CDISC Public Training Courses 2010 in China

1. Introduction to CDISC

This half-day course will give attendees the opportunity to learn about the history, organization, and philosophy of CDISC, the CDISC approach for standards development, the data modeling process, as well as the benefits of CDISC standards. There is a brief introduction to each of the currently published CDISC data standards/models and a discussion of future opportunities. The course is aimed at those who have little or no experience of CDISC and want an introduction to CDISC operations, data standards/models and objectives.

2. Protocol Representation Course

The objective of the Protocol Representation Group is publication of a standard, machine-readable model for protocol representation that will enable interchange of this data among systems and stakeholders. This course will describe the first release of the Protocol Representation Standard, which includes Clinical Trial Registry, Trial Design, and Eligibility Criteria.

3. SDTM Theory & Application

The Study Data Tabulation Model (SDTM) is a specification in the FDA electronic Common Technical Document (eCTD) Guidance as the model for submitting clinical and preclinical data to the FDA in support of marketing applications. This two-day course consists of:

- A detailed review of SDTM concepts, SDTM domain models, and relationship tables
- A discussion of common implementation issues
- Exercises including CRF-annotations and creation of datasets that reinforce attendees' understanding of the SDTM and the SDTM Implementation Guide.

A basic understanding of relational database design is helpful but not required.

4. CDASH Implementation

The CDASH standard describes the basic recommended (minimal) data collection fields for common identifier and timing data, and 16 domains, including demographic, adverse events, and other safety domains that are common to all therapeutic areas and types of clinical research.
This full-day course will provide attendees with an overview of both the CDASH V1.1 standard and key concepts from the CDASH User Guide V1.0. The course includes in-depth implementation information for all of the CDASH domains, with hands-on exercises.
Learning objectives addressed in this course include:

- Understanding the purpose and basic concepts of the CDASH standard
- Understanding the relationship between CDASH and the other CDISC standards
- Understanding conformance rules for CDASH implementations
- Understanding the challenges of collecting data in de-normalized structures
- Understanding the CDASH Best Practice recommendations for data collection

Recommendation: A basic understanding of the clinical data collection process is helpful to understanding the material presented, but not required.

5. ADaM Implementation

The Analysis Dataset Model (ADaM) builds on the SDTM metadata model, adding attributes and examples specific to statistical analysis. This one-day course discusses the purpose of analysis datasets, the basic principles of the ADaM data standard, how ADaM fits in the CDISC framework, and the relationship between ADaM and SDTM. Attendees will learn the specifics about the subject□level analysis data model and how to start to apply the ADaM standards right now.

6. Workshop for Practical Implementation Experiences

Many pharmaceuticals and CROs have started to adopt CDISC SDTM and ADaM standards since the SDTM has been recommended CRT data standard by FDA in 2004. Implementing CDISC SDTM and ADaM standards became critical for submission data. Various processes or scenarios have been developed to create or construct SDTM and ADaM compliant datasets. This one-day course provides the implementation experiences of CDISC SDTM and ADaM based on a submission study. The protocol, study design, annotated CRF, statistical analysis plan, raw and analysis datasets, analysis results, and metadata will be demonstrated by examples. At this workshop, you will learn:

- Study Design – create trial design domains using a clinical study protocol
- Raw/Collected SDTM Data – annotated SDTM domain variables
- Derived SDTM Data – computation methods for derived variables and derived records: study day, data un-blinding, questionnaire, etc.
- Analysis Data (ADaM) – subject-level, basic data structure, traceability, etc.
- Analysis Results – primary efficacy endpoints
- Metadata – dataset, variable, value-level, parameter-level, and analysis results