



CDISC Course Descriptions

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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. 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.

3. Introduction to CDASH-Terminology

This half-day course will provide attendees with an overview of the CDASH and Terminology projects as well as covering the history, organization, and philosophy behind the projects. This course will provide attendees with the information needed to facilitate access, implementation and use of these important standards. Additionally the course will cover:

- The development approach
- Key collaborations
- The interrelationship of these projects
- The relationship to the Study Data Tabulation Model (SDTM)
- How to implement these standards
- Future plans and direction



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 look at basic UML modeling and an introductory look at the BRIDG model.

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. 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.

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.

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.

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.

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

11. SEND Implementation Course

This one-day course consists of the theory behind SEND (Standard for the Exchange of Non-clinical Data) and the format of data that will be required for submission to the FDA.

12. 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.

13. 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.