

Implementing a GxP-Compliant Agentic AI Framework for Accelerating Clinical Trial Data Analysis



Sycamore Clinical Agentic Framework™

SPD 15% MDR 15% DTM 15% DSW 15% SCE 15% CDR 15%

PROTOCOL METADATA TRANSFORM OPEN SOURCE ANALYSIS REPOSITORY

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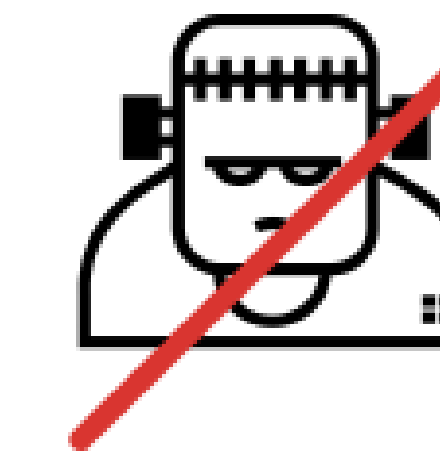
The next frontier in clinical analytics is the successful fusion of Agentic AI with established polyglot environments: SAS, R, and Python. Here, we present our experience in deploying GxP-Compliant Agentic Framework that provides audit-trails with version control, traceability and reproducibility. The framework deploys AI agents (Skills and Workflows) to automate complex, multi-language pipelines, from generating SAS code to executing quality reviews. It also bridges skillset gaps by enabling conversion of SAS assets for modern R workflows, accelerating submission readiness. To guarantee reproducibility and a verifiable chain of custody, the architecture maintains the “Human in Control” for clinical judgement. This ensures all analytical outputs are fully auditable and traceable, version controlled and prepared to withstand rigorous inspection. By integrating open-source and legacy code with governed AI, the framework scales reproducible clinical trial data analysis workflows and accelerates submissions.

Core Foundations of a Statistical Computing Environment (SCE)

Data Integrity	Data is attributable, legible, contemporaneous, accurate, complete, consistent & available for inspection.
Access Control	Data is protected with role-based access control.
Version Control	The reported artifacts are versioned.
End-to-End Traceability	Every reported output is traceable back to source data.
Reproducibility	Analyses can be repeated and produce the same results.
Auditability	All actions and changes are recorded and reviewable. Audit trails must be dynamic and immutable.
Automated Governance	Built-in 21 CFR Part 11, GxP and EU Annex 11 compliance

The Industry Transformation: Shift to Open Source

Traditional SCE	Modern SCE
Single primary analysis tool (SAS)	Polyglot (multi-tool ecosystem - SAS, R, Python) and flexibility to choose preferred IDEs
Static reports	Interactive visualizations and dashboards
Organization-specific custom-developed SAS macros maintained internally	Open-source community-developed functions and tools written in R & Python all over the globe
One Execute version of SAS	Concurrent multi-version R & Python runtime environment for GxP-compliant development
Batch execution of SAS programs in a manually-predefined sequence	Flexible batch execution of programs combining SAS, R, & Python with dependency-driven runs
Isolated team environments, limited data sources, & manual infrastructure expand	Global team shared environments, multiple seamless data streams, and automated elastic scaling



