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Elevating Clinical Research:
Strategic Implementation of CDASH and SDTM Standards

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ABSTRACT

In the ever-evolving landscape of pharmaceutical research and clinical trials, harmonizing data standards is crucial for efficient and reliable data management. This paper presents a comprehensive strategy for implementing Clinical Data Acquisition Standards Harmonization (CDASH) and Study Data Tabulation Model (SDTM) to standardize clinical data management. Clinical research involves extensive data collection, necessitating high data quality, traceability, reusability, and cost-effectiveness. CDASH and SDTM standards serve as a common language for data exchange and reporting, facilitating seamless communication among stakeholders. Effective governance is ensured through the Governance Team, consisting of members from key functional areas responsible for CDASH and SDTM compliance. The three-phase solution includes standardizing Case Report Forms (CRFs), with a focus on Safety CRFs and Therapeutic Area (TA)-specific CRFs, using CDASH and associated metadata. SDTM standardization involves standard CRFs and metadata, along with the development of CDISC SDTM standards, encompassing global, compound, and study specific SDTM standards while incorporating external data standards. A standardized approach for generating Global SDTM Specification Mapping Files enhances data consistency and change management and approval processes ensure documentation and traceability. Before initiating the project, a thorough analysis of past studies and metadata informs the creation of standardized templates and guidelines. Effective data standards management remains at the core of this initiative, facilitated by automation tools such as SAS, R, and Python, ensuring adherence to standard approaches and simplifying updates, reviews, and compliance checks. The benefits include improved data quality, traceability, reusability, and cost savings. This proposed strategy champions data standardization, empowering pharmaceutical organizations to address modern research challenges with enhanced efficiency and data integrity.

INTRODUCTION

Clinical research involves the collection and analysis of vast amounts of data from various sources. To ensure data quality, traceability, reusability, and cost-effectiveness, it is imperative to establish standardized processes and data structures. The adoption of CDASH and SDTM standards facilitates this standardization, enabling seamless data exchange and integration. The following strategic process is used for implementation; Charter and Governance Team, Pre-Phase: Comprehensive Analysis of Current and Prior studies), Phase I: CRF and external data standardization using CDASH, Phase II: Development of CDISC SDTM Standards, and Phase III: Rollout and Maintenance of CDASH and SDTM Standards. The process can be tailored based on the requirements while, retaining the fundamentals.

CHARTER AND GOVERNANCE TEAM

A robust governance structure is essential to oversee the implementation of CDASH and SDTM standards. The Governance Team should comprise of representatives from key functional areas, including Data Management, Safety, pharmacokinetic/pharmacodynamic (PK/PD), Clinical Operations, Biostatistics, Medical Writing, and others. The team's charter should define its roles and responsibilities, decision-making authority, and accountability in ensuring compliance with standards. Furthermore, change management and approval process is essential. Establish a rigorous change management process to ensure that modifications to standards are well-documented and approved by the Governance Team. This process will maintain consistency and traceability throughout the project.

PRE-PHASE: COMPREHENSIVE ANALYSIS OF CURRENT AND PRIOR STUDIES

Prior to initiating the standardization initiative, it is essential to conduct a comprehensive analysis of ongoing and legacy studies, including associated metadata. This foundational step provides valuable insights into historical data structures, safety and therapeutic area-specific data elements, and prior usage of standards across studies.

The analysis should encompass:

- Case Report Forms (CRFs) used across studies.
- Electronic Data Capture (EDC) system configurations and naming conventions.
- External data sources, including laboratory, pharmacokinetic/pharmacodynamic (PK/PD), electronic patient-reported outcomes (ePRO), imaging (e.g., BICR), and biomarkers.
- Metadata collection, such as controlled terminology, value-level metadata, and lab standards.

Cross-functional collaboration with stakeholders in Data Management, Biostatistics, Safety, Clinical Operations, and Regulatory Affairs is vital to identifying both current and legacy data standards. This collaborative effort informs the creation of standardized templates, variable definitions, and guiding documentation, ensuring a solid foundation for the phases that follow.

PHASE I: CRF AND EXTERNAL DATA STANDARDIZATION USING CDASH

Phase I focuses on the standardization of Case Report Forms (CRFs) and external data using CDASH principles as the foundation. CDASH promotes consistency by organizing metadata into logical groupings of related concepts and embedding traceability within variable metadata—particularly through consistent variable naming conventions. Data collection standards must be designed to meet the needs of all stakeholders and, where applicable, share the same controlled terminology used in data tabulation. Additionally, question text and prompts must align precisely with CDASH definitions to ensure clarity, accuracy, and regulatory compliance.

