



## CDISC Operational Procedure COP-019 Volunteer Engagement

### Revision History

Date	Version	Description	Author
15 July 2017	1.0	Initial version	VP Education
06 June 2019	2.0	Major Updates	CDISC Volunteer Coordinator

### Related Documents

CDISC Policy 001 - Code of Ethics and Conflicts of Interest Policy  
CDISC Policy 003 - Intellectual Property  
COP-001 Standards Development  
COP-005 Education  
Volunteer Charter and Handbook

### 1. Purpose

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 final standards reflect and meet the needs of the user community. CDISC is grateful for the contributions and work of each and every volunteer.

This procedure has been established to govern volunteer team participation in a way that facilitates an environment where teams can collaborate effectively and efficiently. The purpose of this procedure is to ensure active, respectful team member engagement in order to meet CDISC organizational goals for standards development.

This document details: how a volunteer submits a request to join a team; how a volunteer is on-boarded onto that team; how their involvement is supported and assessed; and the process for volunteers leaving a team.

## **2. Volunteer and Team Definitions**

### **2.1. Types of Teams**

There are three types of CDISC teams: foundational, foundational subteam, and project-based including therapeutic area. Each type of team is further described below:

#### **Foundational Teams**

A foundational team is established by CDISC, to ensure involvement of volunteer stakeholders in the development and maintenance of foundational standards. There is generally one foundational team per foundational standard.

The current foundational teams are: ADaM, CDASH, Controlled Terminology, Data Exchange, Medical Devices, PGx, QRS, SDS, and SEND.

#### **Foundational Subteams**

A foundational subteam is a team within a foundational team that focuses on development and/or maintenance of standards for a specific topic relevant to the foundational team. A subteam must be accountable to at least one foundational team, but may also be accountable to more than one foundational team depending on their focus. Subteams may be long term (with an ongoing remit to develop and maintain standards for a topic) or task-based (with a finite remit to accomplish a specific task or activity related to a topic). A volunteer must be a member of at least one relevant foundational team to participate on a subteam.

#### **Therapeutic Area or Project-based Teams**

When a project is undertaken by CDISC with the support of volunteers, a specific team may be created and maintained for the duration of the project.

Such projects may include TAUGs, or other adhoc development projects.

### **2.2. Volunteer Roles and Responsibilities**

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 of 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 for team action items, updates to standards 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

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.

### **3. Volunteer Team Leadership Positions**

#### **3.1. Volunteer 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 2 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.

##### **3.1.1. 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

Past Team Leaders are responsible for:

- Supporting the current team leader
- Actively engaging the community to identify potential volunteers and team leaders

### **3.1.2. Team Leader Election Process**

1. Calls for nominations will be sent out in June of each year for all open positions.
2. Nominations for team leaders can be made by current team leadership, team members, the selection committee or CDISC leadership.
3. Nominees should submit their CV by end of August, a written statement describing their commitment to the leadership role and the goals of the team, and should have:
  - A record of active, contributing team membership for at least 12 consecutive months at the time of the call for nomination

- Demonstrated collaboration and cooperation as a volunteer
  - Demonstrated leadership and facilitation skills
  - The ability to devote the time necessary to lead the team
4. Team leaders will be selected by a selection committee composed of the current team leaders from each of the Foundational teams and up to 5 representatives designated by CDISC. Selection should be in early fall (September) and results announced at the US Interchange.
  5. Each Selection committee member will vote for one candidate for each team and the candidate with the most votes will be selected. In the case of a tie, additional voting rounds will take place for the tied candidates, until one candidate receives more votes than the other remaining candidates.
  6. The selection committee should ensure a diverse representation of stakeholders. Selection of more than one leader from the same organization will be avoided.
  7. In cases where there is no candidate for a team, CDISC may appoint a staff member to temporarily lead that team until a volunteer team leader can be identified to complete the current term.
  8. Each term will start on January 1st, with a total commitment of 4 years (as team leader and past team leader).
  9. In the unusual circumstance that a team leader is not able to complete their term, the CDISC Head of Standards (or their delegate) will appoint a temporary team leader to complete the current term.

### **3.1.3. Term Limits**

A team leader cannot apply for a second immediately consecutive term. However, in the event that no candidate comes forward for the team leadership, CDISC may appoint the existing team leader as the temporary team leader.

Past team leaders can apply for another team leadership term.

## **3.2. Global Governance Group (GGG) Representative**

### **3.2.1. Definition and Role**

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. The GGG representative should be an expert in the substantive standard(s) for which the team they represent has responsibility.

There are 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.

### **3.2.2. Appointment and Term**

Each GGG Representative is designated by that team's Team Leader, subject to approval by CDISC Head of Standards. They cannot be a current team leader on a foundational team, but they may be a subteam leader.

Team Leaders should solicit input from other team members prior to designating a GGG Representative.

GGG Representatives are appointed for 1 year. They can be appointed for up to 2 consecutive terms.

Each term will start on January 1st. For teams with more than 1 representative, term starts will be staggered over different years so that not all terms end at the same time.

In the unusual circumstance that a GGG representative is not able to complete their term, the team lead will appoint a temporary GGG representatives team to complete the current term, subject to approval by the CDISC Head of Standards.

