



CDISC Coordinating Committees (3C) Charter

Revision History

Date	Revision	Description	Author
June 2012	0.1	Initial Draft	Rebecca Kush and Pierre-Yves Lastic
July 2012	0.2	Draft 2 – consolidation of 3 C charters	Rebecca Kush, Kiyoteru Takenouchi, Pierre-Yves Lastic, Sheila Leaman
~September 2012	0.3	Incorporation of comments from 3Cs (Japan, Europe, China)	Rebecca Kush
~November 2012	0.4	Second review by 3Cs	Rebecca Kush
January 2013	1.0	Final	Rebecca Kush
June 2016		Update and Revision with input from four 3Cs (Japan, Europe, China, Asia-Pacific)	Rebecca Kush, Barrie Nelson, Diana Harakeh, Marine Laurent, Sheila Leaman
February 2017	1.1	Final	Board Approval
August 2024	1.2	Revision	Chris Decker/Sheila Leaman

1 Introduction

1.1 Purpose

The purpose of this Charter is to describe the responsibilities, membership and scope of work for the CDISC Coordinating Committees.

As CDISC is a non-profit charitable organization, it must adhere to stringent rules regarding adherence to Bylaws and Policies, including neutrality and transparency, and balanced processes as a global Standards Development Organization (SDO). CDISC must

also be diligent regarding the spending of funds received from membership, education, grants and other contributions and the reporting to stakeholders.

A CDISC Coordinating Committee (3C) supports CDISC initiatives in a specific region of the world and to provide regional feedback to the central CDISC organization. They differ from User Groups in that they are sanctioned directly by the CDISC Board of Directors and CDISC Leadership Team.

The primary 3C activities are defined in collaboration with CDISC Leadership Team; these activities should receive appropriate support from CDISC Operations and will require effective communications between the two groups.

The name of 3C reflects the region, e.g. Europe CDISC Coordinating Committee = E3C. This Charter describes the responsibilities, election process and other important aspects of 3Cs.

2 Responsibilities

The main responsibilities and/or opportunities of a 3C can be summarized as follows:

- Develop an action plan each year, in collaboration with the CDISC Leadership Team, that is aligned with the CDISC Strategic Goals (established by the Board of Directors) and the CDISC Operational Goals for that year.
- Provide support in organizing and promoting CDISC Interchanges and events for a specific region; dates, contracts and other related obligations must be formally approved by CDISC Leadership Team.
- Support scheduling and content of authorized training and other educational seminars in the region working with the CDISC Education lead for.
- Support CDISC Education to identify individuals who may wish to be trained to be CDISC authorized instructors.
- Liaise with regulatory authorities, other appropriate institutions and standards developing organizations for the region covered by the 3C in close collaboration with the CDISC Leadership Team; this may include forming value-added collaborations with organizations within the region that can further the CDISC vision and mission.
- Assist in the creation and coordination of any User Groups in the region, as appropriate, and ensure that the feedback from these groups is consolidated and communicated back to the CDISC organization through the CDISC Leadership Team Liaison.
- Report main activities and opportunities in the region to CDISC Leadership Team Liaison on a regular basis. The 3C Chairs (or their representatives) may also be invited to Board meetings as deemed relevant.

3 Composition

The 3Cs should ideally be composed of volunteers from various sectors in research and healthcare, including but not limited to biopharmaceutical companies, academia, CROs, service and technology providers and regulatory agencies. The members of the regional 3C should include at least 6 members and not exceed 20, all of whom should represent CDISC member organizations (unless approved prior to election by CDISC Leadership Team, such as in the case of a government official or regulatory representative or a prior 3C member). To have a well-balanced ratio of members it is recommended to have only one member from each member organization in the 3C.

A Chair and up to two Vice-Chairs, who must be from a CDISC member organization, shall be elected per the process described below.

The 3Cs can invite ex officio attendees to any meeting based upon relevance to the topics to be discussed.

