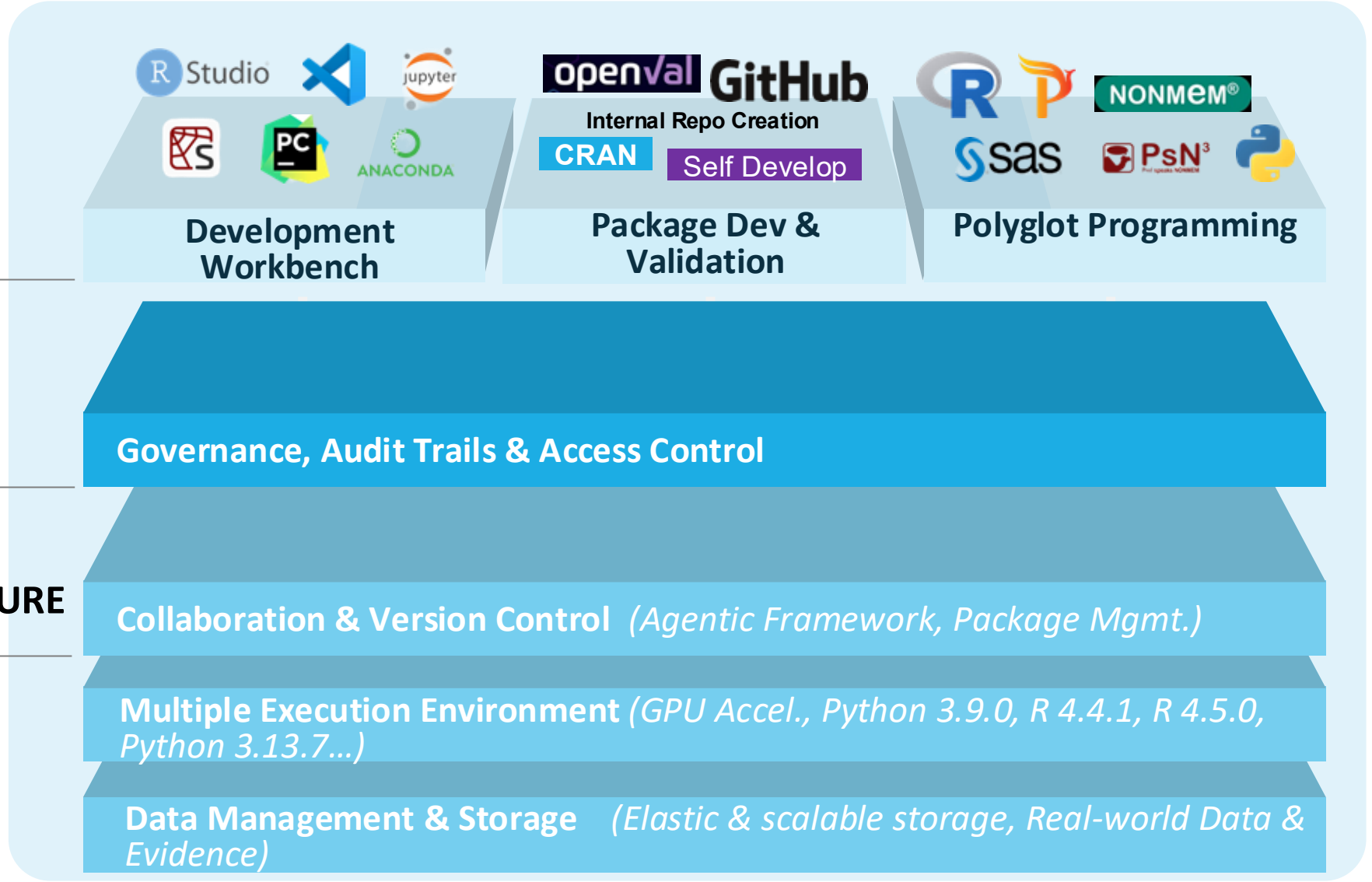
Agentic AI capabilities for intelligent code review, dataset validation, & automated report generation.

7. Visualization & Control

Visual tracking of study progress with one-click validation summary reports for faster business delivery (topline report, CSR, ISS, ISE, etc.).

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Components of a Modern SCE



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Benefits of Modern SCE

TRADITIONAL SCE



Regulatory overwhelm



Outsourced vision, lengthy and error-prone dev



Upfront high-cost, low ROI, walls between teams

from friction

SHIFT

to flow

MODERN SCE



Streamlined submissions



Audit-ready, traceable



Agile data-science culture & shortened development



SaaS, user-centered and team alignment

Traditional constraints

Modern outcomes

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Why did we need to change?

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Legacy Platform Challenges

Aging Technology Platform

Lack of Version Control, Traceability and Audit Trail

User Access Management and sharing

SCE and CDR Combined in One Platform

No Package Version Management

Reliability and Availability Issues

Declining Vendor Support

- Response times and overall support quality had deteriorated.
- Enhancements and modernization opportunities were limited.
- Increasing uncertainty regarding the long-term sustainability of the platform.

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Moving to a validated SCE: practical lessons from Zealand Pharma® and Ascendis Pharma®

IMPLEMENTING A MODERN STATISTICAL COMPUTING ENVIRONMENT

A GxP-validated platform removes the limit on open source

BEFORE

Open source limited by a non-GxP setup

Unvalidated environments create compliance risks and prevent full utilization of modern open source analytical tools.

