QUICK-START GUIDE

For those New to CDISC
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CDISC is a 501(c)(3) global non-profit charitable organization, with over 300 supporting member organizations from across the clinical research and healthcare arenas. Through the efforts of volunteers around the globe, CDISC catalyzes productive collaboration to develop freely available, industry-wide clinical research data standards. The CDISC Vision is to inform patient care and safety through higher quality medical research.

1. **CDISC Quick-Start Guide Overview**

The purpose of this Quick-Start Guide is to provide helpful information for those new to CDISC, regardless of role or capacity. If you are or wish to become a CDISC Member Organization, a CDISC Volunteer, a User Network Member, or any type of a CDISC Supporter, we hope that you find this guide useful. If there are areas we have not addressed, please contact us at our CDISC Office 512.363.5826 Monday–Friday 9:00–5:00 (CST) or info@cdisc.org.

2. **General Information About CDISC**

General information About CDISC can be found on our website conveying the following:

- Mission and Principles
- Strategy and Goals
- Organization and Values
- Bylaws and Policies, including CDISC Operating Procedures (COPs)

3. **How to Stay Informed**

3.1 “What’s New” area on the CDISC Home Page, at www.cdisc.org is the best way to quickly see the most recent information such as standards updates, press releases and more.

You may also find the following information helpful to stay informed of CDISC activities:

- Sign up to receive the CDISC eNewsletter, read the monthly CDISC Press Releases or download the latest CDISC News via the CDISC Website.
- Check out the Resources area, which also includes the links to our Discussion Forum and the CDISC Portal.
- Review the CDISC Technical Plan Project Schedule also known as the “dashboard”. This provides a one-page Gantt Chart overview of significant upcoming CDISC planned project deliverables for the current calendar year.
- Participate in CDISC Events, including Public Webinars for members and for everyone.
- Plan to attend CDISC Interchanges to hear expert speakers and take the opportunity to network with our member base of over 300 companies and organizations in the clinical research, technology and healthcare arenas.
- Follow CDISC on Social Media (LinkedIn, Twitter and Facebook). See the Social Media Section3.3 in this Guide.
3.2 CDISC Website

Visit the [CDISC website](https://cdisc.org) to access helpful documentation and information, for example:

- Regular updates on our Standards, Education, Events, Membership, Success Stories and more
- A list of our Registered Solutions Providers, who can support you with their implementation expertise
- A list of all ODM certified companies
- Articles related to CDISC
- Regulatory information

3.2.1 HELPFUL LINKS

- [CDISC Standards](https://cdisc.org), including Team Charters and Healthcare Link Standards
- [CDISC Resources](https://cdisc.org), including ODM Certified Organizations and Registered Solution Providers
- [Education](https://cdisc.org)
- [Events](https://cdisc.org)
- [Members and Membership Opportunities](https://cdisc.org)

3.3 Follow CDISC on Social Media

- [CDISC Twitter](https://twitter.com/cdisc)
  - Create your account at: [https://twitter.com/login](https://twitter.com/login)
  - Search and follow us using our CDISC Twitter name: @CDISC
- [CDISC Facebook](https://www.facebook.com/cdisc)
  - Create your account at: [https://www.facebook.com/](https://www.facebook.com/)
  - Search for our account and add us as a friend by using our CDISC Facebook name: Clinical Data Interchange Standards Consortium (CDISC)
- [CDISC LinkedIn](https://www.linkedin.com)
  - Create your account at [https://www.linkedin.com](https://www.linkedin.com)
  - You will then be able to follow and join as many groups as you prefer to stay up to date!

4. How to Get Involved

CDISC depends on volunteers to develop our standards to improve clinical research. The following sections will summarize how you can quickly become involved in CDISC development teams.

4.1 Volunteer

- **Volunteer** for a project team or to review a standard:
  - Consult the volunteer guide available here (link) for opportunities and information about volunteering for a CDISC team.
- **Monitor** the [What’s New](https://cdisc.org) section of our website for the release of new standards.
• **Review** a draft standard and comment during the Public Review period. The main benefit of public review is that the people who are going to use the standard have the opportunity to review it and give feedback, thus influencing this standard before it is finalized. We are always looking for attentive, thoughtful commenters.

• **Participate** in Team IntraChanges to work with other CDISC volunteers to develop and improve our standards. Contact [volunteer@cdisc.org](mailto:volunteer@cdisc.org) for more information.

### 4.2 Interact

- **Write** a blog or an eNews article, such as a CDISC success story or send us your thoughts on how standards are important contact [communications@cdisc.org](mailto:communications@cdisc.org).
- **Contribute** to the CDISC standards pages on [Wikipedia](https://en.wikipedia.org).
- **Comment** on the official CDISC [LinkedIn](https://www.linkedin.com), [Twitter](https://twitter.com) or [Facebook](https://www.facebook.com) pages (see the Social Media section below or contact [communications@cdisc.org](mailto:communications@cdisc.org) for further questions).
- **Review** and contribute to the Discussion Forum. CDISC team leaders and members generally respond to issues and questions posted on the forum.
- **Join** our CDISC Webinars that showcase documents that are coming out for public review.

Review [CDISC COP 003](https://cdisc.org/standards/Documents/CDISC-COP-003.pdf) on CDISC Public Relations and Communications Procedures for more information or contact [communications@cdisc.org](mailto:communications@cdisc.org) for more information.

### 4.3 Join the CDISC User Network in your Area/Region

Concurrently with the CDISC outreach efforts described above, self-formed CDISC User Networks in the United States, Europe and Asia enable face-to-face interactions among CDISC users.