The implementation of this phase requires close collaboration with cross-functional teams, including Data Management, Biostatistics, PK/PD, Safety, and Clinical Operations, to identify safety-critical data elements. Based on CDASH and sponsor-specific requirements, standardized CRF templates and external data templates are developed for both core safety domains and therapeutic area-specific needs, such as Oncology and Hematology. The process ensures alignment across variable metadata, value-level metadata, and controlled terminology. Input from the Governance Team further strengthens the consistency and applicability of the standards. Specification documents and CRF standardization guidelines are then created to guide EDC study builds, promoting uniform data structures across clinical programs.

PHASE II: DEVELOPMENT OF CDISC SDTM STANDARDS

The second phase centers on the structured development of SDTM (Study Data Tabulation Model) standards, guided by CDISC principles to ensure consistency, reusability, and regulatory readiness. Foundational to this process is the early determination of the appropriate SDTM class for each clinical concept, followed by alignment with CDISC-defined variable names and semantics prior to assigning an Implementation Guide (IG) domain. Concepts must be represented within consistent domains, preserving their original meaning while ensuring standardized representation across studies. Any proposed modifications to existing structures are carefully evaluated for their broader impact on downstream deliverables and regulatory expectations.

Building upon the CDASH-compliant CRFs and external data templates developed in Phase I, this phase involves creating global, compound-level, and study-specific SDTM standards. Metadata repositories are designed to flag the scope and applicability of each standard, allowing scalability across therapeutic areas and study phases. External data sources—such as laboratory, biomarker, imaging (BICR), pharmacokinetic/pharmacodynamic (PK/PD), and ePRO—are incorporated into a unified SDTM framework to maintain consistency. A key deliverable in this phase is the development of standardized Global SDTM Specification Mapping Files, derived from core safety and TA-specific CRFs. These mapping files include detailed specifications such as variable metadata, value-level metadata, computational rules, code lists, and conditional logic (e.g., WHERE clauses), all of which can be leveraged to generate regulatory submission components such as Define.xml. This structured, metadata-driven approach ensures that SDTM datasets are submission-ready and aligned with CDISC implementation guidelines.

PHASE III: ROLLOUT AND MAINTENANCE OF CDASH AND SDTM STANDARDS

The final phase focuses on the rollout, adoption, and long-term sustainability of CDASH and SDTM standards across the organization. To ensure continued compliance and efficiency, a formal governance and maintenance framework must be established. This includes clearly defined procedures for version control, regular updates, periodic reviews, and routine compliance checks to keep pace with evolving regulatory requirements and therapeutic innovations. By institutionalizing a cycle of feedback and refinement, organizations can proactively address inconsistencies, improve data traceability, and reinforce the integrity of their clinical data pipeline.

To streamline standard implementation and improve scalability, automation plays a pivotal role. Programming languages such as SAS, R, and Python can be leveraged to develop macros and tools along with AI/ML system that automate repetitive tasks and enforce standard conventions. These tools support critical functions, including the automated annotation of SDTM datasets, generation of metadata (e.g., dataset attributes, controlled terminology), and creation of regulatory submission components such as Define.xml files. Automation further enables dynamic quality control processes—such as programmed data checks, data cutoff routines, and external data validations—which help ensure compliance from study build through submission. By embedding automation within the data standards ecosystem, organizations can significantly reduce manual effort, improve turnaround times, and promote reliable, high-quality data across clinical programs.

CONCLUSION

Implementing CDASH and SDTM standards for CRFs and study data is a pivotal step towards achieving data standardization in clinical research. This white paper outlines a comprehensive strategy that emphasizes governance, stakeholder involvement, phased development, change management, and ongoing standards management. By adopting these standards, our organization will be better equipped to meet the challenges of modern pharmaceutical research, ultimately improving data quality, traceability, and efficiency.

REFERENCES

Clinical Data Interchange Standards Consortium (https://www.cdisc.org/)

CDISC CDASH Standards (https://www.cdisc.org/standards/foundational/cdash)

CDISC SDTM Standards - Implementation Guide (https://www.cdisc.org/standards/foundational/sdtmig)

FDA Study Data for Submission to CDER and CBER (https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber)

FDA Technical Conformance Guide (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document)

PMDA Revision of Technical Conformance Guide on Electronic Study Data Submissions (https://www.pmda.go.jp/files/000267935.pdf)

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RECOMMENDED READING

For further insights into data standardization and best practices in clinical research, recommended resources include CDISC's implementation guides for CDASH and SDTM (https://www.cdisc.org), PhUSE's papers on metadata and automation (https://phuse.global), and Lex Jansen's searchable collection of conference papers (https://www.lexjansen.com). These materials provide valuable perspectives on metadata governance, SDTM conversions, and standardization strategies. Exploring these sources will deepen understanding and inform practical application of the concepts discussed.

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