CDISC OVERVIEW

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Agenda

01 Introduction to CDISC

02 CDISC Standards and Scope

03 CDISC Terminology

04 CDISC SHARE

What is CDISC?

CDSIC: **C**linical **D**ata Interchange **S**tandards **C**onsortium

CDSIC Mission Statement

To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

Benefits of implementing CDISC standards include

- Fostered efficiency
- Enhanced innovation
- Facilitated data sharing
- Streamlined processes
- Increased predictability
- Complete traceability
- Improved data quality
- Reduced costs

CDISC Standards are required for regulatory submissions to FDA (U.S.) and PMDA (Japan), endorsed by China FDA, and requested for use by the European Innovative Medicines Initiative (IMI).

CDISC STANDARDS

PRM

- Standard for planning and designing a research protocol
- Focus on study design, eligibility criteria, and requirements from the ClinicalTrials.gov, World Health Organization (WHO) registries, and EudraCT registries.
- Helps in automating CRF creation and EHR configuration to support clinical research and data sharing.

SEND

- SDTM standard for nonclinical studies.
- Helps in collecting and presenting nonclinical data in a consistent format.
- SEND is one of the required standards for data submission to FDA.

CDASH

- Standard way of data collection
- Data collection formats and structures provide clear traceability of submission data into the Study Data Tabulation Model (SDTM),
- More transparency to regulators and others who conduct data review.

SDTM

- A standard for organizing and formatting data to streamline processes in collection, management, analysis and reporting.
- Helps in improving the regulatory review and approval process
- SDTM is one of the required standards for data submission to FDA (U.S.) and PMDA (Japan).

ADaM

- Dataset and metadata standards help in improving efficiency, replication, and review of clinical trial statistical analyses
- Provide traceability between analysis results, analysis data, and data represented in the Study Data Tabulation Model (SDTM).
- ADaM is one of the required standards for data submission to FDA (U.S.) and PMDA (Japan).

CDISC Standards for Transporting Data

Clinical Trial Registry (CTR-XML)

- "write once, use many times" solution based on a single XML file
- Holds the information needed to generate submissions for multiple clinical trials for clinical trial registry submissions
- Primarily submissions to the World Health Organization (WHO), European Medicines Agency (EMA) EudraCT Registry and
- United States ClinicalTrials.gov.

Operational Data Model (ODM-XML)

- Vendor-neutral, platform-independent format
- For exchanging and archiving clinical and translational research data, along with their associated metadata, administrative data, reference data, and audit information.
- ODM-XML facilitates the regulatory-compliant acquisition, archival and exchange of metadata and data.
- It has become the language of choice for representing CRF content in many electronic data capture (EDC) tools.

Study/Trial Design Model in XML (SDM-XML)

- Extension of ODM-XML
- Allows machine-readable, interchangeable descriptions of the designs of clinical studies, including treatment plans, eligibility and times and events.
- Defines three key sub-modules – Structure, Workflow, and Timing

Define.XML

- Transmits metadata that describes any tabular dataset structure.
- It provides the metadata for human and animal model datasets using the SDTM and/or SEND standards and analysis datasets using ADaM.
- Helps in informing the regulators which datasets, variables, controlled terms, and other specified metadata were used.
- **Define-XML is one of the required standards for data submission to FDA (U.S.) and PMDA (Japan).**

CDISC Standards for Transporting data (Contd…)

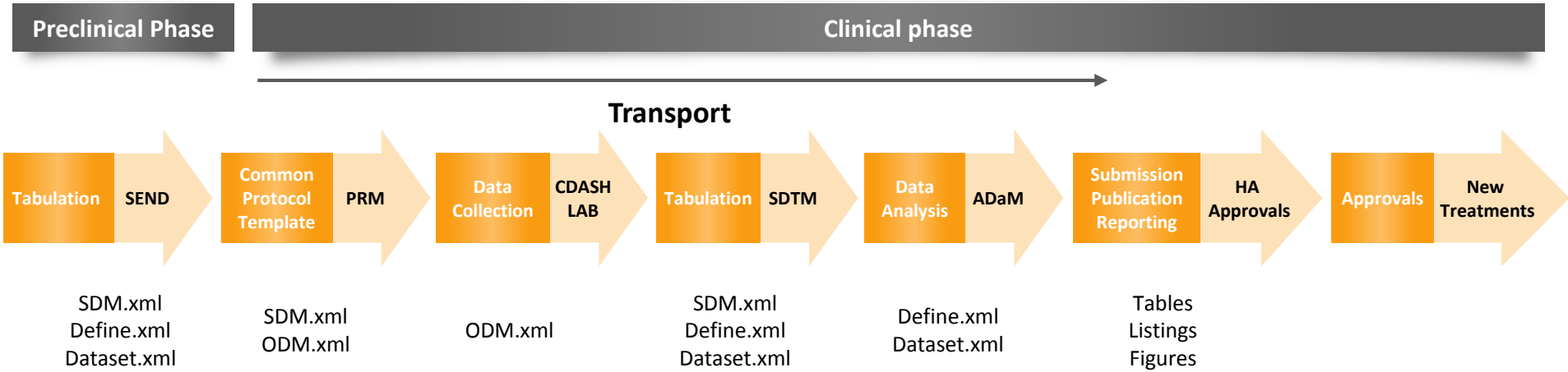
Dataset-XML

- Supports the exchange of dataset data based on Define-XML metadata.
- Dataset-XML complements Define-XML and provides an alternative to the SAS V5 Transport format for the exchange of study datasets for CDISC's Foundational standards.
- Dataset-XML is a truly non-proprietary, global standard, removing many SAS V5 Transport file restrictions (the current file format required by the FDA and PMDA), such as 8-character variable names and 200-character text fields.