### **3.3. Subteam Leaders**

Subteam leaders and co-leaders are nominated by the relevant team leader, subject to approval by the CDISC Head of Standards.

Their main responsibilities include:

- Managing subteam meeting schedules and agenda
- Maintaining a current list of subteam members
- Working with the Team Leader or other subteams to develop project plans, as needed
- Working with the Team Leader to ensure concepts or deliverables are presented to team and GGG governance, as needed

## 4. CDISC Volunteer Support

### 4.1. Volunteer Administrator

The Volunteer Administrator is the “go-to” person for any general volunteer administrative questions from volunteers. The Volunteer Administrator manages the onboarding process of new volunteers, supports the volunteer teams by taking on their generic administrative duties (including maintenance of mailing lists), and ensures the database of active volunteer is up-to-date and any change is processed in a timely manner. They manage the generic [volunteer@cdisc.org](mailto:volunteer@cdisc.org) mailbox, ensuring administrative questions from volunteers and triaging other requests as appropriate.

### 4.2. 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, going through the governance process and supporting team members use of the process
- Providing or otherwise 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
- Coordinates the approval of subteams and subteam leaders with Head of Standards Performing the annual assessment of team needs and volunteer engagement, in coordination with the relevant Team Leaders

## 5. Volunteer Requests and On-boarding

Individuals who wish to volunteer for a team must submit a request via the volunteer page on the CDISC website.

Submission of a CDISC volunteer request includes:

- Review of the CDISC Policies and Procedures Training video
- Acknowledgment and agreement with the CDISC Ethics Policy and the Volunteer Charter
- Specifying which team they are requesting to join (at least one but no more than three)

After an individual has submitted a request, they will be onboarded to prepare them for volunteer work, provided there is no opposition from the CDISC Head of Standards.

A volunteer request may be denied in some instances, such as (but not limited to):

- Requested team currently not accepting new volunteers
- Inappropriate prior conduct of requestor
- Insufficient relevant professional experience.

In the event a request is denied, an explanation will be provided by CDISC to the requestor. The requestor may appeal that decision to the CSO, who will make the final decision to grant or not a volunteer request.

The onboarding process is as follows:

1. After a request has been completed, an automatic notification is generated to: volunteer@cdisc.org.
2. Upon receiving the notification, the Volunteer Administrator will take the following steps to complete the onboarding process:
  - Creates JIRA ticket to confirm or create a Wiki account and grant volunteer contributor access to volunteer space
  - Adds the volunteer to team lists on SimpleList.com
  - Adds the new volunteer to the active volunteer tracking spreadsheet
3. Once the onboarding process is complete, the Volunteer Administrator:
  - Sends a welcome email to the volunteer to notify the onboarding process is complete and asks for sub-team interests, as appropriate
  - Copies the CDISC Team Coordinator for the relevant team to inform them that a new volunteer has been added
  - The team lead, subteam lead, or their designee should then welcome the new volunteer and orient them to the team

## **6. Volunteer Maintenance**

### **6.1. Updating Volunteer Information**

Any requests to update contact or team membership information (for instance following a change of company) by a volunteer should be sent by email by the volunteer to the CDISC Volunteer Administrator.

After a request is received, the CDISC Volunteer Administrator will ensure the volunteer's



information is updated in all relevant CDISC volunteer tools, including:

- Active Volunteer Data Spreadsheet
- Wiki and Jira accounts
- Team Mailing list

## **6.2. Active Volunteer Data Spreadsheet**

The main tool for volunteer information maintenance is the Active Volunteer Data Spreadsheet, maintained by the CDISC Volunteer Administrator.

This tool is used to track the following information for active volunteers:

- Organization and contact information
- Team membership
- Enrollment date
- Leadership role, if any,
- Completion of compliance tasks (policy acknowledgement, onboarding webinar attendance, etc.)
- Any additional information as needed

## **6.3. Volunteer Engagement**

Volunteers are responsible for active, respectful, collaborative engagement with their team.

Active engagement by a volunteer may be measured by various quantitative measures, such as:

- Collaborative tool activity as measured by the number of page changes, likes and other saved actions
- Comments on draft standards (creating or resolving issues)
- Actively leading teams or sub-teams and making progress on deliverables
- Regular attendance of team meetings
- Attendance at Interchanges and/or Working Group Meetings

Volunteer participation may also be assessed by qualitative measures including, for instance:

- Participation on team calls
- Active contribution to discussions, thoughts, ideas, provides sample information/documents (CRFs, mock data, etc.)
- Active participation on course development teams
- Quality contributions to internal review and/or public review of standards and other documents

#### **6.4. Annual Assessment and Recognition**

For each team, the team leader and CDISC Team Coordinator will review the active volunteer list annually to determine, based on measures of team volunteer engagement, if any team member(s) should be deemed inactive.

Volunteers may be removed or suspended from the active volunteer list if they are determined to be inactive during this review. The CDISC Team Coordinator will endeavor to get feedback from the volunteers deemed inactive prior to the final decision. CDISC Head of Standards (or their delegate) will make the final decision in case the team leader and CDISC Team Coordinator disagree on the assessment for a specific team member.

