

CDISC SDTM-ADaM Data Standards Implementation

Comprehensive Clinical Data Conversion Services



Ensuring Clinical Data Ready for Submission

Data standardization into SDTM-ADaM standards improves the overall quality of data and efficiency review by regulatory authorities

SDTM standard package

- Mapping to SDTM standards
- SDTM annotated CRFs
- .xpt file generation
- xml and define.pdf file creation from SDTM dataset definitions
- Validation of data and define .xml files
- Creation of clinical study data reviewer's guide (cSDRG)
- SDTM format allows pooling of clinical trials for integrated summaries of safety & efficacy (ISS/ISE)

Production of ADaM datasets

- Creation of dataset specification file
- define.xml and define.pdf file creation from ADaM dataset definitions
- Electronic validation of CDISC compliance to ADaM standards
- Creation of integrated ADaM datasets for integrated summaries of safety & efficacy (ISS/ISE)



As a CDISC Solutions Provider, IDDI offers professional expertise for the conversion of clinical data to CDISC SDTM and ADaM standards.



IDDI is a trusted clinical data science partner. With 35+ years of research-driven experience, we combine therapeutic expertise, biostatistical leadership, and regulatory insight to mitigate risk from design to registration and beyond. We deliver uncompromising excellence in biostatistics, strategic consulting, clinical data management, IDMCs, and supporting eClinical technologies, because when every data point represents a patient, perfection is the only option.