



## CDISC Course Descriptions

### All courses are listed below

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7. LAB Implementation
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13. SEND Implementation
14. Controlled Terminology Implementation
15. CDISC: A Global Approach to Medical Research

**1. Introduction to CDISC (this course will be replaced in 2010 see below, CDISC: A Global Approach for Medical Research)**

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.

**Prerequisite: None**

**2. 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-based domain models, relationship tables, and trial design.
- A discussion of common implementation issues
- Exercises including the annotation of CRFs and the creation of datasets that reinforce attendees' understanding of the SDTM and the SDTM Implementation Guide.

**Recommendation: A basic understanding of relational database design and clinical data flow is helpful but not required**



### 3. 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**

### 4. Introduction to BRIDG

The BRIDG Model is a Domain Analysis Model (DAM) that is being developed through a collaborative effort of stakeholders from CDISC, the HL7 Regulated Clinical Research Information Management Technical Committee (RCRIM TC), the National Cancer Institute (NCI), and the US Food and Drug Administration (FDA). This half-day course will cover a brief history of BRIDG, a quick basic UML modelling tutorial and an introductory look at the BRIDG model.

**Prerequisite: None**

### 5. ADaM Implementation

The Analysis Dataset Model (ADaM) specifies principles for analysis datasets and standards for a subject-level analysis file and for a basic data structure, which can be used for a wide variety of analysis methods. This one-day course discusses the purpose of ADaM, the basic principles of the ADaM data standard, the standard ADaM dataset structures and variables, ADaM metadata, maintaining the relationship between ADaM and SDTM, and how to apply ADaM to common analysis situations.

**Recommendation: Basic understanding of statistical principles used in clinical research is helpful but not required**

### 6. ODM Implementation

The Operational Data Model (ODM) is a vendor-independent format used to store, interchange between data management systems, or archive study data, study metadata or administrative data associated with clinical trials. The ODM has been presented to the FDA as the standard for data archiving. This one-day course consists of the technical framework for ODM, an in-depth understanding of the model structure, an overview of the XSL and other tools for working with XML, and strategies for implementing ODM within your organization.

**Recommendation: working knowledge of XML or other mark-up languages is helpful**



## 7. LAB Implementation

The LAB Data Model is a vendor-independent format used to store and interchange lab data between clinical lab vendors and sponsor companies. The LAB model is an approved HL7 model. This one-day course consists of the technical framework for LAB, an in-depth understanding of the model structure, an overview of the implementation modes, and strategies for implementing LAB within your organization.

**Recommendation: Knowledge of clinical laboratory data is helpful**

## 8. CDISC Standards End-to-End

This workshop will provide an understanding of how the main components of the CDISC standards – the Operational Data Model (ODM), the Study Data Tabulation Model (SDTM), the Analysis Data Model (ADaM), The Laboratory Model (LAB) and the Protocol Model – can work together to move data from the point of trial design through data capture, submission and subsequent long-term archive. The workshop will use a combination of theory and practical demonstrations to provide participants with a comprehensive overview of how the eClinical trial can be implemented today.

**Prerequisite: General knowledge about the CDISC standards is helpful**

## 9. Legacy Data Conversion Workshop

This workshop will focus on methods and tools used to convert legacy data to the CDISC SDTM standard. There will be 3-4 case studies presented with discussion and demonstration of examples included.

**Prerequisite: 2 day SDTM Theory and Implementation or equivalent experience**

## 10. CDISC and HL7: Collaborative Standards Initiatives for Clinical Research and Healthcare

Topics for discussion:

- Data Standards: The foundation of interoperability in information interchange
- The BRIDG Model: Representing the clinical research domain in the context of healthcare standards
- The HL7 Development Process
- CDISC and HL7 Collaborative Projects

**Prerequisite: None**

## 11. Protocol Representation Course

The CDISC Protocol Representation Model is intended for those involved in the planning and design of a research protocol. It provides a standard, machine-readable model for protocol representation that enables interchange of protocol information among systems and stakeholders. The model focuses on the characteristics of a study and the definition and association of activities within the protocols. The scope of this model includes protocol content including Study Design, Eligibility Criteria, and the requirements from the ClinicalTrials.gov and World Health Organization (WHO) registries.

This course describes the Protocol Representation Standard, its relationship to CDISC models and BRIDG, and the uses of the model.

**Prerequisite: Introduction to BRIDG; general knowledge of clinical trial process and protocol development helpful**

## 12. Healthcare Link Course

The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.



CDISC has several initiatives underway that support the link between medical research and healthcare. This course will include an introduction to the basics of the CDISC Healthcare Link initiative, including the following:

- CDISC interactions with health informatics standards organizations such as HL7 and ISO TC 215
- The Biomedical Research Integrated Domain Group (BRIDG) model
- Activities of CDISC with FDA and EMEA around recommendations for eSource and standards
- Scenarios for the use of electronic health records for clinical research
- The RFD (Retrieve Form for Data Capture), an IHE (Integrating the Healthcare Enterprise) integration profile in use now to support various EHR-research related use cases

The RFD integration profile, which was developed through a CDISC-IHE collaboration, will be the focal point of the course. There will be an explanation of this profile, examples of use cases and hands-on activities designed to ensure that the participants can leave being able to implement this integration profile.

**Prerequisite: None**

## **Courses in development**

### **13. SEND Implementation**

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. SEND (Standard for the Exchange of Non-clinical Data) is an Implementation Guide based on SDTM for preclinical / nonclinical data. This two-day course consists of:

- A detailed review of SDTM concepts, SDTM-based SEND domain models, and relationship tables
- A discussion of common implementation issues

**Prerequisite: A basic understanding of relational database design and clinical data flow is helpful but not required**

### **14. Controlled Terminology Implementation**

This half-day course consists of an overview of how CDISC controlled terminology is developed and maintained, key partnerships (e.g., NCI EVS) in that process, the relationship of terminology to other CDISC standards, and specific implementation concepts.

**Pre-requisite: None**

### **15. CDISC: A Global Approach to Medical Research - replaces Introduction to CDISC**

This first part of this half-day course will give attendees a perspective on the business, scientific and regulatory benefits of using standards; provide information about the CDISC organization and how standards are developed; include a high level discussion of the end-to-end process to show how the standards provide these benefits throughout the research lifecycle; and talk about the future of the CDISC standards. The second part will give a brief, non-technical overview of each of the published CDISC standards and where they fit in the research lifecycle.

**Pre-requisite: None**