USER LAYER

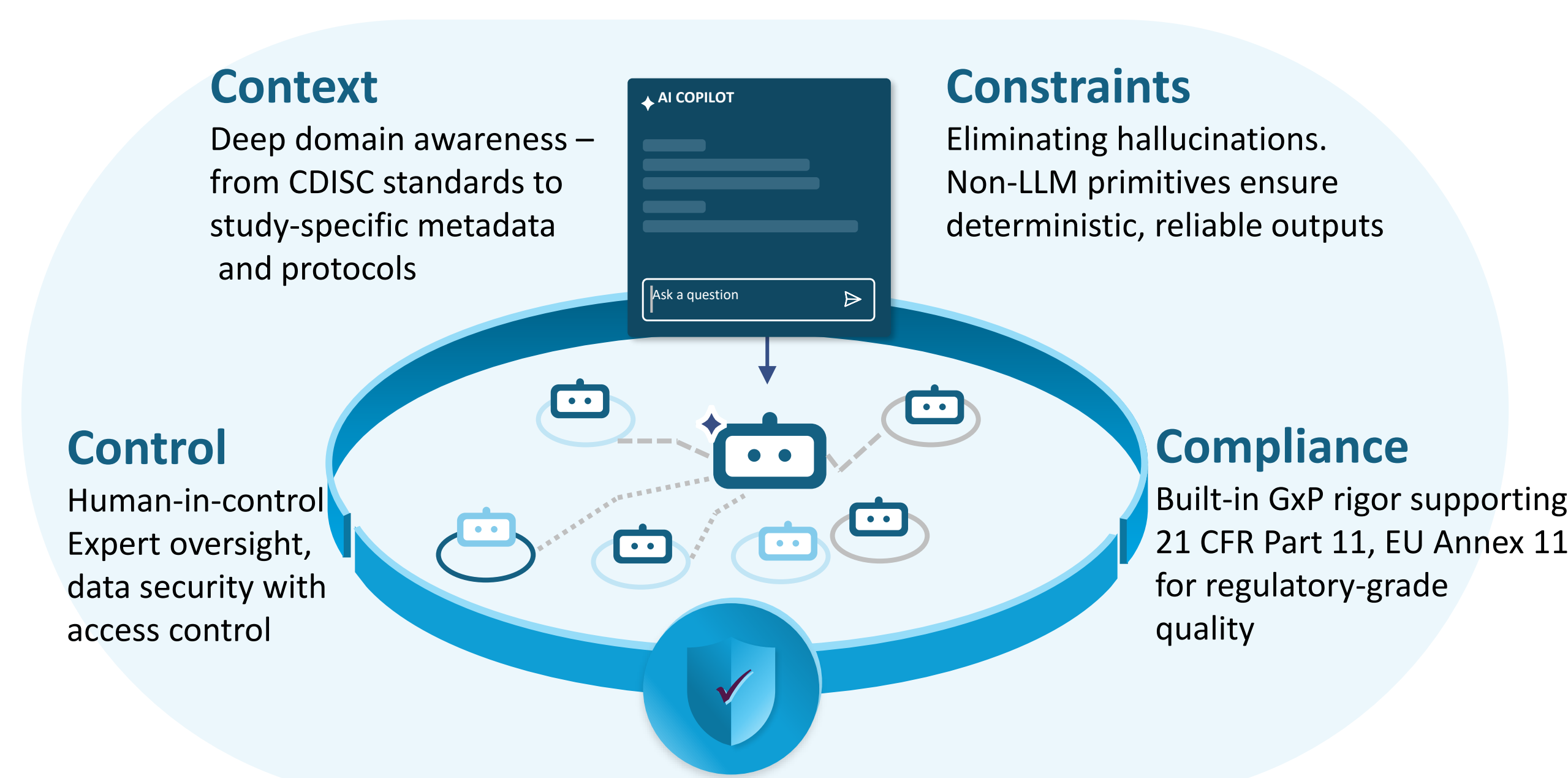
SECURITY LAYER

INFRASTRUCTURE LAYER

Modern SCE