LAB

- Provides a standard model for the acquisition and exchange of laboratory data,
- Primarily between labs and sponsors or CROs.
- The LAB standard was specifically designed for the interchange of lab data acquired in clinical trials.

CDSIC Standards and Scope



SEND: Implementation of SDTM for non-clinical data.

PRM: Protocol standards that allow for information interchange between trials and companies.

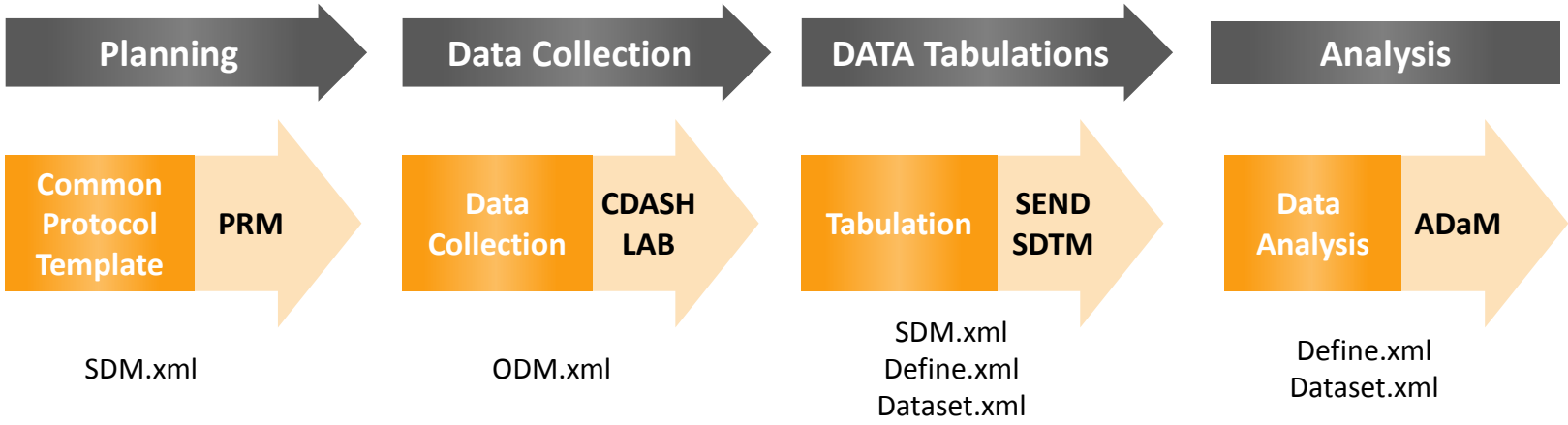
CDASH: A CDISC-led collaborative initiative to develop the content standard for basic data collection fields in case report forms. This standard is based upon the SDTM.
LAB: The content and format standard for data transfer between clinical laboratories and Study Sponsors and/or CROs

SDTM: The content and tabulation standard for regulatory submission of case report form data tabulations in clinical research studies.

ADaM: The content standard for regulatory submission of analysis datasets and associated files.

SDM: Submission Data Model
ODM: Operational Data Model

CDSIC Standards and Scope



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CDSIC standards and Scope

Solutions

- CFAST Therapeutic Area Products
- Medical device Products
- Pharmacogenomics/ Genetics
- Other Specialty Areas
- Questionnaires, Ratings and scales
- CDISC-IHE Healthcare Link Products

Semantics

- CDISC Controlled Terminology (powered by NCI EVS)
- CDISC Glossary
- BRIDG Biomedical Research Domain Analysis Model

CDISC SHARE

- CDISC standards are open and freely available as published PDFs on CDISC Website.
- CDISC Shared Health And Research Electronic library (SHARE) was launched o provide machine-readable versions of CDISC standards, the .
- The standards allow developing, integrating and accessing CDISC standards metadata electronically.
- CDISC SHARE eases the implementation of CDISC standards in electronic systems such as clinical data management systems, mobile apps, and learning health systems.
- It also increases accessibility of these standards to programmers, data managers and biostatisticians.
- Implementing CDISC SHARE's standards facilitates collecting, aggregating and analyzing standardized data from early design to end analysis.
- CDISC SHARE supports in developing, managing and re-using metadata for new Therapeutic Area standards, other specialized implementations of the Standard Data Tabulation Model (SDTM) such as the Pharmacogenomics/Genetics and Medical devices Implementation Guides.
- CDISC SHARE serves as a critical tool for developing and sharing biomedical concepts and furthering CDISC innovations for the clinical research community.

Controlled TERMINOLOGY

- CDISC Controlled Terminology is the set of CDISC-developed or CDISC-adopted standard expressions (values) used with data items within CDISC-defined datasets.
- CDISC, in collaboration with the National Cancer Institute's Enterprise Vocabulary Services (EVS), supports the controlled terminology needs of CDISC Foundational and Therapeutic Area Standards.
- CDISC Controlled Terminology is maintained and distributed as part of NCI Thesaurus on an NCI File Transfer Protocol (FTP) site and is available for direct download on the page.
- It is available in Excel, text, odm.xml, pdf, html and OWL/RDF formats.
- New requests or changes to existing terminology can be accessed through the NCI/EVS New Term Request Page and is available for direct download on the page.
- As of 29 September 2017 the CDASH, SDTM, SEND, ADaM, and Protocol Controlled Terminology files have been updated on the NCI-EVS Ftp site.
- The dates of the new files are 2017-09-29.
- These terminology files replace all older CDASH, SDTM, SEND, ADaM and Protocol files and include terms from Review Package 31.
- There are approximately 617 new QRS terms and 371 new terms across CDASH, SDTM, SEND, ADaM and Protocol.
- CDISC Controlled Terminology is also available through SHARE Exports.

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