IMPLEMENTING CDISC SDTM AND ADAM IN A SAS® ENVIRONMENT

THE STANDARDIZATION PLATFORM

- SDTM Metadata Customization Provision as per CDISC ODM for future Trials
- Generalized Programs for Creating Study Specifications which includes Annotated & Blank CRFs, Blank Datasets, Study Flow Chart as per Customized Metadata

- CDISC SDTM and ADaM Metadata set up for Legacy trials transformation.
- Control Terminology and Medical Dictionaries Provision

- Generalized algorithms for Clinical Data Analysis and automatic provision of generating other Deliverables like Patient Profiles, Define.xml etc. through the same framework.

DATA TRACEABILITY

VALIDATION

FLEXIBILITY

IMPLEMENTATION SET-UP FOR LEGACY AND FUTURE TRIALS

PROCESS FOR LEGACY TRIALS

- Storing SDTM and ADaM Metadata in SAS Datasets
  - One SAS Dataset for Control Terminology METADATA and the other for values
  - Medical Dictionaries Datasets: WhoDrug MedDra and Others
- SAS Codes for Customizing the SDTM Metadata and Generating the Study Specifications for new Trial Set up
- Empty Datasets with Customised Metadata for new Trials
- Annotated CRFs
- Other Study Specific Documents
- Data Analysis using Adam Metadata
- Other Processes

- Source Data (Oracle Data, SAS Datasets, Transport Files and Clinical Data Sources)
- Metadata and Source Data Integration
- Generating Standardized Data

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- Clinical Database
- Data Integrity and Metadata Compliance Check using SAS Codes and open CDISC validator
- Submission Deliverables Directory

CLINICAL DATA SOURCES

- Oracle or other Database
- SAS Datasets
- Transport Files
- Other Clinical Data Sources

- Data Integration & Data Quality
- Clinical Domains Metadata
- Analysis Data
- Clinical Database
- Standardized Data
- Regulatory Response
- Mining Reporting
- Analytical Tools for creating the Standardized Framework
- Base SAS(Windows or Unix) SAS Datasets for Holding the SDTM, ADaM Metadata and Clinical Database Base
- SAS Codes for Integrating Source Data and SDTM (For Legacy Trials), Data Analysis using ADaM Metadata or Customized Metadata (For Future Trials)
- Base SAS Codes for generation of Standardized Datasets, Study Specifications Package and Clinical Database Loading.

GUI (.Net or Java or SAS A/F)

Automated SAS Codes for Validating Source, Standardized and Analysis Dataset Levels