NOW

Open source on a validated, controlled platform

✓ Full GxP compliance & package governance
✓ Enterprise-grade reliability and security

THE PLATFORM SUPPORTS

Open-source packages

R, Python, and modern data science language ecosystems

SAS

Full support for standard SAS procedures and legacy clinical analytics

NONMEM and other PK/PD tools

Specialized quantitative pharmacology and modeling software

All backed by a solid, controlled package platform

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From an IT-run server to a controlled GxP system

BEFORE

Legacy Server Setup

- Old server setup
- Supported purely by IT
- Inadequate control and governance of open-source tools
- Version control and disaster recovery limitations

NOW

Controlled GxP Environment

✓ Audit trail

✓ Access control and roles

✓ Documented restrictions

✓ Backups in place

✓ User-friendly interface

And multiple tools now work together in one environment.

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A new wardrobe: the same trusted basics, far more to choose from

Stylish & modern

Every statistical programmer still gets the essentials they rely on, now in a fresher, more modern cut.

Controlled & secure

The wardrobe stays locked: governed access, validated packages and full traceability keep every item in its place, and only the right people hold the key.

Accessories

R packages, Shiny apps, AI assistants and containers let each team put together the right look for every study, without compromising compliance.

Up to today's standards, and ready for what comes next

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More than one year of URS, POC, Sprints and testing before Go Live

Go-live

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POC	Testing	Dev implementation	Re-testing	Training	Migration
Questions and backlog from the start. Access to system	Issues logged and fixed with the vendor	Roles, folder templates, SOPs	Test cases in Veeva, backlog follow-up	User adoption training	Final push, onboarding all users

Ascendis Pharma:

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URS	Dev implementation I	Sprints	Dev implementation II / Testing	Training	Migration
List os requirements (long!) and dialogue	BLC, Roles etc,	”PoC” where Sycamore demonstrated the URS and our BLC	Standard macros, validation and OQ/PQ/URS testing, SOP, WI, UG	User adoption training (2 day workshop)	Migration Priorities: 1. Closed trials and milestones 2. Active (live) trials and milestones

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Key success factors, and lessons learned

Statistical Programming Does Not Work in Isolation: Managing Upstream and Downstream Process Changes



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Seven areas had to move together



- Stakeholders
- Migration planning
- Validation
- Infrastructure
- User adoption
- Governance
- Day-to-day support

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Plan the migration early and together

layers01

Never underestimate the migration

Moving from one SCE to another is never easy

update02

Time the move around system updates

Release timing can collide with your plan

groups03

Collaborate closely on the migration

Vendor and internal teams side by side

bolt04

Pick a vendor who resolves issues fast

Issues raised in testing were taken seriously

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Conclusion & Strategic Value

Transforming Statistical Computing without Operational Disruption

Unified Open-Source Architecture

Seamlessly connects R, Python, and SAS within a single GxP-compliant ecosystem, modernizing workflows without sacrificing regulatory integrity.

Zero-Disruption Migration

Phased implementation and stakeholder alignment strategies guarantee business continuity, automated governance, and full end-to-end traceability.

Agentic AI Integration

Empowers statistical programming with automated code reviews, package validation, and rapid reporting to accelerate clinical study delivery.

Key Takeaway

A modern SCE bridges open-source innovation and strict regulatory compliance, creating a scalable, future-proof foundation for clinical analytics.

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Toni Auene Tuxen
Director, Statistical Programming
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Toni Auene Tuxen has more than 25 years of experience in the pharmaceutical industry, primarily within diabetes and obesity. He has held leadership roles in statistical programming, most notably as International Lead Statistical Programmer for Wegovy®, where he defended the data package for the FDA.

Toni holds a degree in Mathematics and Economics from the University of Copenhagen and is currently Director, Head of Statistical Programming at Zealand Pharma. He is passionate about efficient processes, regulatory requirements and scalable, compliant systems, and about moving the industry from managing data to enabling faster, data-driven decisions.

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Experienced statistical programming leader within the pharmaceutical industry, with extensive expertise in SAS programming and CDISC standards, particularly ADaM.
Claus holds a Master's degree in Biology from the University of Copenhagen and a PhD from the University of Bergen. Prior to transitioning into the pharmaceutical industry, he worked as a research scientist from 1996 to 2014 at institutions across Greenland, Norway, and Denmark.
Throughout his pharmaceutical career, Claus has held senior statistical programming positions at Novo Nordisk and LEO Pharma, contributing to the delivery of clinical development programs and regulatory submissions. He currently serves as Director, Statistical Programming at Ascendis Pharma in Hellerup, Denmark, where he heads up the statistical programming unit and drives initiatives focused on quality, innovation, automation, and efficient clinical trial data delivery.

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Kala Shivali is a seasoned leader with over 30 years of experience across BioPharma, Biotechnology, and IT. Her career includes leadership roles in statistical programming, program management, customer engagement, and strategic delivery. Holding a degree in Computer Science and an MBA in Biosciences, Kala excels at bridging the gap between technology, operations, and clinical development.

Currently, at Sycamore Informatics, she focuses on modernizing clinical development through AI, automation, and next-generation data analytics. Kala is passionate about leading global teams, driving large-scale transformations, and shifting the industry from managing data to enabling faster, data-driven decisions.

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