The Volunteer Administrator will communicate directly with the volunteer to let them know of the decision, and implement the suspension or removal process described below.

For all volunteers that are deemed active, CDISC will issue an annual personal “CDISC volunteer certificate” to recognize their participation.

### **7. Annual Team Maintenance**

#### **7.1. Evaluation of Team Recruitment Needs**

Every year, the CDISC Volunteer Administrator will review the teams’ recruitment needs with the team leadership and then work with Communication to design an appropriate recruitment-related communication plan.

#### **7.2. Team Health Check Survey**

A Team Health Check Survey is a survey designed to assess both the efficiency of a given team, and the positive experience it should provide to its active volunteers.

This survey including both generic volunteer and team-specific questions will be administered annually by the Volunteer Administrator. The results will be shared with the relevant teams together with any suggested action items.

### **8. Volunteer Status Pause / Suspension and Removal**

#### **8.1. Reasons for Suspension or Removal**

There are several ways a volunteer’s active status may be suspended or removed.

#### 1. Removal request by volunteer

Any volunteer may request to be removed from an active volunteer team. Such a request should be sent by email to the Volunteer Administrator for processing.

After a request is made by the volunteer the Volunteer Administrator will:

- Remove the volunteer from CDISC volunteer tools as appropriate.
- Inform both the team leader and the CDISC Team Coordinator.
- Inform the volunteer that the steps above have been completed.

#### 2. End of project

When a task-oriented team that was put together for a specific deliverable (e.g., TAUG), completes its work, then the team will be disbanded. Volunteers from the will no longer be considered active, unless they are part of another, continuing volunteer team.

#### 3. Incomplete onboarding process

In the event that a new volunteer doesn't complete the onboarding process within 2 months of being granted access to that team, their active status will be suspended. If they don't complete the process within 6 months, they will be removed from the active volunteer database.

#### 4. Inactive volunteer

When a volunteer seems unable to participate enough to maintain an active status, as assessed during the annual review, they will be contacted by the Team Leader to discuss their availability to participate. If the volunteer is unable to participate, they will be considered an inactive volunteer and their active status will be paused until they are able to rejoin the team (for up to one year).

#### 5. Suspension or Removal of a volunteer for cause

Should a volunteer fail to adhere to CDISC policies or should a volunteer fail to promote an environment of mutual respect, it may be necessary to remove the volunteer from the team and all collaboration tools. The process for removal will be as follows:

- Team leader, staff member, or other member of the CDISC community reports a volunteer has failed to adhere to a CDISC policy or that a volunteer failed to promote an environment of mutual respect. This report is made via email or letter to the Chief Standards Officer (CSO).
- CSO investigates the allegation gathering relevant information and determines whether removal or other remedy is warranted. CSO may

elect any of the following remedies:

- Permanent removal of a volunteer
  - Temporary suspension of a volunteer
  - A warning to a volunteer that behavior is unacceptable but removal at this time will not occur. In this remedy, the CSO or Team Leader will provide the volunteer with counseling as to what better behavior or action is acceptable.
  - No action taken due to insufficient support for an action or due to lack of severity
- In the unlikely event a volunteer engages in egregious verbal or written statements including harassment or discriminatory language or engages in egregious conduct, the CSO is empowered to make an immediate determination to remove that volunteer without additional investigation.
  - In the event of a suspension or removal of a volunteer by CSO, the volunteer may appeal the decision by email to CDISC President and CEO within 15 calendar days. The decision of President and CEO will be final.
6. 2-year inactive WIKI account with volunteer access
- Every year, the IT team will review WIKI accounts. Volunteers with WIKI Accounts that have been inactive for 2 years will be contacted to confirm their email address and the team leader will be asked to confirm active involvement of that volunteer. In the case no satisfactory confirmation is received, that volunteer will be removed from the team.

## **8.2. Effect of Pause/Suspension and Removal**

**Pause / Suspension:** In the event a volunteer active status is paused or suspended, they will be deemed an “inactive volunteer” and removed from that team’s mailing list, meeting invitations, and any other team-specific tools.

The CDISC Team Coordinator will ensure that the corresponding team lead and the Volunteer Administrator are aware of the expected re-activation date.

The CDISC Volunteer Administrator will contact the inactive volunteer ahead of the expected re-activation date to confirm their availability, in coordination with the CDISC Team Coordinator. If a suspended volunteer is unable to rejoin within a year of the suspension, they may be removed from the active volunteer list (“removal”).

**Removal:** in the event a volunteer is removed from a team due to one of the cases

highlighted above, that volunteer will be removed from that team's mailing list, meeting invitations, and any other team-specific tools, as well as the active volunteer list.

If a volunteer is not active in any team, their volunteer Wiki access and any other volunteer-generic tool will be removed as well, and they will lose their active volunteer status.

## **9. Authorization**

This document is approved by the CDISC Executive Team and should be followed by CDISC staff, consultants and volunteers. This document has been approved and is effect on this date:

**Approved by:**

**Date:**

**David R. Bobbitt  
President and CEO**

**June 12 2019**