



## CDISC Coordinating Committees Charter

### Revision History

<b>Date</b>	<b>Revision</b>	<b>Description</b>	<b>Author</b>
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
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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			Board approval

# CDISC Coordinating Committees (3Cs) Charter

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

### 1.2 Background

CDISC Coordinating Committees (3Cs) were founded to support global CDISC initiatives within specific regions 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 Executive Operations.

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

The CDISC Board of Directors approves the creation of (and may disband) each individual 3C, based on regional activity, member involvement, 3C effectiveness and any other relevant criteria.

## 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 CDISC Executive Operations, that is aligned with the CDISC Strategic Goals (established by the Board of Directors) and the CDISC Operational Goals for that year.
- Provide support to organize and promote CDISC Interchanges and events for a specific region; dates, contracts and other related obligations must be formally approved by CDISC Executive Operations.
- Provide assistance regarding the scheduling and content of authorized training and other educational seminars in the region, working with the CDISC lead for Education.

- 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 CDISC Executive Operations; this may include forming value-added collaborations with organizations within the region that can further the CDISC vision and mission communicating interactions to CDISC Executive Operations such as complementary organizations.
- Assist in the creation and coordination of any User Networks/User Groups or Work Groups in the region, as appropriate, and ensure that the feedback from the User Networks/User Groups or Work Groups is consolidated and communicated back into the CDISC organization through the CDISC Executive Operations Liaison to the 3C.
- Report main activities and opportunities in the region to CDISC Board on a regular basis. For this purpose, the Board will invite all 3C Chairs (or their representatives) to the face-to-face Board meetings and any other Board or Board Committee 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 Executive Operations, such as in the case of a government official or regulatory representative or a prior 3C member).

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 on the CDISC website and announced by email to the 3C members by the CDISC Executive Operations 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.

User Group Leaders and current or past CDISC Board members may be elected to the 3C through the process described below.

The elections may be conducted by electronic vote set up and monitored by the CDISC Executive Operations 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.

#### **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.

#### **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 CDISC Executive Operations.

In the case of a newly formed 3C, or if the current Chair resigns before the end of their mandate, CDISC Executive Operations 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 CDISC Operations 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, or when necessary at the call of 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 Operations (through their CDISC Executive Operations 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 Executive Operations 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 Executive Operations 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.

The 3Cs are expected to send reports or articles for quarterly eNewsletters, to develop content for their areas of the CDISC website and to provide regular updates.

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 Portal 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:

Board of Directors	
Date	14 February 2017