



vLearning from CDISC

In collaboration with member companies, Destiny Corporation and Michael Palmer, CDISC is proud to announce the launch of the first course in a series of virtual learning programs. Entitled, **CDISC Submission Readiness**, this offering is a companion to the CDISC SDTM Training Course. Additional programs will be announced on the CDISC website as they become available.

Who will benefit from the CDISC Submission Readiness vLearning course?

Organizations within three years of making a marketing application.

Individuals that will benefit from this training are those with roles and responsibility in regulatory affairs, biostatistics, data management, programming, information technology, standards, database design, clinical research operations and pre-clinical safety studies.

What prior knowledge is needed?

Knowledge and understanding of a CRF.

What will participants learn?

At the end of the training participants should be able to:

1. Contribute to their organization's readiness to submit CDISC-compliant study data to the FDA.
2. Develop a plan to make the organization CDISC-ready.
3. Understand CDISC's and FDA's near-term intentions for study data submissions
4. Implement a CDISC readiness plan which includes mapping case report form data to CDISC and mapping internal data definitions to CDISC metadata.
5. Manage CDISC-readiness and CDISC compliance programs.

Course Pricing Information (in US Dollars):

Package	Users	Length	Non-member List price		Associate members		Corporate Members		Corporate Sponsors		Corporate Benefactors, Academic, Non-profit, Government	
			Purchase	Renewal	Purchase	Renewal	Purchase	Renewal	Purchase	Renewal	Purchase	Renewal
Single User 90 Day	1	90 Days	\$2,400	\$1,200	\$1,800	\$900	\$1,560	\$780	\$1,080	\$540	\$600	\$300
20 Pack 90 Day	20	90 Days	\$15,000	\$7,500	\$11,250	\$5,625	\$9,750	\$4,875	\$6,750	\$3,375	\$3,750	\$1,875
Single User 1 Year	1	1 Year	\$6,000	\$3,000	\$4,500	\$2,250	\$3,900	\$1,950	\$2,700	\$1,350	\$1,500	\$750
20 Pack 1 Year	20	1 Year	\$37,500	\$18,750	\$28,125	\$14,063	\$24,375	\$12,188	\$16,875	\$8,438	\$9,375	\$4,688

Detailed Course Content

Principles

- * FDA and CDISC requirements and recommendations
- * FDA and CDISC model for study data in a submission
- * Differences between FDA and CDISC requirements, recommendations and specifications
- * Benefits and risks of CDISC adoption for an organization

CDISC Standards

- * FDA submission data requirements
- * FDA's own CDISC based toolkit for study data review
- * Different types of submission data and CDISC relevance
- * CDISC documentation and resources
- * CDISC conformance

Universal Concepts

- * Class, Domain, Observation and Role
- * Metadata-dataset level, field level and value level
- * Variable roles
- * Value lists
- * Converting CRFs to CDISC

CDISC in the Business Process

- * Benefits and risks of different SDTM adoption strategies
- * Identification of features within the workplace which could facilitate or hinder CDISC adoption
- * Development of CDISC readiness plan and CDISC submission plan
- * Data transformation for eCTD Study Data Submission
- * CDISC information model for data definitions
- * Basic steps to convert CRF data to CDISC submission data
- * Define.xml standard
- * CRF data and data definitions conversion Case Report Forms to CDISC Domains
- * Mapping of CRF data to predefined domains
- * SDTM Observation Model
- * Value Lists

New Domain Creation

- * General observation classes
- * Identifiers and timing variables
- * The Findings class
- * Creation of new domains that are CDISC compliant

Representing Relationships

- * Relationship domains vs. data domains
- * Function and operation of relationship domains
- * Create CDISC relationship domains
- * SUPPQUAL
- * RELREC links domains

Define.xml

- * Defining data definitions and metadata
- * Contrasting define.xml model with define.pdf model
- * Populating the define.xml information model
- * Creating CRTDDS instances in XML
- * Flowchart for CDISC compliant data definition documents

Special Topics

- * CDISC trial designs terms and applying them to clinical studies
- * Study data and metadata for submission from analysis data and metadata for submission.
- * CDISC analysis data and issues
- * Location of CDISC submission in the eCTD

Trial Design Datasets

- * Trial design using CDISC terminology
- * Trial design with CDISC concepts of class, domain, observation and role
- * Translating your study designs into CDISC format
- * Trial design domains and study data domains

Analysis Data

- * Similarities and differences between CDISC study tabulation data and CDISC analysis data
- * Extensions made by the analysis data model (ADaM) to the Study Tabulation Data Model (SDTM)
- * ADaM's departures from SDTM
- * Analysis metadata into ADaM
- * Create CDISC analysis data and metadata

Further Information
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