



CDISC Operational Procedure CDISC-COP-011 CDISC User Network Policy

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
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Table of Contents

1	Introduction	2
1.1	Purpose.....	2
1.2	Background.....	2
1.2.1	CDISC Advisory Board	2
1.2.2	CDISC Coordinating Committees	2
1.2.3	User Network.....	2
2	Principles of CDISC User Networks.....	3
3	Purpose and Benefits of CDISC User Networks	3
4	CDISC Role.....	3
5	User Networks Role.....	4
6	Authorization	5

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1 Introduction

1.1 Purpose

This document defines the appropriate roles and expectations between the User Networks and CDISC. This is important to define since CDISC is a non-profit organization with a product consisting of freely available, open CDISC standards, which are produced largely by volunteers through a consensus process.

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

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 unique in the fact that it is the only standards development organization (SDO) in the healthcare arena that offers its standards openly and freely. CDISC revenue streams have traditionally been through membership contributions (e.g. joining and renewal fees) and educational courses. These revenue streams are essential to allow CDISC to: (i) provide the necessary infrastructure to continue leading development of global clinical research standards; (ii) maintain the standards; and (iii) continue providing its standards free of charge via the CDISC website.

CDISC operates as a virtual organization composed of a small staff. In addition, CDISC partners with the following volunteer groups to support and promote the CDISC mission globally:

1.2.1 CDISC Advisory Board

The CDISC Advisory Board (CAB) is composed of one member from each CDISC Platinum Member Organization. This group provides advice to CDISC through its Board representatives and representation on Board Committees.

1.2.2 CDISC Coordinating Committees (3Cs)

In 2002, CDISC established CDISC Coordinating Committees (3Cs) in Europe and Japan to represent CDISC in those regions. The 3Cs also organize annual CDISC Interchanges in their respective regions. More recently, CDISC Coordinating Committees were established in China and Korea. Others may be established in more geographic regions in the future. CDISC leadership may organize a NA3C (North America CDISC Coordinating Committee) comprised of User Network Leaders.

1.2.3 CDISC User Networks

Concurrently with the CDISC outreach efforts described above, self-formed User Networks developed in the United States to enable face-to-face interactions among CDISC users. In Europe, E3C encouraged User Network formation centered around five language areas: French, German, Italian, Nordic and English. There are now additional User Networks in Korea, Japan and China.

CDISC User Networks can provide significant value to CDISC Users and the CDISC organization if there is a synergistic relationship and ongoing mutual benefit.

2. Purpose and Benefits of CDISC User Networks

- Share CDISC implementation experiences periodically in a given region or language
- Discuss draft standards and 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

3. Principles of CDISC User Networks

The following sections of this Policy take into account certain principles for ensuring a successful synergistic relationship, including a) that User Networks should not be redundant to the CAB or the 3Cs, i.e. they should have a unique purpose and benefit to CDISC Users; and b) User Networks should not compete with CDISC revenue streams, especially with regard to CDISC Education.

These principles are important in that they have a significant impact on CDISC's ability to continue to provide products and services in support of its stakeholders.

4. CDISC Role

Since User Networks are independently formed and in various forms and stages of maturity, they will request or desire different levels of support from CDISC. In countries where there is a 3C, the User Networks can generally obtain support through the 3C, although central CDISC support can be made available as appropriate. This section provides a list of areas where the central CDISC organization may be able to provide some support, where feasible and upon request, to the User Networks :

- Use of the CDISC Logo (as is, not modified)
- Coordinate with User Networks when CDISC Operations staff are in the area, to arrange for a 'CDISC Day' or a presentation for that region.
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- 3C and/or CDISC staff support of a User Network (i.e. interactions with regional 3C, meetings, communications or other such logistical support)
- Place presentation materials in User Network Portal: Overview to CDISC and How to Initiate a CDISC User Network Presentation.
- Listserve to manage User Network members (to be researched if sufficient interest)
- Provide portals for User Networks
- Advertise User Network meetings and accomplishments in the CDISC eNewsletter
- Offer CDISC public education courses in the User Network regions, arranged through CDISC Director of Education, and given preferential opportunities to host public training to User Network organizations.

5. User Networks' Role

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

- Ensure that their User Network is identified in the CDISC User Network Portal.
- Keep CDISC (sleaman@cdisc.org) updated whenever there is a change in User Network leadership so CDISC knows primary contact.
- CDISC User Network may use the CDISC logo as is (i.e. the CDISC 'ball' and the letters "CDISC" together comprise a registered trademark and this integrity must not be compromised).
- CDISC User Network will place current schedules, announcements and presentations in the CDISC User Network Portal area.
- CDISC User Networks are prohibited from competing with CDISC Educational Courses. 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 Networks would help CDISC by providing feedback helpful to CDISC in improving its standards. Valuable input to the CDISC Vice President of Strategic Initiatives (bkisler@cdisc.org) would be, for example, implementation use cases, key lessons learned, presentations for Interchanges, articles, sample CRFs.
- CDISC User Networks will encourage, but not require, CDISC membership from its members. (Per the list in the prior section, User Networks may collect fees from attendees to offset costs of meetings and these fees may differ depending upon whether or not a company is a CDISC member.)

- CDISC User Network Leaders will provide an open forum for exchange of information but will not speak on behalf of CDISC, unless the User Network Leader is a member of CDISC leadership (Board) or staff.

This Policy is developed in the spirit of supporting and encouraging User Networks to be successful through a mutually beneficial relationship with CDISC. Consequently, it is essential to support the CDISC mission and User Network goals while ensuring an adequate revenue stream for CDISC to continue to develop, maintain and offer its standards freely.

6. Authorization

This document has been authorized by:

Rebecca Kush	CDISC Chief Executive Officer
Date	15 February 2011