

1. Introduction

Volunteers are an invaluable resource to CDISC. Volunteers support development and maintenance of CDISC standards through active participation on standards development teams or other CDISC project teams. This participation ensures CDISC standards reflect and meet the needs of the user community.

CDISC desires to set clear expectations and organizational support for volunteers who are engaging in CDISC activities and supporting the development of CDISC standards. This charter establishes the framework for volunteer team leaders and team members to work together effectively and respectfully.

2. Volunteer Role and Commitment

2.1 Definition

An individual can become a volunteer and will be considered active when the following conditions are met:

- The volunteer can fulfill engagement commitments for a team or project, as outlined below and in section 2.2.
- The volunteer can adhere to principles of good conduct, as described in section 3.

In general, a volunteer may fill one of two roles on a CDISC team: lead or member. A volunteer may fulfil only one role within a single team, but may be a lead or a member across multiple teams.

Regardless of role, all CDISC volunteers are expected to actively participate within their team. General expectations for active participation include, but are not limited to:

- Engagement in team communication; including attendance at team meetings (e.g., teleconferences, face-to-face meeting)
- Participate in the development of new and updated standards, including the Internal and Public Reviews of standards

- Provision of subject matter expertise and consultation in support of development and maintenance of CDISC standards
- Completion of tasks in support of development and maintenance of CDISC standards (e.g., follow-up on team action items, updates to materials)
- Assist in evaluation and resolution of review comments for draft standards at the conclusion of Internal and Public Review periods
- Assist in the development of team training materials

2.2 Engagement Commitment

In general, the time commitment for active participation on a single team is:

- Attendance of one weekly or biweekly meeting (typically 1-2 hours in duration)
- Up to four hours of additional work per week depending on team needs

The specific requirement commitments are managed and communicated to all team members by the Team Leader and / or CDISC Team Coordinator.

In addition, CDISC holds regular face-to-face team meetings that volunteers are encouraged to attend. Such meetings include:

- Annual Working Group Meeting
- Project Team Meetings at CDISC Interchanges
- Other ad hoc face-to-face meetings

3. Good Conduct Commitment

CDISC is a community of mutual respect. All volunteers are expected to adhere to generally accepted principles of good conduct, including:

- Participating in all CDISC meetings and activities with professionalism and respect Complying with the CDISC Ethics, Intellectual Property and Standard Development Policies
- Complying with all relevant laws and regulations, and abiding by all other relevant CDISC policies and procedures; all current CDISC policies and procedures are accessible on the CDISC website
- Contributing their knowledge and experience to further the development of CDISC standards and models
- Keeping CDISC activities and materials free of marketing presentations and unauthorized promotional material
- Meeting the stated volunteer engagement commitment
- Using required CDISC IT tools

Any volunteer not complying with this good conduct commitment may be suspended or removed from their team, as per the process detailed in the CDISC Operating Procedure #19 – Volunteer Engagement.

CDISC standards support key research in a variety of settings globally and thus it is imperative to constrain who can speak on behalf of CDISC. CDISC volunteers agree that they can never present themselves as speaking on behalf of CDISC to any member company, regulatory agency representative, or any other person or entity without prior express permission of the CDISC Chief Standards Officer (CSO) or President and CEO. Any violation of this policy may rise to the level of egregious conduct as stated in CDISC Operating Procedure #19—Volunteer Engagement and could result in disciplinary action including termination from CDISC teams.

4. Leadership and Support

4.1 Team Leaders

For Foundational teams, the Volunteer Team Leadership is comprised of:

- A current Team Leader, with a 2-year term of engagement
- A past Team Leader, with a 2-year term of engagement

In the case of larger teams, the CDISC head of Standards may decide to open multiple co-leader positions instead of a single team leader. The need for co-leaders instead of a single leader is assessed at the beginning of each election cycle for that team.

For TA teams, the CDISC Project Manager acts as the Team Leader.

For other project-based teams, the Team Lead is appointed by CDISC as needed based on the specificities of the project.

