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Effective WorkFlow Process: Rapid SDTMs and Compliance Dashboards

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ABSTRACT

Now that the pharmaceutical industry has established a formalized process for SDTM development, do standards and compliance dashboards seamlessly integrate into your workflow with each milestone (IA, DSMB/IDMC, DBL)? The utilization of a meticulously designed product, equipped with traceability and controls, empowers teams to standardize SDTMs, thereby eliminating the need for redundant programming and effectively reducing associated costs. The incorporation of a unified raw data to SDTM mapping layer not only results in cost efficiencies but also expedites the creation of SDTMs that meet stringent quality assurance (QA) standards and are well-prepared for downstream analysis. Proactive management of medical coding, controlled terminology, adherence to CDISC requirements, resolution of clinical data issues, mitigation of paired variable inconsistencies, and oversight of derived variables collectively contribute to a streamlined and highly efficient operational framework.

This poster systematically evaluates standardized methodologies to enhance the data review and compliance processes, thereby elevating data quality and optimizing submission deliverables. It advocates proactive practices, such as the active tagging and resolution of data issues, to streamline the query and correction procedures. Rather than reloading SDTMs for compliance validation, the adoption of a built-in compliance check process during each SDTM refresh is proposed for a more streamlined and effective system. This approach cultivates an environment conducive to in-depth data reviews, ultimately mitigating the occurrence of false positives.

Key inquiries addressed in this context encompass:

- Can data issues, such as those pertaining to medical coding or lab standard units, be discerned through compliance checks?
- Is it practicable to conduct a thorough data review to eliminate false positives?
- In what manner does reviewing data and monitoring compliance dashboards empower the biometrics community to proactively address issues and enhance understanding of SDTM structures?
- What insights can be derived about SDTM codelists through the process of reviewing data?
- Has the confirmation of the requisite SDTM variables been ensured?
- Are paired variables consistently maintained?

These inquiries serve as focal points for advancing comprehension and application of standardized methods, contributing to the refinement of data quality and compliance within the biometrics domain.

INTRODUCTION

Rapid and compliance SDTMs should be integrated within the workflow process for optimization. Along with passing all CDISC and FDA compliance, infrastructure for control terminology is essential to identify clinical data issues.

- The Whole 9 Yards
- Can it be Achieved?
- eDataValidator(eDV)Technical Specifications and Common FAQs

THE WHOLE 9 YARDS

The 9 steps below provide the structure for rapid SDTM workflow process:

1. **Understand SDTM Standards:** Familiarize yourself with CDISC SDTM standards. Understanding the structure and requirements will help you organize and prepare your data accordingly.

2. **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.

3. **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.

4. **Automation Technology:** Leverage technology to write programming languages like SAS, Python, or R to automate the transformation process.

5. **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.

6. **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?

7. **Traceability & Reproducibility:** Creating a system that can scale, trace, and reproduce the same result is like finding a safe haven. Pay Attention while choosing/building your system

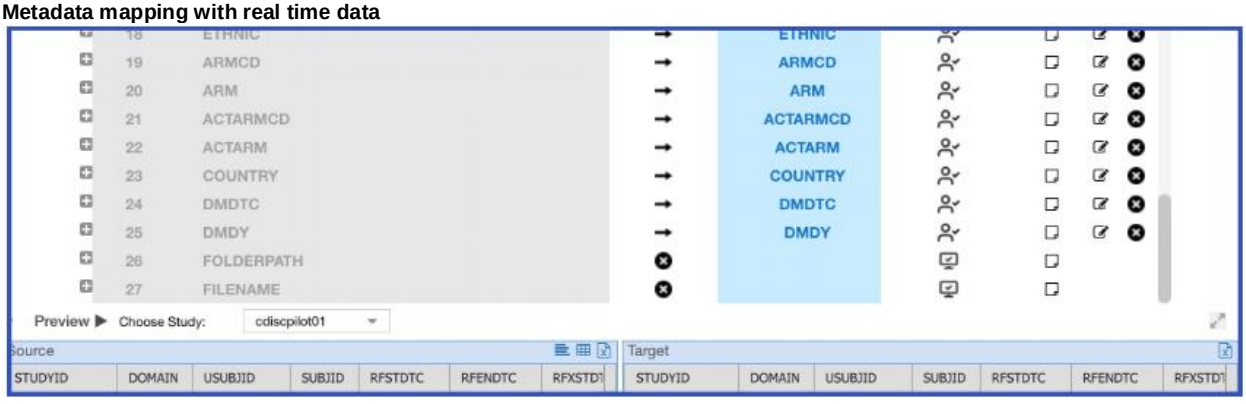
8. **Change Management:** It's a structured and systematic approach in adopting new technology. Implement changes effectively, minimize resistance, and maximize positive outcomes. "*Change before you have to." - Jack Welch*

