

German CDISC User Group: Bylaws Document

Article 1 – Name

The name of the organization shall be the German CDISC User Group, hereto after referred to as “the User Group.”

Article 2 – Purpose and Objectives

Purpose - The User Group is an independent, grassroots community of CDISC Users, committed to the open exchange of knowledge and information on the implementation of CDISC standards with local users from german-speaking European countries. Other interested parties are welcome to participate as well.

Objectives – The objectives of the User Group are to:

- a) Provide a venue for presentations and discussions about the CDISC standards
- b) Provide a forum for participants to share knowledge and cooperatively address CDISC standards implementation issues
- c) Elevate the level of familiarity of CDISC among participants and within participating organizations
- d) Act as a liaison to the national and regional CDISC organizations
- e) Provide a cooperative voice for pharmaceutical and biotechnology companies, universities and institutions, and service providers from german-speaking European countries for discussion of standards and related regulations

Article 3 – Membership

Participation in the User Group shall be open to all who share in its purpose.

Article 4 – Committees

Members for the Executive Committee will be elected by the German CDISC User Group participants in a general meeting and by a simple majority and will serve for a term of approximately 2 years. The Executive Committee shall consist of a minimum of 3 people.

The Executive Committee shall manage the business of the User Group. The Executive Committee may eliminate committees and may establish new committees as necessary to carry out the objectives of the User Group. The responsibilities of the Executive Committee are;

- a) Plan and run general meetings
- b) Communicate with membership
- c) Communicate with CDISC and other organizations
- d) Maintain Bylaws document

- e) Form and/or participate on subcommittees or work streams
- f) Any other business of the User Group as required

The Executive Committee will elect a Chair who will serve a term of approximately 2 years. Candidates for the Executive Committee Chair should have an active record of service in the User Group and should usually have served on the Executive Committee.

The Executive Committee may charter permanent or ad hoc committees or work streams as necessary to carry out the objectives of the User Group. Working procedures of the ad hoc committees or work streams will be determined by their corresponding members. The Executive Committee will solicit participation on these committees or work streams from the general membership. An Executive Committee member will lead each committee or working group.

The Executive Committee and other committees or work streams shall generally make decisions regarding User Group business based on consensus. In the event that a committee or working group chooses to take a vote on a matter, all present at the meeting shall have the right to one vote and decisions will be made by a simple majority.

Article 5 – Meetings

Executive Committee Meetings – Teleconferences shall be held on a bi-monthly basis, or as deemed necessary by the Executive Committee. Members shall be notified of the time and place of the Meeting with 7 day minimum notice.

General User Group Meetings – approximately two to three meetings shall be held over the course of each year at a place and time determined by the Executive Committee or its designee. Members shall be notified of the time and place of the Meeting with 3 months minimum notice and a draft agenda shall be submitted with 28 day minimum notice.

Other committees or work streams shall meet as deemed necessary. All meetings and teleconferences of the User Group shall be open to all.

Article 6 – Voting

All present at a Meeting shall have the right to one vote, except as otherwise specifically provided in the Bylaws.

Decisions will be made by simple majority of the participants present if unanimous consensus cannot be reached. There is, however, an exception for amendments to the Bylaws (see Article 8).

Article 7 – Dues

The User Group shall not charge dues for membership. Voluntary contributions such as providing meeting facilities, teleconference services, or refreshments are welcomed.

Article 8 – Amendments

Amendments to the Bylaws may be proposed by any participant of the User Group. The Bylaws must be amended by at least ten participants and constituting two-thirds affirmative vote of those present.

Notice of proposed changes to the Bylaws must be announced by the Executive Committee to the General Membership at least 28 days prior to each vote.

Amended Bylaws will be effective immediately upon approval, unless otherwise requested in the proposed change or recommended by the Executive Committee.

Article 9 – Dissolution

Dissolution of the User Group will occur by a general meeting and has to be agreed by a two-thirds affirmative vote of those present.