

Clinical Data Interchange Standards Consortium (CDISC)

Enabling the interoperability of information systems is critical to supporting health care research. Westat provides CDISC-compliant data so that your study moves fluidly through the FDA submission process.

SERVICES

- Building CDISC global library
- Creating CDISC-compliant eCRFs
- Mapping legacy eCRF questions to CDISC variables
- Training study build teams for CDISC compliance
- Submitting SDTM and ADaM datasets

Ensuring your data are CDISC compliant can be a daunting process. That's where Westat can help. As a premier research organization, Westat has partnered with the CDISC community to advance the use of data standards to improve overall data quality and efficiency of clinical trial conduct that we support.

Our statisticians, programmers, and data managers approach the implementation of CDISC standards by creating tools and processes to improve efficiency, developing training programs, and reimagining how project teams collaborate to ensure data sets submitted to the FDA are compliant.

We guarantee adherence to CDISC standards and a streamlined, hassle-free study, end to end.



Clinical Data Acquisition Standards Harmonization (CDASH)

Westat's mechanism for collecting data conforms with CDASH principles. This tool allows data to flow directly into the Study Data Tabulation Model (SDTM), reducing the need for programmatic data manipulation and heightening data transparency for reviewers and regulators.

Study Data Tabulation Model (SDTM)

Westat uses industry-available and in-house tools to ensure that your data are SDTM-compliant, including a customizable specifications document and macros that automatically check for errors. These tools improve the quality of the datasets and facilitate submission.

Analysis Data Model (ADaM)

Westat supports clinical trial statistical analyses with ADaM datasets that provide the traceability among analysis results, analysis data, and data represented in the SDTM data.

Define.XML

Westat has tools in place to simplify development of documentation of metadata including Define.XML.

CONTACT

Whitney Smith
Data Management Lead
WhitneySmith@westat.com
713-353-7948

Deepak Khattry, PhD
Associate Director
DeepakKhattry@westat.com
301-279-4588

www.westat.com



An Employee-Owned Research Corporation®

1600 Research Boulevard
Rockville, MD 20850

marketing@westat.com
301-251-1500