Team Leader Roles

All Team Leaders, regardless of the type of team, are responsible for:

- Adhering to all relevant CDISC policies and procedures, including the CDISC standards development process and the associated team governance processes
- Modeling the principles of good conduct for volunteers
- Estimating team workload and project milestones, as needed and with CDISC support
- Prioritizing their team (and sub-teams' work, if applicable) in line with CDISC priorities
- Completing sanctioned project deliverables, supported by a CDISC project manager

- Escalating unresolvable standards development issues to the CDISC Global Governance Group (GGG)
- Communicating team meeting information to all active team members
- Convening and facilitating team meetings on a scheduled basis
- Documenting team discussions and other work using CDISC tools and systems
- Suggesting subteam creation or removal to the CDISC Head of Standards
- Suggesting subteam leader to the CDISC Head of Standards
- Reviewing the charter on an annual basis
- Encouraging attendance and participation of volunteers
- Actively participating in annual reviews of volunteer engagement and the assessment of active status with the CDISC Team Coordinator
- Reviewing current team member lists in coordination with the CDISC Team Coordinator, to ensure accuracy
- Escalating issues with volunteers to CDISC Heads of standards

4.2 Global Governance Group (GGG) Representative

The GGG Representative represents their team on the GGG.

As part of their duties, they attend GGG meetings, review documents as required and sign off on draft and final documents on behalf of their team.

There is one to three GGG Representatives for each Foundational Team. The number for each team is agreed upon by each team's Lead and CDISC Head of Standards.

4.3 CDISC Team Coordinator

The CDISC Team Coordinator is the "go-to" person for any team-specific and operational questions from volunteers of their respective team.

Among other duties, the CDISC Team Coordinator is responsible for:

- Monitoring team deliverables and supporting the team as the deliverables go through the governance and publication processes
- Providing or obtaining training for teams on CDISC collaboration tools, when requested by team leaders
- Regularly attending team leadership meetings for planning purposes
- Identifying high-performing commenters and inviting them to join the team
- On-boarding and orienting new volunteers onto the appropriate team
- Performing the annual assessment of team needs and volunteer engagement, in coordination with the relevant team leaders

4.4 Volunteer Administrator

The Volunteer Administrator is the "go-to" person for any general volunteer administrative questions.

The Volunteer Administrator manages the onboarding process of new volunteers, supports the volunteer teams by maintaining their mailing lists, and ensures the database of active volunteers is up-to-date and any change is processed in a timely manner. They manage the <u>volunteer@cdisc.org</u> mailbox, ensure administrative questions from volunteers are addressed, and triage other requests as appropriate.

5. Team Charters

Each Standards Development team maintains a team charter. Team charters detail each team's mission, scope, collaboration and stakeholders, as well as the specificities of that team's operating model. They are posted on the CDISC Wiki.

6. Education and other resources

CDISC provides a number of resources to facilitate and support the work of volunteers.

6.1 Education Resources

There are a series of courses and technical guides, either mandatory or optional, available to help new team members get started and be successful.

Each new volunteer should take the Volunteer Onboarding Course, which is freely available on the CDISC LMS. This course includes a presentation of the volunteer team organization, an introduction to available tools and software, and an explanation of CDISC's key policies, including the Standards Development Policy and the Ethics Policy.

6.2 IT Tools

CDISC has implemented a number of IT tools to support the work of volunteers. These tools include:

- Wiki and Jira: collaborative tools to support the on-going work of each team
- Wiki calendaring: to automatically provide updates on team meetings invitations
- Free Conference Calls: suggested for remote team meetings
- Simplelists: for team-wide email communication

Most of these tools are presented in the Volunteer Onboarding Course. Should you require any additional support to utilize them, please contact <u>wikijiraadmin@cdisc.org</u>.

CDISC Volunteer Charter and Handbook Acknowledgement

I, _____, have read and understood the CDISC Volunteer Charter and Handbook version 2.0—2019 and agree to abide by its contents.

Signature

Date