9. **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?

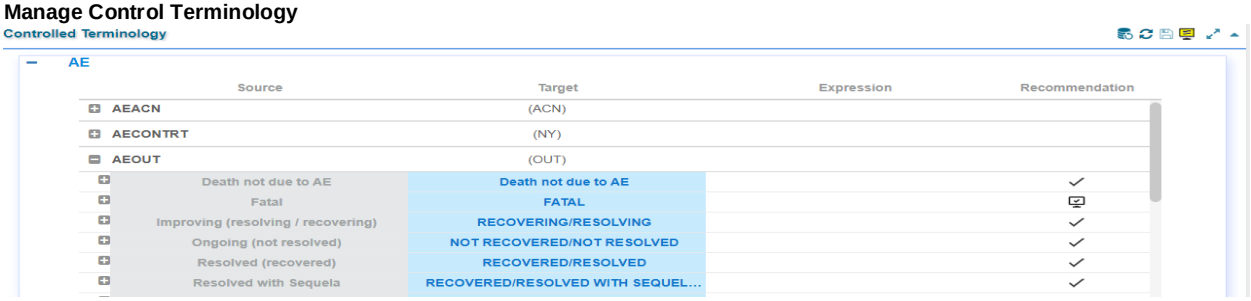
Below are examples of how rapid and compliance SDTMs can be achieved.

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.

Manage Control Terminology

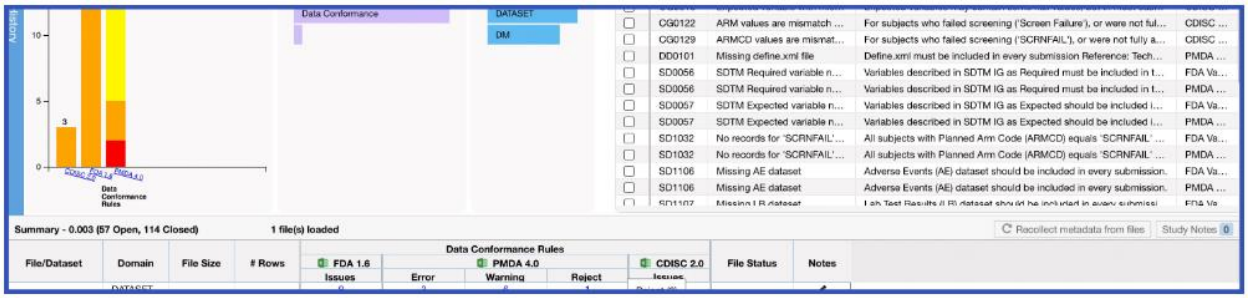


Automate the process of CT mapping along during your metadata mapping to generate SDTM. Recommendation engines to suggest the correct CT. Reusable across Studies. CT are up-to-date maintained in the global Metadata repository.

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.

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.

EDV TECHNICAL SPECIFICATIONS

eDV technical specifications comply with current industry and CDISC standards for SDTM and ADaM checks. The eDV dashboard helps to actively monitor and be proactive with each SDTM and ADaM refresh. There are many unique features in the eDV Dashboard: Rapid SDTM Compares, Interactive Issues with Drill Down, Issues across SDTMs and cost savings since SDTM compliance checks are by users instead of by studies.

