

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.

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