4 Nomination, Election Process and Member Terms

Members and leaders of the 3C must be nominated and approved through a transparent process. Open positions for members and 3C leaders must be posted through external CDISC communications (e.g. website, social media post, user group email lists) and announced by email to the 3C members by the CDISC Leadership Team Liaison at least 1 month prior to the election date.

Candidates must provide a resume and a letter expressing their involvement/experience with CDISC, and their interest to be on the 3C. Candidates should ideally be endorsed by at least one existing 3C member, although new candidates and current members may self-nominate without such an endorsement.

4.1 3C member election process

Nominations will be reviewed and approved by the 3C Chair and Vice Chair(s) before being posted for election. Nominated 3C members will be elected by a simple majority of the 3C voting members and voting will be repeated until all posts are filled.

Elections may be conducted by electronic vote set up and monitored by the CDISC Leadership Team Liaison who will send the final voting results to the 3C Chair and Vice-Chairs. The 3C Chair will notify the new members/leaders, within one week of the results, of their election to the 3C.

Elections should only be held once annually. If a 3C member is unable to complete their term, this position will be on hold till the next election cycle.

4.2 3C leaders election process

The Chair and Vice-chair(s) of the 3C must be nominated through the same process; however, the Chair and Vice-Chair candidates must be approved in advance (prior to the election) by the CDISC Leadership Team.

In the case of a newly formed 3C, or if the current Chair resigns before the end of their mandate, the CDISC Leadership Team may nominate an Acting Chair until an appropriate election takes place (no more than one year after the creation for the 3C or the departure of the elected Chair).

4.3 Ex-officio Voting members

Two representatives from the CDISC Leadership Team will participate on each 3C as ex officio voting members. Other personnel may be invited to participate in the 3C but will not have a vote.

4.4 Terms

All members are elected for a renewable 3-year-term. When a member is elected Chair or Vice-Chair, their current term is extended until the end of their Chair or Vice-Chair term.

Terms for Chair and Vice Chair(s) are for 3 years with an opportunity to renew one time - a member can serve up to 2 consecutive or non-consecutive terms as Chair and/or Vice-Chair.

4.5 Governing policies

All 3C members agree to act in accordance with CDISC Bylaws, Policies and Charters and will adhere to CDISC Operating and Internal Procedures where relevant.

5 Meetings and Decision-Making Process

Each 3C should meet via teleconference approximately once per quarter, as deemed necessary by the Chair. Meeting dates and times should be specified well in advance.

A majority of the Committee members, present and voting, shall constitute a quorum. Decisions should be taken by consensus as much as possible. If a consensus is not possible, decision should be made using a simple majority vote.

6 Authority

The 3C will provide information and guidance back to the CDISC Leadership Team (through the CDISC Leadership Team Liaison) on specific regional issues. The 3C may act as a conduit to discussions between regional organizations or authorities and CDISC; however, the 3C members do not have the authority to sign agreements (e.g. contracts or MOUs) or speak on behalf of CDISC.

CDISC has no financial obligation to a 3C. Any request for financial contributions from CDISC must be submitted in advance to CDISC Leadership Team and will be approved on a case-by-case basis. Funds collected on behalf of CDISC (e.g. at CDISC Interchanges) should be collected through CDISC and belong to CDISC. CDISC Operations staff reserves the right to schedule educational activities, certify instructors and develop collaborations in the region independently of the 3C. In addition, all CDISC standards are the intellectual property (IP) of CDISC as are any translations of these standards, per the CDISC Intellectual Property Policy. This ensures that they remain open and freely available.

7 Communications

The 3Cs are expected to communicate to CDISC Operations (via their CDISC Leadership Team Liaison) any and all interactions with regulatory authorities in the region, changes in composition or leadership of the 3C, events (including educational events related to CDISC) in the region or other significant 3C activities.

CDISC will communicate to the 3C any significant activities that are conducted by CDISC in that region and important decisions of the CDISC Board of Directors. CDISC will provide a dedicated online space (either on the CDISC Wiki area or any other relevant site) for each 3C to upload and share documents.

8 Authorization

This document has been approved and is in effect on this date:

Name	Board of Directors
Date	27 September 2024