



CDISC Operational Procedure CDISC-COP-011 CDISC User Groups

Revision History

Date	Revision	Description	Author
20 June 2010	0.1	Initial Draft MOU – sent to User Network leaders for review	Sheila Leaman and Rebecca Kush
7 Oct 2010	0.2	Draft COP based upon the MOU, comments from UN leaders	Sheila Leaman
17 Nov 2010	0.3	Addressed comments from UN leaders	Sheila Leaman and Rebecca Kush
19 Nov 2010	0.4	Issued for final review to P-Y Lastic, Sue Dubman, Frank Newby, Kiyoteru Takenouchi, Chris Decker, Shannon Labout	
15 Feb 2011	1.0	Approved Final COP	Sheila Leaman and Rebecca Kush
13 December 2017			Nicole Harmon and Sheila Leaman

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CDISC User Groups

1 Introduction

1.1 Purpose

This document defines the appropriate roles and expectations between CDISC as an organization and stakeholders that represent users, members, and liaisons throughout the world. This Policy is developed in the spirit of supporting and encouraging User Groups to be successful through a mutually beneficial relationship with CDISC.

1.2.1 CDISC Coordinating Committees (3Cs)

CDISC has formed CDISC Coordinating Committees (3Cs) in Europe (E3C), Japan (J3C), China (C3C) and Asia-Pacific (AP3C) to represent CDISC activities and outreach in these regions. The role and responsibilities of 3Cs are defined in a specific document – 3C Charter, available on the CDISC website.

1.2.2 CDISC User Groups

CDISC User Groups are autonomous volunteer-led organizations where CDISC users provide mutual support to help users utilize CDISC standards. The purpose of user groups is to support the further implementation of CDISC standards. In general, user groups are composed of stakeholders who are actively meeting face-to-face regionally or actively meeting virtually to discuss implementation of CDISC standards and can provide a feedback loop to the CDISC Standards Development Teams.

CDISC User Groups are fully independent bodies, whose legal and operational structure is at the discretion of their members. They are not, and should not represent themselves to be, part of CDISC the 501(c)3 organization (including as a subsidiary, controlled-entity, etc). The support that CDISC provides to recognized user groups is only meant to foster awareness and adoption of CDISC standards, and does not imply any sort of control, legal or otherwise, over these organizations.

1.2.3 Alignment of 3Cs and User Groups

CDISC seeks to have open communication with each User Group through the regional 3C in each continent. Where a regional 3C does not exist, the User Group may have a liaison to a CDISC-designated CDISC staff member or another 3C.

2. Benefits of CDISC User Groups

As autonomous organizations, CDISC User Groups are free to set their own goals and agendas. Common goals of such groups often include, but are not limited to:

- Share CDISC implementation experiences periodically
- Discuss draft standards and provide comments to CDISC
- Discuss mature standards and feedback to CDISC on usefulness
- Discuss new ideas to be channeled into CDISC
- Network among colleagues
- Share recent conference participation and learning
- Support CDISC utilization across languages, across cultures, and across user communities

3. CDISC Support

User Groups are independently formed and in various stages of maturity, and may request or need different levels of support from CDISC. As a nonprofit with limited resources, CDISC seeks to support user groups with realistic commitments of staff time and other resources. In countries where there is a 3C, the User Groups can generally obtain support through the 3C, although CDISC support may also be made available as appropriate. This section provides a list of areas where CDISC staff may be able to provide support to the User Groups:

- A formal letter of authorization, indicating the User Group is an official CDISC User Group and expressing the geographic, language, or other membership scope of the User Group
- Electronic copy of the of the CDISC logo and a limited license to re-use the CDISC logo and name, subject to Section 5, below
- Coordinate with User Groups when CDISC staff are on work-related travel in the area, to arrange for a 'CDISC Day' or other presentation for that User Group
- 3C and/or CDISC staff support of a User Group (i.e. interactions with regional 3C, meetings, communications or other such logistical support)
- Offer updated presentation materials on CDISC activities
- Provide Wiki pages for User Groups
- Advertise User Group meetings and accomplishments in the CDISC Newsletter, website and through social media

CDISC support for User Groups is always subject to CDISC leadership judgments on feasibility and resource availability. CDISC may withdraw recognition for any User Group if it becomes apparent in the sole opinion of CDISC's management that the User Group has ceased to operate and/or ceased to support the CDISC mission or purpose of a User Group.

4. User Groups' Role

In order to qualify as a CDISC User Group and benefit from the above CDISC offerings, the User Group leaders are responsible for the following:

- Ensure that their User Group information in the CDISC User Group Wiki is accurate and up to date
- Provide a yearly update to the 3C designated contact on User Group leadership and a primary point of contact for new users and for CDISC

- Utilize the CDISC logo without modification under a limited re-use license, subject to Section 5, below
- Utilize the CDISC name under a limited license, subject to Section 5, below
- If using a CDISC User Group Wiki area, ensure it is regularly maintained, including current meeting schedules, announcements and presentations.
- Provide an open forum for exchange of information and a collegial, welcoming environment
- In the event that a regulator, member of the media, a community stakeholder, or member of the public contact a User Group, liaise with the 3C Chair (or in the absence of a 3C, the CDISC staff contact) to provide an appropriate response to the inquiring party.
- If requested by the regional 3C or the CDISC staff liaison:
 - Provide feedback on implementation challenges and opportunities to help CDISC in improving standards including but not limited to feedback on examples, implementation use cases, key lessons learned, presentations for Interchanges, articles, sample CRFs
 - Disseminate information to User Group participants on joining CDISC Working Groups, 3C, and other volunteer opportunities available at CDISC
 - Disseminate information to User Group participants on joining CDISC via membership from its members

4.1 Prohibitions of Certain Activities by User Groups or User group Participants

- CDISC User Groups Members are prohibited from competing with CDISC Educational Courses including distribution of CDISC-branded educational materials. Specifically, CDISC Educational Course materials are branded and are CDISC intellectual property. These are only to be used by CDISC approved instructors performing CDISC-authorized training – [see COP-005.]
- CDISC User Groups Members are prohibited from speaking on behalf of CDISC

5. Limited License to Utilize the CDISC Name and Logo

As a part of their normal course of operations, a User Group may utilize the CDISC name and logo, subject to the following conditions:

- The User Group acknowledges that the CDISC name and logo are protected by intellectual property laws and remain solely the property of CDISC
- The User Group will establish a name (subject to approval by CDISC) utilizing the format
CDISC {User Group identifier} User Group e.g. CDISC French-Speaking User Group; CDISC Professional Computer Programmers User Group
- The CDISC logo may not be modified. The CDISC logo may not be edited into a derivative logo specific to the User Group.

- The CDISC name and logo may never be used in a context such that it would appear to a casual observer that CDISC or the User Group are endorsing a commercial product, company, or service.
- The CDISC logo and User Group name will be utilized solely to raise awareness of the User Group and more generally of CDISC standards.
- In the event that CDISC withdraws recognition of a User Group (Section 3, above), User Group participants agree to cease utilizing the CDISC name and logo, and User Group participants agree to delete any electronic versions of the CDISC logo.

6. Authorization

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

David R. Bobbitt	CDISC President and CEO
Date	31 January 2017