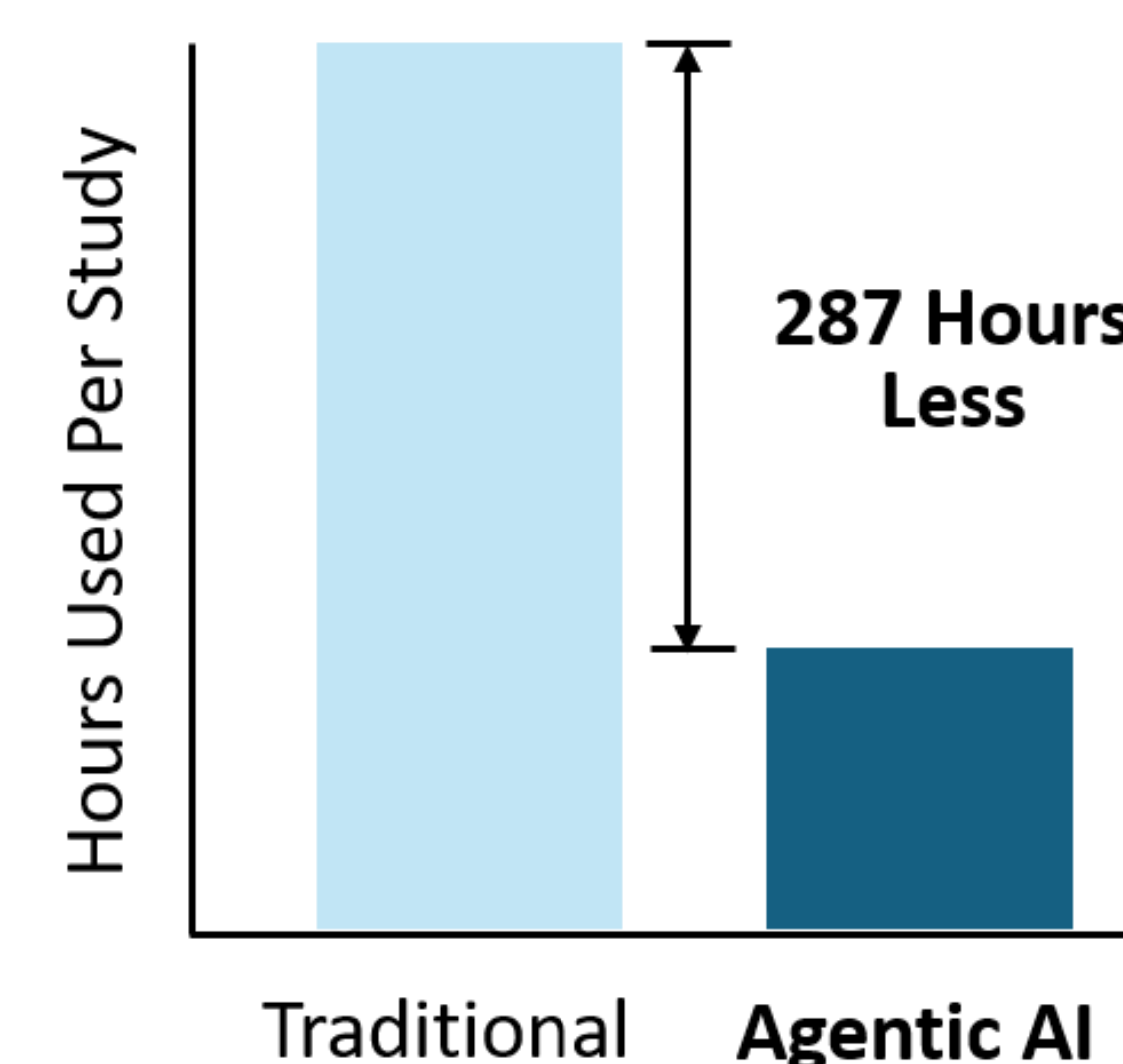


SCE Agentic AI Framework: Deterministic Outputs with Unparalleled Acceleration, Efficiency



