

Sponsors are receiving clinical information of increased complexity, from multiple sources and different formats. As a result, clinical data submission has become time-consuming, costly and error-prone.

To tackle this challenge, CDISC® (Clinical Data Interchange Standards Consortium) has been establishing new data standards to speed up data-review and improve clinical data exchange, storage and archival. CDISC SDTM was recommended by the FDA in 2006 for electronic submissions to accelerate the FDA review process.

Clinovo offers consulting services and a free development tool, CDISC Express, to improve and accelerate your CDISC implementation.



CLINOVO CDISC SERVICES

- CDISC capability assessments
- Creation of CDISC ADaM data for statistical analysis
- Implementation of client custom SDTM specifications
- CDISC data aggregation for ISS and ISR reporting
- CDISC conversion from any clinical database
- Implementation of CDASH compliant CRFs
- CDISC submission review
- CDISC training

CDISC® express



CDISC Express is a free SAS® application that automatically converts clinical data into CDISC SDTM.

CDISC Express was designed in-house to facilitate and accelerate FDA review. It is an innovative tool that has proven to successfully speed up data submission while reducing implementation costs.

Our technology edge combined to our experience in standards implementation allows us to develop tailored CDISC solutions that answer your needs.

FEATURES

- Excel based mapping definitions
- Global SDTM definitions
- Extensible function library
- Lab standard units and toxicity levels
- Generic SDTM validation tool
- Define.XML

BENEFITS

- Download the application free of charge
- 4x Speed-up of CDISC conversion
- Seamless maintenance of CDISC mapping
- Portability of Excel
- User friendly web interface
- Reusable macros

Download CDISC Express now! Visit www.clinovo.com/cdisc

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ABOUT CLINOVO

Clinovo is your leading edge Clinical Data Solutions Provider. We provide local medical device, biotechnology and pharmaceutical companies with full service biometrics, such as Clinical Data Management, Electronic Data Capture, Biostatistics, and CDISC mapping. By leveraging best-of-breed technology, we develop and customize turn key solutions that accelerate the clinical trial process and speed up regulatory review.

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