



SDTM Navigator

Redefine Submission Timelines with Agentic Intelligence

The BRAIN SDTM (Study Data Tabulation Model) Navigator is not just automation; it is the evolution of Agentic Orchestration. Moving beyond simple GenAI, the Navigator deploys a swarm of specialized agents to execute the entire SDTM lifecycle—from raw data to a complete submission package—in a streamlined experience. It bridges the gap between AI speed and submission-grade accuracy, powered by an internal agentic loop designed to generate near-perfect programs before human intervention.

Benefits

Zero-Error Precision

Utilizing an internal iterative loop (with Agentic AI), the system auto-executes programs, validates against Pinnacle 21, and self-corrects based on error reports. The result is a near-perfect draft ready for final review.

Total Explainability

Eliminate the "black box" phenomenon. The Navigator provides full observability into the engine's reasoning, mapping generated outputs back to source documents for absolute audit readiness.

Substantial Time Reduction

Realize a 50% reduction in spec creation time and a 69% reduction in programming and QC effort for first-draft datasets.

Guided Intelligence UI

A new wizard-based, modernized interface handholds users through the process, providing not just visibility into the outcome but also allowing interventions as the agents are working.

Features



Entire SDTM Package Generation

Upload protocol and raw datasets to instantly generate the full package: SDTM Specifications, Programs, Datasets, aCRF, Define.XML, and cSDRG — ready for review.



Historical Data & Standards Leverage

Seamlessly incorporate existing specifications and standard company macros to maintain consistency and foster reusability across programs and studies.



Agentic Iteration, Governance & QC

The solution auto-executes and self-corrects program drafts using validation feedback, guarded by hallucination checks, drift monitoring, and integrated Pinnacle 21/CDISC Core validation for full submission readiness.



Native integration with BRAIN

Seamless flow of artifacts to and from BRAIN gives users full traceability, audit trail, and variable-level lineage of transformations to support impact assessment.



Language Agnostic Interface

Full support for SAS and R lets programmers work through the native programming interfaces they already trust and know well.



Manage edge cases with Chat

A chat-based interface helps programmers work through complicated derivations and edge cases by querying the Standards, Specs, and Study Documents, and making updates directly via chat.

The Saama Difference

Saama is pioneering the move from monolithic GenAI for SDTM specs and programs to a modular Agentic AI approach. By specializing agents for tasks—like protocol extraction or domain identification—we deliver superior accuracy, modular management, and scale to a comprehensive swarm of clinical agents. Accelerate SDTM preparation with intelligence engineered for control, quality, and trust.

Contact info@saama.com to schedule a personalized demonstration.