Cdisc Sdtm Services Section Home

History

The origins of CDISC-SDTM trace back to the late 1990s when CDISC was established to develop global standards for clinical research data. The lack of consistent data representation hindered data exchange and analysis across diverse stakeholders, prompting the need for standardization. CDISC-SDTM was introduced to provide a common framework for organizing and submitting clinical trial data to regulatory agencies.

Evolution till Date

CDISC-SDTM has evolved significantly since its inception. The initial versions focused on standardizing the presentation of data for regulatory submissions, ensuring that data could be consistently reviewed by regulatory agencies. As technology advanced, SDTM expanded to accommodate various types of clinical data, such as pharmacogenomics, adverse events, and medical histories. This evolution was essential to ensure that diverse datasets could be accurately integrated and analyzed across trials, improving data quality and reducing duplication efforts.

Regulatory Submissions

SDTM facilitates the submission of standardized data to regulatory agencies, expediting the review and approval process for new therapies.
2.

Clinical Data Integration

SDTM enables the integration of data from various sources, supporting comprehensive analysis and evidence-based decision-making.
4.

Electronic Health Records

SDTM principles have influenced the development of electronic health record (EHR) systems, improving data exchange between clinical and research settings.
6.

Pharmacovigilance

Adverse event data can be consistently represented in SDTM format, improving safety monitoring and reporting.
8.

Data Sharing

SDTM s structured format facilitates data sharing and collaboration among researchers, organizations, and academia.
10.