Data Management and Database Development Services

Westat performs comprehensive data services — ensuring a prompt response to your study-specific needs, achievement of your study goals, and the fluid submission of your study to the Food and Drug Administration (FDA).

SERVICES

- Design and develop data collection systems to optimize reporting and FDA submission
- Use targeted approach to identify critical data issues
- Collaborate with clinical sites to ensure timely data cleaning and real-time data entry
- Develop partnerships with sponsors to achieve defined study goals and outcomes
- Provide comprehensive approach to data collection, cleaning, and reporting through our partnership with Medidata Solutions

Who We Are

Westat is a leading provider of clinical trial research support, end to end, with extensive experience managing large, complex, time-sensitive databases for commercial companies, government agencies, academic institutions, and international organizations.

What We Do

We take the complexity out of required activities, such as electronic data loading from external sources, validating data from multiple sources, or setting up or processing serious adverse events (SAE) report systems. By supporting each step of the process, we guarantee delivery of reliable, high-quality data compliant with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and federal standards, good clinical practice (GCP) and Clinical Data Interchange Standards Consortium (CDISC) guidelines, and individual client requirements.

How We Can Help

- Create thorough Data Management Plans detailing all data management aspects of the trial
- Develop study databases that lead to CDISC compliance
- Design data collection forms that comply with CDASH standards
- Establish & support computerized subject eligibility screening and randomization
- Capture and process data in real-time
- Clean data using smart programmed edit checks and custom functions in EDC
- Conduct quality and control audits by manually reviewing data in aggregate identifying potential training needs, protocol deviations, and site compliance factors
- Provide trainings and user support using communication vehicles such as web-based learning modules, live web broadcast sessions, and one-on-one interaction
- Deliver FDA-compliant packages of
  - Study Data Tabulation Model (SDTM)
  - Analysis Data Model (ADaM) datasets
  - Annotated case report forms (CRFs)
  - Define Files

Photos are for illustrative purposes only. Any person depicted in the photos is a model.

CONTACT

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