CDISC Compliance Features: SDTMs and ADaMs	**eDV Dashboard**
Measure Compliance Improvements - *with each Iteration*	*
Auto Compare previous Compliance Versions (Unchanged, Decreased, Increased) *- No Need for Proc Compare Results, P21 Comparisons are limited to metadata only*	*
Interactive and Drill Down to Record Level – *by Domain, Issue number*	*
Group and Assign Common Issues and Solutions – *by Domain, Issue number*	*
Record Level Review of Issues – *view all domain variables*	*
Execute validation on filtered/selected Rules	*
CDISC, FDA and PDMA Compliance Rules – *includes Rejects, Business and Regulatory*	*
Create and validate define.xml	*
SDRG data-driven issues and solutions – *with notes to CDM*	*

SUPPORTED VALIDATION RULES:

- FDA Validator Rules v1.6
- FDA Validator Rules v1.5 (SDTM, SEND)
- PMDA Validation Rules v4.0 (SDTM, ADaM)
- PMDA Validation Rules v3.0 (SDTM, ADaM)
- CDISC SEND Conformance Rules v4.0
- CDISC SDTM Conformance Rules v2.0
- CDISC ADaM Conformance Rules v4.0
- CDISC Define Conformance Rules for Define 2.0 & 2.1
- PMDA Define Rules v4.0 (SDTM, SEND & ADaM)
- PMDA Define Rules v3.0 (SDTM, SEND & ADaM)
- FDA Rejection Criteria (FDA TRC Rules)
- PointCross Extended checks

USES OF EDATAVALIDATOR:

- Validate final and interim study data against all SDTM, ADaM & SEND files in any format (CSV, XPT, SAS7BDAT, EXCEL).
- Validate Define.xml (version 1.0, 2.0, 2.1) with PMDA & CDISC Define validation rules.
- Validate study data against all published CDISC CT versions, external dictionaries and proprietary CT's
- CLI to integrate to existing applications.
- Perform Data Consistency checks on study datasets to verify structural and metadata correctness.
- Generate draft SDRG template for SEND and SDTM.
- Generate define files.
- Converting XPT datasets to an Excel format.

CONCLUSION

In conclusion, the implementation of a rapid and compliant SDTM workflow is essential for optimizing processes in SDTM creation. Ensuring adherence to CDISC and HA compliance standards, coupled with a robust infrastructure for control terminology, forms the bedrock for identifying and addressing clinical data issues effectively.

The nine-step framework presented provides a structured approach to navigating the complexities of SDTM development and validation:

- **Understanding SDTM Standards:** A foundational comprehension of CDISC SDTM standards lays the groundwork for organized and prepared data.
- **Meta(Data) Mapping:** Comprehensive mapping of raw data to SDTM domains is crucial for establishing clear correspondences between variables.
- **Smart SDTM Mapper:** Utilizing CDISC-compliant software automates the conversion process, minimizing manual efforts and ensuring strict adherence to SDTM standards.
- **Automation Technology:** Leveraging programming languages enhances efficiency and accuracy in automating the transformation process.
- **Standardized Metadata (MDR/MDM):** Maintaining standardized metadata repositories ensures consistency across studies and facilitates information reuse.
- **Validation & Data Quality:** Implementing validation checks is critical for upholding data integrity and compliance, and exploring technological solutions can enhance efficiency.
- **Traceability & Reproducibility:** Establishing a scalable and reproducible system is pivotal for ensuring consistent results in the workflow.
- **Change Management:** Adopting new technology in a structured and systematic manner minimizes resistance and maximizes positive outcomes.
- **Submission Ready SDTMs:** The implementation of a system capable of automating the generation of essential documents aligns with CDISC standards for submission packages.

This holistic approach, encompassing technological innovation, standardized processes, and strategic change management, positions organizations to streamline their SDTM workflow, ultimately contributing to enhanced efficiency, data quality, and regulatory compliance in the pharmaceutical industry.

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