The purpose and benefits of joining a CDISC User Network are to:

- Share CDISC implementation experiences periodically in a given region or language
- Discuss draft standards and provide comments to CDISC
- Discuss mature standards and provide feedback to CDISC
- Discuss new ideas to be channeled into CDISC
- Network among colleagues
- Share recent conference participation and learning

Review our CDISC COP 011 User Networks Operational Procedure for more information, or contact [communications@cdisc.org](mailto:communications@cdisc.org).

### 4.4 Nominate for a Position on a CDISC Coordinating Committee

CDISC has 3Cs in Europe, Japan, China and the Asia-Pacific. Watch for calls for new nominations on the CDISC website, you can nominate yourself or another person!

A few responsibilities of a 3C can be summarized as follows:

- Develop an action plan each year, in collaboration with CDISC Executive Operations that is aligned with the CDISC Strategic Goals.
5. Getting the Most Out of CDISC Membership

CDISC Membership is the primary support mechanism for the CDISC mission. CDISC standards and related innovations would not be possible without the dedicated efforts and financial assistance of CDISC member companies and organizations. Following are a few suggestions for maximizing the benefits of CDISC membership:

- **Register** to become a member
- Confirm your organization is a CDISC member by checking the list of members.
- As an employee in a CDISC Platinum Member Organization, you may contact your CDISC Advisory Council Representative.
  - If you are not sure who your representative is, contact membership@cdisc.org
- View the CDISC membership benefits for discounts on Education Courses, CDISC Interchanges and Webcast Training available to Members Only
- If your organization is a member, but does not have access to the "Members Only" area of our website, click here,
  - Ensure that you are using your company email (e.g. john@abc.com) to gain access to the ‘Forgot Password’ tool.
- Use your **Members Only** access to review:
  - Archived Webinars and Presentations
  - The complete CDISC business case (all stages) for using Standards
  - Minutes from FDA-CDISC meetings
  - The CDISC ePrimer, "Introducing the CDISC Standards - New Efficiencies for Medical Research" (available in English or Japanese)
  - SDTM variable names and other standard metadata in a usable format to expedite your programming activities
  - The CDASH User Guide
  - CDISC Standards in Japanese (translated by TRI)
  - Early drafts of standards and user guides

6. CDISC Standards Implementation Assistance

All CDISC standards are publically available (free) on the CDISC website. New standards are constantly being developed and enhancing the CDISC Foundation Standards. See “Standards” on the CDISC website.

In addition to CDISC Education, as further help to implementers, CDISC has a program for Registered Solutions Providers (RSP) and ODM certified vendors.

- Take a CDISC Education Course (Section 7 below).
7. **CDISC Training Opportunities: Learn CDISC from CDISC!**

The goal of the CDISC Education Team is to assist organizations in building the skills and expertise necessary to implement CDISC standards at all relevant stages of the drug development process. All CDISC training is developed and authorized by the CDISC Education Team, including Subject Matter Expert members from every standards technical team. Care is taken to ensure that all CDISC course instructors are qualified through years of experience in the development and implementation of CDISC standards. Following are some helpful links to learn more about CDISC authorized training.

- Learn more about our authorized instructors and course material developers.
  - Read CDISC COP 005 Curriculum Development and Ownership.
- View CDISC course descriptions on the CDISC website.
- View the schedules for upcoming free CDISC Standards Webinars.
- View the schedules for upcoming and archived Members Only Training Webcasts.
- Determine what kind of CDISC technical training courses fit your organization’s needs:
  - Public Training Courses held at venues hosted by our Member organizations
  - Private (In-House) Training Courses for your organization at the location of your choice
    - Licensed Training – deliver your own in-house training using authorized materials
- Register for self-paced, on-demand CDISC Online Training.
- Attend training offered in connection with CDISC Interchanges.

8. **CDISC Portal**

The CDISC Portal is reserved for use specifically for our members, teams/volunteers, instructors and staff. The CDISC portal is the repository of CDISC standards development team documentation, (e.g. draft standards, working documents, presentations, meeting minutes, and other related documents), documents relevant to CDISC staff (e.g. CDISC Internal Procedures) and Communications templates and documents.

The CDISC portal also includes a Calendar of Events area that is accessible to the public. The calendar is updated frequently and includes schedules on CDISC Training events, Interchanges, and global CDISC User Groups.

- A Portal User Guide is available to help navigate and use the CDISC Portal
- If you need access or have forgotten your login credentials to the Portal, please contact the CDISC Portal Admin (portaladmin@cdisc.org).
- To join a team or obtain access to your team area, see the Section 4.1
9. CDISC Wiki

The CDISC Wiki is a collaborative tool to facilitate CDISC team communication and to share timely information relevant to development of CDISC standards. This tool is accessible by anyone who would like to follow or contribute to team activities.

- Self-register at http://wiki.cdisc.org on the login page for read only public access information. Contact your Team Lead to request contributor access.
- To obtain further assistance with logging-in, please refer to the Confluence (Wiki) User Guide or contact itsupport@cdisc.org
- To join a team or obtain access to your team area, see the Section 4.1

10. CDISC SHARE

CDISC SHARE is CDISC’s new electronic repository for CDISC standards. It is a cornerstone of the CDISC technical roadmap and is envisioned to help users find, understand and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently, and to improve integration and traceability of clinical data from protocol through analysis. On the SHARE page of the CDISC website, you can see a short video about SHARE, volunteer for a SHARE team, subscribe to SHARE News, and more.

11. Contact Us

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