



## **Introduction to CDISC Course** **3 hour virtual learning course**

### **Course Overview and Benefits**

This course will provide 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 will be a brief introduction to each of the current published CDISC data standards and a discussion of future opportunities.

### **Audience**

The course is aimed at those who have little or no experience of CDISC and want an introduction to the CDISC organization, development process, data standards and objectives.

### **Detailed Course Content**

#### *Introduction to CDISC*

- CDISC Vision
- Standards
- Current State of Clinical Information and Clinical Data Transfer
- Clinical Development Cycle and Industry Tools
- Standards to Facilitate Data Flow
- Benefits of Standards- Operational & Scientific

#### *What is CDISC?*

- CDISC Principles
- CDISC Organization and Board of Directors
- IAB
- Committees and User Networks
- Where CDISC fits in the "World of Standards"
- Relevant Definitions and Processes
- How Data Standards can help you
- Introduction to CDISC Models

#### *Data and Metadata*

- Importance of Metadata
- CDISC Standards Development Process
- Scope of CDISC Models
- eCT Clinical Research Cycle

#### *Operational Data Model (ODM)*

- ODM Vision and Timeline
- XML
- ODM Glossary
- Model Features

#### *Laboratory Data Model (LAB)*

- LAB Vision
- LAB Model Logic
- Core Model Levels
- Implementation
- XML



#### *Study Data Tabulation Model (SDTM)*

- What is SDTM?
- Fundamentals of SDTM related to Domains and Variables
- SDTM Basics
- General Observation Classes
- Special Purpose Datasets
- Standard Domains and Study Data Domains
- SDTM Examples
- Variable Characteristics

#### *Standard for Exchange of Nonclinical Data (SEND)*

- SEND Team
- Standard Exchange of Nonclinical Data
- SEND v2.0 and Findings Domains
- Current Status and Next Steps

#### *Analysis Data Model (ADaM)*

- SDTM and how it relates to Analysis Datasets
- The Current ADaM Model
- Analysis Dataset Example
- Analysis Variable Metadata
- Dataset Documentation
- ADaM Work in Progress

#### *Protocol Representation (PR)*

- Format Conventions Approach
- Protocol Hierarchy
- Sample Sections, Sub-sections and Elements
- Clinical Trial Protocol

#### *Terminology*

- CDISC Specific Terminology
- Working Principals
- Where to find it
- Standard Controlled Terminology
- SDTM Terminology Projects
- Collaboration with NCI EVS
- Priorities for 2008

#### *Clinical Data Acquisition Standards Harmonization (CDASH)*

- CDASH Initiative
- Critical Path Opportunities
- Practical Experience
- CDASH Project Process, Status and Future

#### *Biomedical Research Integrated Domain Group Model (BRIDG)*

- BRIDG Initiative
- Brief Overview of the BRIDG Model
- Why BRIDG? Why Now?