Biometrics Research and Analysis Information Network

Accelerate Your Submission Timelines — Today

BRAIN is the foundational module of Saama's Biometrics Platform, centralizing statistical programming and biostatistics workflows to accelerate submission timelines. Users digitize study specs and generate submission-ready datasets and TLFs. Saama's knowledge graph auto-tracks program and spec lineage, ensuring full traceability from source data to TLFs. The platform enables regulatory compliance via QC workflows, issue management, and audit trails, and integrates with Saama's agentic GenAI apps to generate SDTM/ ADaM specs and programs.

Benefits

Unified Workspace

Manage source data, metadata, programs, submission datasets, TLFs, and associated artifacts in a single environment.

Full Traceability

The system auto-maintains lineage of reused programs, creating end-to-end traceability from source data to final artifacts.

Business Efficiency

Manage standard metadata, programs, and macros to enable study teams to leverage these already tested and validated artifacts, minimizing the need for recreation from scratch and further reducing the intensity of QC effort.

Team Collaboration

The solution has integrated configurable task management capabilities that enable the Statistical Programming Lead to plan, direct, and review the progress of the generation of all submission artifacts by the members of the study team.

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Features

Multi-Language & AI-Assisted Programming

Programmers work in SAS, R, or Python via native interfaces, with compliant GenAI assistance for program generation and updates.

Code Promotion Workflow

Distinct areas for development, QC review, and production archival, so programs and artifacts are reviewed and approved before release.

Lineage Tracking

The system automatically tracks how a program has traversed through the entire system, enabling users to alert downstream users if the program has been updated in the source.

Digital Specifications

With digitized analysis and reporting (A&R) specifications, users can create CDISC Define-compliant SDTM, ADaM, and Analysis Definitions and reuse them across studies without recreating them.

Issue Tracking & Access Control

Track issues on specs, programs, and outputs in one place, with owner notifications and automatic resolution history tracking. Configurable role-based access at the TA/Compound/Study level gives fine-grained folder-level control.

Knowledge Graph & Search

A proprietary graph database digitizes specs, tracks lineage, and traces linkage from source data to submission artifacts. Intuitive search helps users quickly find artifacts among millions in the repository.

The Saama Difference

No other solution lets statistical programmers and biostatisticians collaborate in a single, traceable environment to complete the complex data transformations and analysis required for regulatory submissions, from source data through to final deliverables. Accelerate your submission process — today — with Saama.

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