PP29

Effective WorkFlow Process: Rapid SDTMs and Compliance Dashboards

Harinarayan Gopichandran, PointCross, Foster City, USA (harinarayan@pointcross.com)
Sunil Gupta, Gupta Programming, Simi Valley, USA (sunil.gupta@pointcross.com)
Raja Ramesh, PointCross, Bangalore, India (raja@pointcross.com)
Rahul Madhavan, PointCross, Foster City, USA (rahul@pointcross.com)

pointcrosslifesciences.com

Abstract

Now that the pharmaceutical industry has a process for SDTM development, are standards and compliance dashboards part of your workflow process with each refresh? By designing a mapping tool with traceability and controls, teams can standardize SDTMs and eliminate the requirement for double programming which reduces costs. A single raw data mapping layer reduces costs and enables rapid SDTMS that are fit for QA and downstream analysis. By actively medical coding, control terminology, CDISC requirements, clinical data-issues, paired variable inconsistency and derived variables, for example.

This poster reviews standardized methods to enhance the data review and compliance process for improving data quality and submission deliverables. For example, teams should actively tag and address data issues for query and correction. Instead of reloading SDTMs to check for compliance, a built-in process for compliance checks with each SDTM refresh is a better system. This provides and an environment for in-depth review of data to eliminate false positives.

With the eDV dashboard and each SDTM improvement, it is possible to

- Compare SDTM versions
- Uncover data issues such as medical coding or lab standard units
- Be proactive to monitor raw data quality and milestones
- Learn about SDTM codelists
- Confirm SDTM structures
- Confirm required SDTM variables
- In-depth data review to eliminate false positives

The Whole 9 Yards

01 Understand SDTM Standards

· Familiarize yourself with CDISC SDTM standards. Understanding the structure and requirements will help you organize and prepare your data accordingly.

02 Meta(Data) Mapping

Map your raw data to SDTM domains. Develop a comprehensive mapping document that clearly defines how each variable in your raw data corresponds to SDTM domains and variables.

03 Smart SDTM Mapper

Utilize CDISC-compliant software designed for SDTM conversion. These products can automate the process, reducing manual effort and ensuring compliance with SDTM standards.

04 Automation Technology

Leverage technology to write programming languages like SAS, Python, or R to automate the transformation process.

05 Standardized Metadata (MDR/MDM)

Develop and maintain standardized metadata repositories. Having a centralized repository for metadata ensures consistency across studies and facilitates the reuse of mapping information.

06 Validation & Data Quality

Implement validation checks to ensure data integrity and compliance with SDTM standards. It's one of the critical steps and always requires laborious effort.

Can technology help?

07 Tracebility & Reproducibility

Creating a system that can scale, trace, and reproduce same result is like finding a safe haven.

Pay Attention while choosing/building your system

08 Change Management

It's a structured and systematic approach in adopting to new technology. Implement changes effectively, minimize resistance, and maximize the positive outcomes.

"Change before you have to." - Jack Welch

09 Submission Ready SDTMs

Implementation of a system that can automate the generation of aCRF, Define.xml, cSDRG according to CDISC MSG

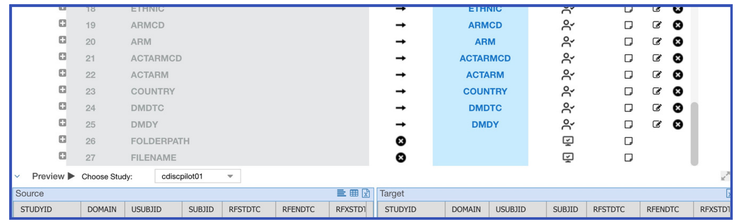
Does your product automate the Submission Package?

Can it be achieved?

Whole 9 Yards in Xbiom Platform

 # Metadata mapping with real time data:

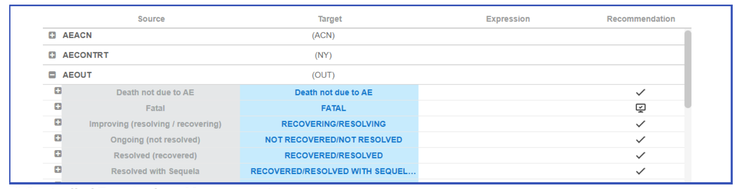
- Automate the process of metadata mapping along with transformational logic to generate SDTM
- Write your own transformations macros of the language of your choice (SAS, R, Python, SQL)
- Use the OTB (Out-of-Box) function from Xbiom Smart Transformation module in your SDTM mappings.
- Controlled workflow, approval process, audit trial and traceability.
- Real time data preview to check your mappings from Source to SDTM



 # Metadata mappings with real time data

 # Manage Control Terminology

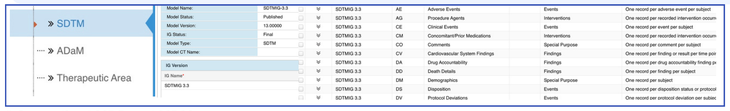
- Automate the process of CT mapping along during your metadata mapping to generate SDTM
- Recommendation engines to suggest the correct CT
- Reusable across Studies
- CT are up-to-date maintained in the global Metadata repository



 # Controlled Terminology Management

 # Centralized Metadata Data Management

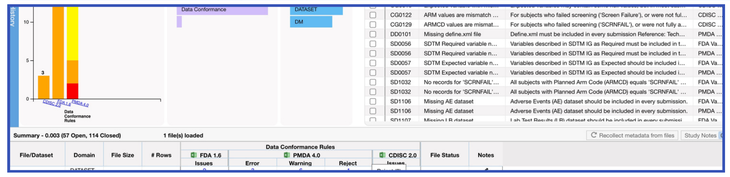
- Manage your Data collection, SDTM, ADaM, TA specific and Custom metadata modules in a centralized global repository
- Xbiom regularly deploys the most recent CDISC updates like SDTM, ADAM and CT from NCI
- Global mapping template to define source to SDTM mappings and re-use across studies hierarchy



 # Centralized MDR and MDM

 # eDataValidator

- Our most advanced one stop Validation and CDISC compliance quality module
- Enable CDSIC/FDA/PMDA rules
- eDV not only provides a structural check, but it also compares the validation dataset to provide a consolidated dashboard
- Interactive graphics helps to drill down to the bottom of the issue along with the data associated with it
- Custom rules can be deployed for special cases followed in an Organization



#eDataValidator to run your CDISC/FDA/PMDA Compliance rules