WebSDM™

PHASE•FORWARD™

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"WebSDM lets me **browse my data** using an FDA standard submission tool."

WebSDM: Web Submission Data Manager

In today's complex world of clinical research, biopharmaceutical companies, CROs and regulatory agencies are all increasingly challenged by the inefficiencies of exchanging and reviewing quality clinical trial data. The emergence and acceptance of data standards in the biopharmaceutical industry has changed the way that companies collect, format and submit clinical trial data to the FDA. The Clinical Data Interchange Standards Consortium's (CDISC) Study Data Tabulation Model (SDTM) data format is the recommended format for case report tabulations under the FDA's eCTD implementation. CDISC SDTM-compliant clinical trial data is increasingly becoming the preferred standard for companies facing the challenge of integrating clinical datasets from multiple sources.

CDISC Advantages

Thanks to an unprecedented collaboration among industry and FDA, CDISC developed the SDTM model, which was adopted by FDA as the standard specification for eCTD submissions in 2004. Yet, effectively implementing and using these data standards remains an intricate process.

Whether clinical trial data is collected on paper or using EDC, correctly converting it to the CDISC SDTM so it can be utilized by standard review tools is still a challenging proposition. Beyond the mechanics of the actual data transformation, understanding the way that standard data can be used by reviewers is also important to companies seeking regulatory approval of new drugs based on trial results.

Implement a Smart Standards Strategy

Data standards should expedite integration and analysis of data for sponsors, not slow them down. The right tools and services can help sponsors realize the benefits of data standards within the aggressive time-frame of an NDA, while the long term benefits will accrue in future projects. With electronic submissions increasingly becoming the norm, adoption of data standards is becoming a critical priority for biopharmaceutical companies.

WebSDM: Submission Data Management

A data review tool that streamlines operations with submission-ready files for clinical trial data.

- Load and validate CDISC SDTM-format clinical trial data files so you can submit data with confidence
- Browse data using an FDA standard submission review tool
- Drill down to individual subject data supported with graphical patient profiles using the integrated DataMontage graphs or with built-in links to PPD Patient Profiles
- Ease integration and analysis of trial data, including pooling data across studies
- Respond to FDA queries with online reporting and analysis
- Fully integrated with Lincoln's Clinical Trials Signal Detection system, allowing access to clinical trial safety signal detection from within the same user interface

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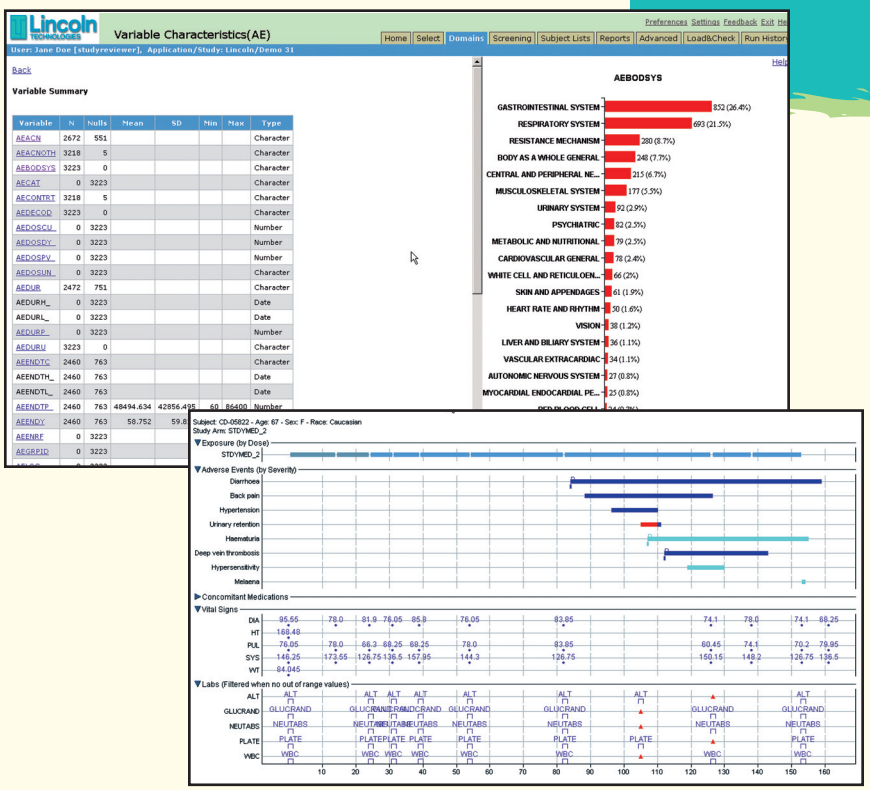

WebSDM supports all standard CDISC SDTM domains. For each domain, users can access variable summary statistics, data visualization tools and drill down into individual subject data and patient profiles.

Developed with the FDA

WebSDM was developed under a Cooperative Research and Development Agreement (CRADA) between the FDA and Lincoln Technologies, a Phase Forward company, with the goal of providing a user-friendly environment for browsing and reviewing CDISC SDTM-compliant clinical trial data. The WebSDM product, which has been in use at the FDA since 2004, is now available to industry.

The WebSDM application allows users to load SDTM-format data, check and correct errors and inconsistencies, and browse data in a variety of tabular and graphical formats. Users may browse studies one-at-a-time or perform pooling of data across studies for combined analysis. WebSDM allows companies to create submission files that they can present to regulatory agencies with confidence.

Comprehensive Standards Implementation Support

As a registered CDISC solution provider, Lincoln experts are available to provide services including training, conversion of legacy study data to the CDISC SDTM standard and assistance with development of a CDISC implementation strategy. These services may be used in combination with the WebSDM tool or separately.

Integrated Safety Analysis

WebSDM is fully integrated with Lincoln's Clinical Trial Signal Detection (CTSD) system – allowing access to vital safety analysis from within the same user interface. The WebSDM and CTSD products can be used in a 21 CFR 11-compliant environment. Additional integration options with Phase Forward's EDC, clinical data management and pharmacovigilance tools are available. Phase Forward also offers Lincoln's WebVDME and WebVDME Signal Management tools for post-marketing signal detection.

WebSDM features:

- Supports CDISC SDTM
- Error checking against SDTM specifications and implementation guide
- Checking includes structural and consistency errors
- Prioritize errors by severity
- Natural language error messages
- Drill down to rule definition and subject data
- Built-in annotation utility
- Filter and sort capabilities for error review
- Data browsing with graphical display tools in a web-based user interface
- Identifies record relationships and comments
- Custom and predefined reports
- Cross-study reporting
- Allows exchange of custom report definitions and results with FDA reviewers to resolve queries
- Supports Define.XML metadata transmission
- Integration with Patient Profiles, SAS and Excel

Multiple License and Service Options:

- Pilot option to evaluate an initial study
- Submission checking service provides temporary access for data verification of upcoming submissions
- Full license option provides for ongoing use in support of a CDISC-compliant electronic NDA submission
- In-house or hosted deployment
- Special licensing program for CRO partners
- Full data conversion services for converting legacy data to CDISC format
- Technical consulting to support standards implementation and data warehouse construction
- Strategic consulting for CDISC planning

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