

SCE WHITE PAPER 2.0

**A MODERNISED FRAMEWORK FOR THE
NEXT GENERATION OF DATA ANALYSIS**

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INTRODUCTION

MODERN TRACKS FOR MODERN ANALYTICS INTRODUCING SCE 2.0



300 km/h (186 mph)



600 km/h (373 mph)
(maglev train)

Our trusted train met a new rail network (AI, RWD, GPUs, open-source, ...)
SCE 2.0 modernizes the journey

Resources:

https://zolimacitymag.com/wp-content/uploads/2024/01/High-Speed-1-_HS1_c-Daniel-Clements5_Arup_zolima_citymag.webp
<https://www.republicworld.com/world-news/china-tests-worlds-fastest-maglev-train-capable-of-reaching-speeds-of-up-to-700-kmph-in-2-seconds>



ORIGINAL SCE DEFINITION

KEY FEATURES OF THE ORIGINAL SCE (2019–2021)



A GxP-Controlled Analytics Environment

- Multi-faceted, software-agnostic, highly controlled platform designed for regulated clinical trial reporting.
- Enabled creation of SDTM, ADaM, and TLG outputs, plus all submission deliverables.

Core Technical Foundations

- Built on cloud-native or cloud-agnostic infrastructure.
- Supported multi-language compute (SAS, R, others).
- Standardized workflows: DEV → VAL → PROD.
- Version control, audit trails, traceability, reproducibility, and automation were central elements.

Integrated Tools & Capabilities

- Program and documentation management.
- Metadata, codelists, and standards governance.
- Project management, metrics, visualization, and workflow tools, all designed to ensure transparency and rigor.

KEY FEATURES OF THE ORIGINAL SCE (2019–2021)



Data Sources & Deliverables

- Integrated with CDMS/EDC, MDR, CRO environments, and external vendor feeds.
- Supported CSRs, ad-hoc analyses, annual/periodic safety reports, and other regulatory deliverables.

Scope & Purpose

- Primarily focused on **regulated clinical trial reporting**.
- Provided a controlled space for statistical modeling and simulations within strict compliance boundaries.



UPDATED SCE DEFINITION

FROM REPORTING TOOL TO A BROADER ANALYTICS PLATFORM



Shift to Scalable Analytics

SCE evolved from traditional clinical reporting to a dynamic, scalable analytics ecosystem supporting enterprise-wide data.

Metadata Repository and Automation

The Metadata Repository drives standards-based automation, ensuring data consistency and lineage awareness across the platform.

FROM REPORTING TOOL TO A BROADER ANALYTICS PLATFORM



Exploratory Analytics Environment

Enables AI/ML development, real-world data integration, simulation, and prototyping for collaborative data science and research.

Enterprise Principles Expansion

Transparency, traceability, and reproducibility extend to AI/ML, reusable standards, real-time integrations, and enterprise data strategies.



**FUTURE
ENHANCEMENTS
AND OPERATIONAL
CAPABILITIES**

AI GOVERNANCE, LLMOPS, AND ADVANCED COMPUTE



AI Governance and Compliance

Critical for model credibility, bias assessment, and lifecycle controls to ensure trustworthy AI systems.

LLMOps Management

Governance for large language models with prompt logging, evaluation, and supervised usage guardrails.

Advanced Compute and Security

GPU-accelerated compute and confidential computing ensure efficient, reproducible, and secure data processing.

Data Mesh and Synthetic Data

Structured governance and synthetic data pipelines enable lineage tracking, privacy, and accelerated testing.



AUTOMATION AND REPRODUCIBILITY

METADATA-DRIVEN AUTOMATION AND STATISTICAL DIAGNOSTICS



Metadata-Driven Pipelines

Standardized pipelines use MDR metadata to automate SDTM, ADaM, and TLG outputs, improving efficiency and accuracy.

Reproducibility and Traceability

Execution metadata, environment hashes, and container digests enhance reproducibility, traceability, and regulatory confidence.

Automated Statistical Diagnostics

Automated detection of outliers, data drift, and model diagnostics reduces manual checks and improves analysis quality.

Focus on Interpretation

Automation enables teams to focus on interpreting results and innovating rather than manual report reviews.



**STRATEGIC
CONSIDERATIONS:
COST, GOVERNANCE,
AND COLLABORATION**

COLLABORATION, COST MODELS, AND SHARED CAPABILITIES



Enhanced Collaboration Frameworks

Collaboration includes trustzone environments, federated QC, and joint contributions, improving scalability and quality across teams.

Comprehensive Cost Management

Cost models cover cloud compute, GPU use, storage, validation, maintenance, training, and data governance for sustainability.

Unified Statistical and Data Science

Shared capabilities unify biostatistics and data science for standardized tools, governance, and cross-functional workflows.

Strategic Infrastructure and UX Balance

A strategic roadmap balances backend modernization with frontend usability to optimize user experience and infrastructure.



CONCLUSION

SCE 2.0 AS A FUTURE-READY ANALYTICS ECOSYSTEM



Core Principles Maintained

SCE 2.0 preserves transparency, traceability, reproducibility, auditability, and strong documentation in analytics platforms.

MDR-driven Automation & Data Hub

The ecosystem centers on MDR-driven automation and a governed Clinical Data Repository enabling faster, quality submissions at scale.

Unified Exploratory and Regulated Workflows

SCE 2.0 unifies exploratory and regulated analyses supporting modern computational methods and integration of real-world data.

Future-Ready and Collaborative Framework

The framework supports federated analysis, evolving modalities, and alignment across companies and regulatory bodies.