



BRAIN SDTM

Accelerate Your Submission
Timelines — Today

About

The BRAIN SDTM module accelerates delivery of the entire SDTM submission package by automating not just the Specifications and Programs, but also Annotated CRF and Define.XML by using a combination of GenAI and Standards based approach.

Benefits

1

Time reduction

50% reduction in time to generate Specifications and 69% reduction in time to Generate & QC first draft SDTM datasets - leading to faster regulatory submissions.

2

Reusability

Users can leverage existing specifications and programs that have already been tested and validated, eliminating the need to recreate similar artifacts from scratch.

3

Language Agnostic

Leverage diverse programming languages, foster flexibility, innovation, and enhance scalability.

4

Full Traceability

Full audit trail and lineage of transformation at variable level to support impact assessment.

Features



Autogenerated Specifications & Programs Using GenAI & Standards

Generate SDTM Specifications faster using the power of Generative AI and Standards based approach. Our solution automatically generates the executable Program based on specifications.



Standards Management

Maintain SDTM standards including global functions and out of the box functions in an hierarchical manner to enable reusability and jump start SDTM generation.



GenAI Based Code Assistant

Programmers can author new programs / functions by feeding prompts to our natively available and study context aware GenAI based Code Assistant.



Automated aCRF and Define-XML Generation

Our solution autogenerates Annotated CRF and Define.XML based on Specifications eliminating the duplicate effort and ensuring 'consistency by design'.



SAS / R / Python Support

Programmers can work seamlessly with the programming language of their choice (SAS / R / Python), leveraging the native programming interfaces of those languages.



Integrated Quality Control

Beyond running the validations using the natively integrated Pinnacle 21 Enterprise, our solution has inbuilt validations based on Pharmaverse community's SDTM checks package and user-provided custom checks - ensuring compliance with CDISC standards and submission readiness.



The Saama Difference

Saama's SDTM solution enables statistical programmers to speed up SDTM Transformation by leveraging a combination of GenAI and Standards based prediction models - providing higher accuracy in generating specifications as well as programs. Accelerate your submission processes — today — with Saama.

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