



CDISC Operational Procedure CDISC-COP-005 Education Curriculum Development and Ownership, and Qualification of Course Developers and Trainers

Revision History

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CDISC-COP-005

Education Curriculum Development and Ownership, and Qualification of Course Developers and Trainers

1 Introduction

1.1 Purpose

This document describes the policies and processes related to the development and maintenance of the CDISC Education curriculum, ownership of CDISC Educational course materials, and qualification of trainers.

1.2 Background

The Clinical Data Interchange Standards Consortium (CDISC) is an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trials data and metadata for medical and biopharmaceutical product development.

The mission of CDISC 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 is committed to providing education to the biopharmaceutical industry on the current CDISC production standards. This education will be provided through various public and private venues including conferences, classroom training, company workshops, webinars and tutorials.

For more information on CDISC objectives and principles, please see the CDISC website at www.cdisc.org.

1.3 Authority

This document is approved by the CDISC Chief Executive Officer and should be used by CDISC staff, consultants, volunteers and technical teams for the development and maintenance of all CDISC training courses, and for the selection and management of course developers and/or trainers. The CDISC Director of Education has primary responsibility for the implementation of this policy and the related processes.

1.4 Definitions

Term	Definition
technical team	the team that is responsible for developing and maintaining a particular standard (e.g., SDS team)
technical team lead	the person who is leading a particular standards or project team; usually the TLC member for the standard

Term Definition	
course development lead	the person who has accepted responsibility for coordinating all of the activities involved in training material development

1.5 References

The following information sources are referenced in this document:

- **CDISC Website:** www.cdisc.org

2 CDISC Course Ownership and Licensing

1. Ownership of Training Materials, Exercises and Intellectual Property
 - a. All training materials and exercises developed under this Procedure will be owned by CDISC regardless of who participated in the development of said materials.
 - b. Any training materials and exercises developed under this Procedure may not be used to provide training outside of CDISC authorized training events, or to develop unauthorized training materials.
2. All training using CDISC developed course materials will be provided by CDISC authorized trainers at CDISC authorized venues.
3. Train the Trainer and Licensing Fees
 - a. CDISC may, when deemed appropriate, employ a “train the trainer” method of instruction.
 - b. CDISC education materials may be licensed for use by other trainers, training organizations or individual companies. CDISC will grant these licenses on a case-by-case basis.

3 Process for Education Course Development

1. Curriculum Development Strategy
 - a. The CDISC Director of Education, in collaboration with the technical team leads who are members of the Technical Leadership Committee (TLC), and TLC-designated individuals as deemed appropriate, will define the basic curriculum development strategy, which may include:
 - i. Courses which should be developed or upgraded based on
 1. new or updates standards
 2. feedback from instructors and attendees
 - ii. Priority for course development and upgrades
 - iii. Where the courses should be presented
 - iv. Method for delivery (e.g., in-person, video conference, webinars, eTraining)
2. Curriculum Development and Update Process
 - a. Once priority has been established for course development and/or updates, the following cooperative process will occur for each course:
 - i. A course development lead will be established to lead and facilitate the development team activities.

- ii. A course development team will be assembled by the course development lead.
 - iii. The course development team will develop an outline for the course and timeline goals for development.
 - iv. The course development team lead will review the draft course outline and timeline goals with the CDISC Director of Education or designee and both will approve before the course materials are drafted.
 - v. The course development lead will oversee the drafting and review of the course materials using an appropriate process of development review, feedback and updates.
 - vi. The development team may utilize the services of a curriculum developer as deemed appropriate by the team, and with the approval of the CDISC Director of Education.
 - vii. The technical team lead will solicit review of the draft course from the technical team, and provide the feedback to the course development team.
 - viii. The course will be updated from the technical team feedback received, and a final draft will be produced.
 - ix. The technical team lead will solicit review of the final draft from the technical team, and provide any feedback to the course development team.
 - x. The final draft will be prepared and submitted for versioning.
 - xi. The technical team lead and the CDISC Director of Education will approve the final draft of the course materials.
 - xii. The approved materials will be versioned and dated and be placed in the training materials document control environment for use by CDISC trainers.
- b. The CDISC Director of Education or designee will maintain the final approved version of the course materials in an appropriately controlled environment.
 - c. The need for updates will be identified and prioritized as a collaborative process between the Director of Education, the trainers and the technical team leads.
 - d. Updates will follow a similar development and review process as described in section 2.a, but may be abbreviated at the discretion of the TLC lead.
 - e. All final, approved course materials will be versioned and dated, and will be maintained in a controlled environment.
 - f. Unless prior approval is given by the CDISC Director of Education, only final, approved versions of course materials will be used to deliver CDISC training.
 - g. Temporary approval for using training materials that have not been developed under this process will be granted on a case-by-case basis.

4 Course and Instructor Evaluations and Continuous Improvement

1. Course Evaluations


- a. Each time a training course is presented, CDISC will gather feedback from attendees on the course materials and instructor using a course evaluation form.
 - b. If there is more than one course instructor, each instructor will be evaluated separately.
 - c. Each time a training course is presented CDISC will solicit feedback from the course instructors using a trainer course evaluation form.
 - d. All evaluation forms will be forwarded to the CDISC Manager of Education who will enter the results into a database.
2. Continuous Improvement
- a. The CDISC Director of Education will periodically review the summary statistics and verbatim comments from the attendee evaluations.
 - b. The CDISC Director of Education will facilitate periodic reviews of the evaluation results with the technical team leads and course instructors.
 - c. Feedback from both instructors and attendees will be considered during course development and upgrade activities.

5 Qualification of Course Developers and Trainers

1. Since CDISC is predominately a volunteer organization, course developers should be chosen from the technical teams, and should be unpaid volunteers and / or CDISC staff whenever possible.
2. If no qualified course developers are available on a volunteer basis, paid consultants can be employed at a rate established by CDISC in accordance with their level of experience, expertise and other relevant factors.
3. All course developers and instructors selected to teach CDISC courses will
 - a. have documented experience for a minimum of three years in the technical aspects of the CDISC standard in which they are training, or
 - b. be current or past active, contributing members for a minimum of one year on the team that developed the standard they are training , or
 - c. have an equivalent combination of team participation and/or experience, and
 - d. agree not to use the course materials for any purpose that is not authorized by CDISC.
4. Instructors should be chosen from qualified CDISC staff first whenever possible, and then from CDISC certified instructors who are under contract to CDISC, or who have other agreements or arrangements with CDISC to perform training.
5. The CDISC Director of Education or designee will maintain a list of qualified trainers for each training course.

Authorization

This document has been authorized by:

Name (printed)	Chief Executive Officer (signature)
	Rebecca D. Kush
Date: 7 October 2010	

