CDISC Operational Procedure CDISC-COP-014
CDISC Coordinating Committees

1 Introduction

1.1 Purpose
A CDISC Coordinating Committee (3C) supports CDISC initiatives in a specific region of the world. The name of the 3C reflects the region, e.g. European CDISC Coordinating Committee = E3C. This COP describes responsibilities and other important aspects of 3Cs.

The main responsibilities 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.
- Organize and promote CDISC Interchanges for a specific region with prior approval of dates, contracts and other related obligations from 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 certified 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 in the region, as appropriate, and ensure that the feedback from the User Networks/User Groups is consolidated and communicated back into the CDISC organization through the CDISC Executive Operations liaison to the 3C and CDISC Communications representative.
- Place documentation for the 3Cs in the CDISC Portal and communicate activities through CDISC website and eNewsletters.

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.

2 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. The members of the regional 3C should include at least 6 members and not exceed 12, 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). User Group Leaders may be members of the 3C if elected through the following process. A Chair and a Vice-Chair, 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.

3 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 for at least 1 month on the CDISC website and announced in the CDISC eNewsletter. Candidates must provide a resume and a letter expressing their interest to be on the 3C and should ideally be endorsed by at least one existing 3C member, although new candidates and current members may self-nominate without such an endorsement. Nominated 3C members will be elected by a simple majority of a quorum (two-thirds of the 3C voting members) of the 3C members and votes will be repeated until a majority is achieved. The Chair and Vice-chair 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 Executive Operations. An Acting Chair may take the lead for a newly formed 3C until an appropriate election takes place.

Two individuals from CDISC Operations will participate on each 3C as ex officio voting members. Any CDISC Board members who are permanently residing in the region of the 3C will also be provided the opportunity to be a 3C member. Administrative personnel may be invited to participate in the 3C, but will not have a vote. The elections may be conducted by electronic vote with an appointed neutral (non-voting) individual, ideally from CDISC Operations, to receive the votes.

All terms for Chair and Vice Chair are for 2 years with an opportunity to renew one time. Normal members are elected for a 3 year term that can be extended once subject to the normal election process by the 3C.
4 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 do not have the authority to sign agreements (e.g. contracts or MOUs) 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. Once this COP is approved by the 3Cs and CDISC Board of Directors and Executive Operations, it will be subject to a reassessment and reconfirmation at least once every 2 years.

5 Communications

The 3C will be expected to communicate to CDISC Operations (via their CDISC Executive Operations Liaison or CDISC Communications 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. The 3Cs are expected to send reports to CDISC Communications for monthly eNewsletters, to develop content for their areas of the CDISC website and to provide regular updates.

6. Authorization

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

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<tr>
<th>Rebecca Kush</th>
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