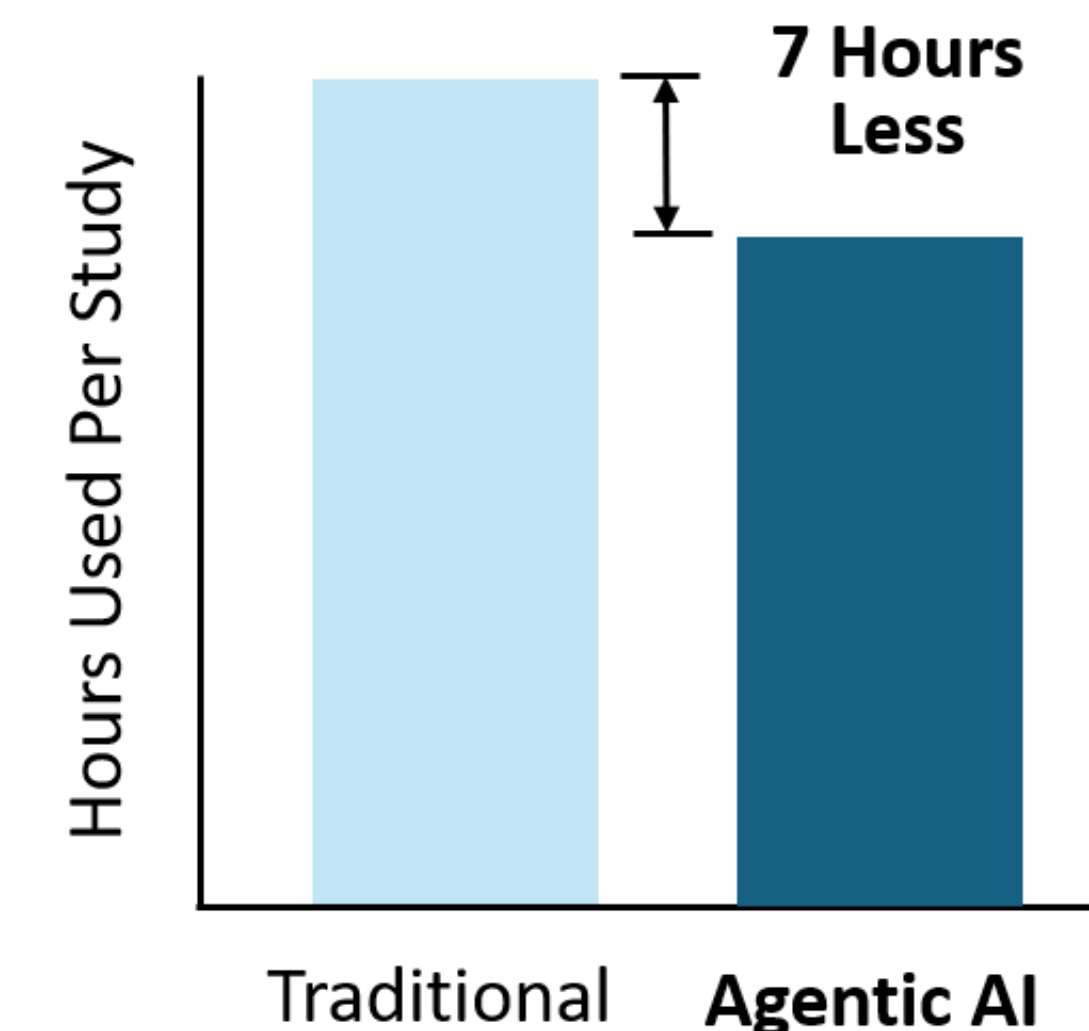
Agentic AI Flow Example: Real-World ROI Achieved by Our Customers

SDTM Generation



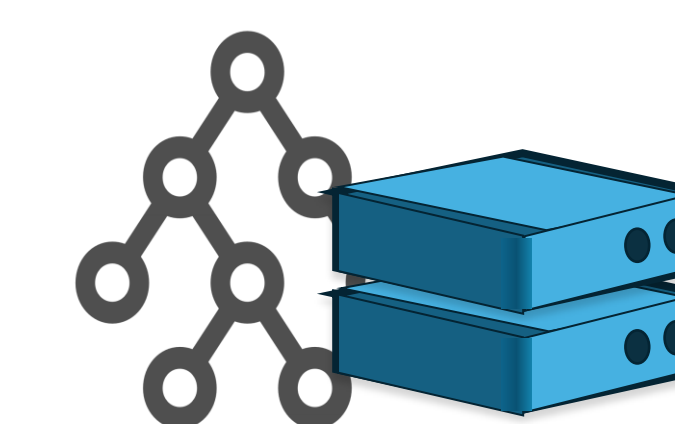
80% Faster
SDTM Generation

SDTM Review



29% Shorter
SDTM Review

Modern SCE with Agentic AI Framework: Innovation Without Compromise



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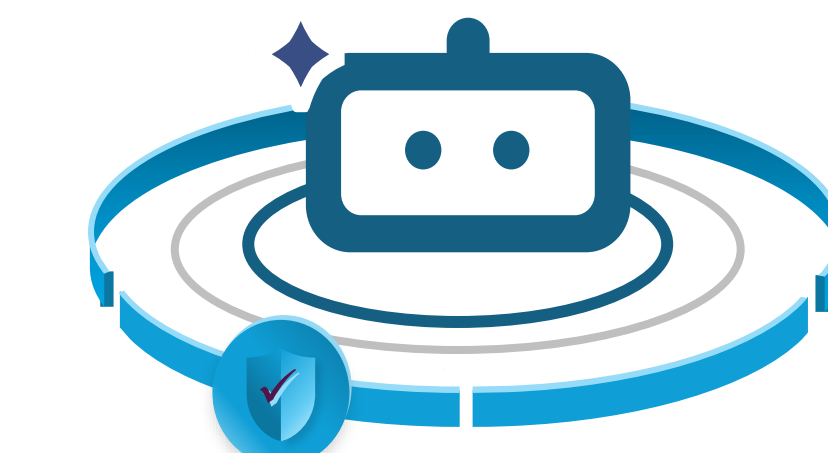
Unified Analytics Engine

- ✓ **Hybrid Integration:** Seamlessly bridges traditional SAS architectures with modern open-source languages (R, Python).
- ✓ **Cohesive UX:** Data scientist & clinical programmer consolidated user experiences without the friction of environment switching.

Unbroken GxP Compliance

- ✓ **Regulatory Rigor:** Built-in frameworks to guarantee data integrity, strict access control, and absolute security.
- ✓ **Audit Readiness:** Fully traceable, version-controlled, and reproducible pipelines that automate end-to-end auditability.

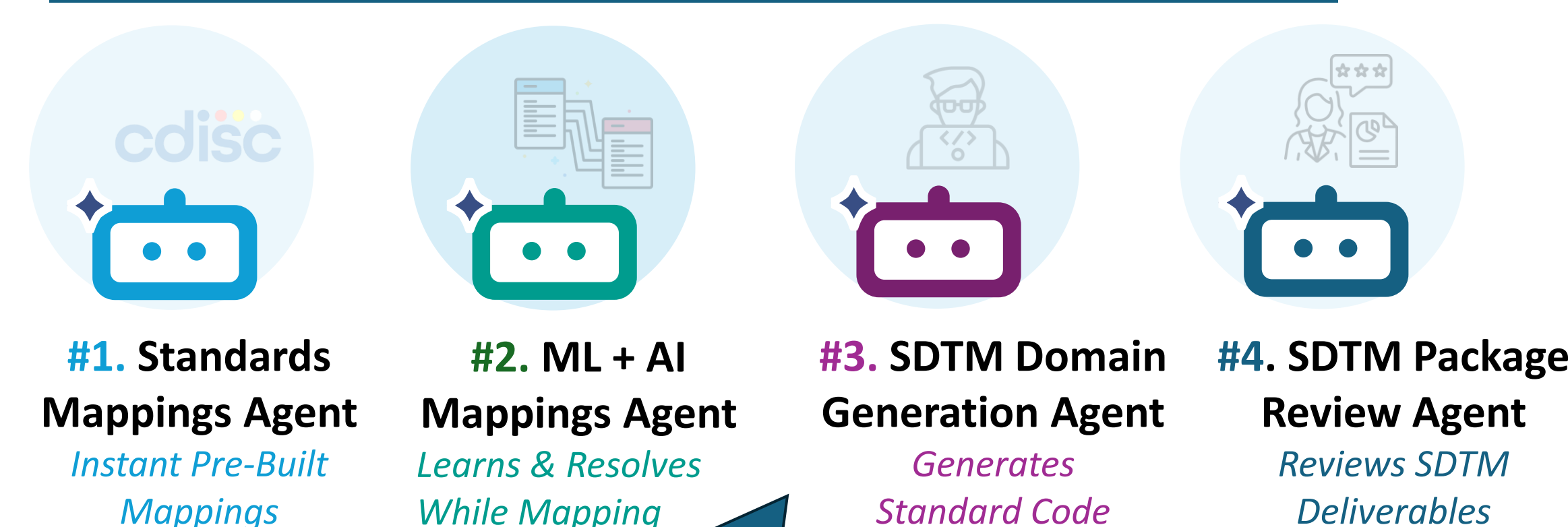
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Governed Agentic AI

- ✓ **Intelligent Workflows:** Safely layers in advanced AI skills and automated agentic flows to optimize repetitive tasks.
- ✓ **Built-in Guardrails:** Protects study integrity with lineage tracking, contextual isolation, & mandatory Human-in-the-Loop validation.

Agentic AI Flow Example: SDTM Generation & Review



Regulatory compliance should be a byproduct of your work, not the work itself.

Agentic AI is not just automation. It is intelligent, goal-driven execution within a modern Statistical Computing Environment (SCE).

