



CDISC Operating Procedure CDISC-COP-001 Standards Development

Revision History

Date	Revision	Description	Author
18 October 2001	0.1	Original	Rebecca Kush
7 November 2001	0.2	Revisions	Julie Evans
16 November 2001	0.3	Revisions	Wayne Kubick
27 November 2001	0.4	Revisions	Julie Evans
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4 February 2002	1.0	Revisions/approval	Shirley Williams/Board of Directors
1 January 2006	1.1	Revisions required to align with current CDISC organization and procedures	CDISC Operations

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CDISC Operating Procedure CDISC-COP-001

Standards Development

1 Introduction

1.1 Purpose

The purpose of this CDISC Operating Procedure is to describe the procedure used to develop and update CDISC standards.

1.2 Background

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.

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

1.3 Authority

This document is approved by the CDISC President and should be followed by all CDISC Operations staff, team/project leaders, CDISC consultants and representatives, including volunteers participating in teams/projects or in user networks.

1.4 References

The following information sources are referenced in this document:

- **CDISC Website:** www.cdisc.org

2 Procedure

2.1 Stage I: Standard Definition and Team Initiation

This stage describes the procedures for taking a concept of a standard to the point where there is a defined purpose, work plan, team, and team leader to initiate the actual standards development.

- To initiate the development of a new CDISC standard (and/or new team to develop a standard), any CDISC participant or stakeholder may submit a proposal through Global Operations to be reviewed by the Board of Directors. The proposal would include purpose and objectives, along with any additional details such as projected resource or budget requirements.
- The Board will review the proposal, verify that it is consistent with the CDISC mission, scope, principles, budget, and priorities; suggest changes where necessary; and make a decision regarding whether the request should be directed to an existing team or whether a new team should be formed.
- If a new team is approved, CDISC Global Operations will appoint a team leader and form a qualified, core, multidisciplinary team of 3-12 members from CDISC

participants through an invitation and selection process. The representation will be from relevant and diverse companies.

- This core group will develop a charter and working plan consistent with the purpose and objectives for the team. This plan will include timelines, milestones, deliverables, communication mechanisms, and resource requirements and will be posted on the CDISC website.
- If, at any point, the team's work efforts can be expanded to efficiently involve the participation of additional CDISC contributors (e.g. focus groups, sub-teams, or external review groups), this should be done.
- The team will execute the plan, holding regular conference calls and face-to-face meetings, as appropriate, to achieve their objectives. Meeting minutes should be provided to the team members, Global Operations, and other teams by posting them to the members-only section of the CDISC website.
- Through the team leader, the team will provide a quarterly update to Program Management including progress to date, issues, and next steps.
- Global Operations can provide infrastructure services for team support, including mechanisms of communication and resources for documentation and glossary compilation.
- The team should provide relevant information to Global Operations for the Glossary and to the Education Team (EDU) for educational materials.
- All team participants will be expected to follow all CDISC policies and procedures.
- The team will maintain the principles of CDISC in all of its actions.
- The team should harmonize its work with that of other CDISC teams.
- When the team has completed its work, it will be disbanded.

2.2 Stage II: Standards Development / Review / Version 1.0 Release

This section covers the high-level steps for developing a standard model from the initial version to the final version; however, due to the variation in the types of standards or standard models CDISC develops, these steps may vary in detail as deemed appropriate for each individual case.

- The team develops an initial version of a CDISC standard model and reaches consensus on this version. This may be done by creating a 'strawman' from scratch, by consolidating standards or models that have been contributed in an open manner to CDISC, or by any other appropriate means. The team should also begin developing the following documentation at this time:
 - Purpose of the standard developed
 - Description of model usage and assumptions used in its development
 - Use cases or examples of use
 - Summary of documented testing
 - A list of external references, if appropriate
 - Any known outstanding issues or development yet to be done
 - Directions for submitting commentsThis is called the Consensus (Initial) Version of the CDISC standard, and should be labeled as a Draft with the date of release.
- This Version is reviewed by the Production Standards Coordinating Committee (PSCC), which will ensure that it is harmonized with other CDISC models and standards, and then approve this model for review by an external group. If the PSCC doesn't approve the standard, the TPSCC will specify the reasons and the

team will respond to the PSCC by addressing each reason in writing. Additional version increments between 0 and 1 can be applied as needed for revisions. The version resulting from the PSCC review is called the Harmonized Version.

- An External Review Committee consisting of individuals who have expertise in an area relevant to the model that is being developed will be requested to review the Harmonized Version of the CDISC model and to provide written comments. This review may occur via the private CDISC website and/or at a meeting held for this purpose, from which minutes will be posted.
- The comments from the External Review Committee will be addressed in writing and, where deemed appropriate by the team and the reviewers, the model will be modified to reflect the advice of the reviewers. The addressed comments will be posted on the website. This resulting product will be the Review Version.
- Testing may occur at any point deemed appropriate by the team, with assistance from OIS as needed. Initial testing may take place within the team, the external reviewers may conduct testing, or testing may be conducted by resources identified via OIS. In any case, the testing plans and outcomes should be appropriately documented.
- Once the External Review comments have been adequately addressed through responses or revisions, the model may be posted on the public CDISC website for public review with a comment period of at least 30 days. The posting of this Review Version should be accompanied by an announcement via e-mail to the CDISC participant database and possibly a press release. This version may be released with a documented list of any known deficiencies, omissions, questions, and issues.
- The team will review the comments received from the open review, respond to these in writing, and modify the model as deemed appropriate. During this period, additional features and improvements identified by the team may also be added.
- Publication of the final standard should describe all testing and review that has been done during the standards development period.
- Documentation that the above procedure has been followed will then be presented to the Board of Directors. This documentation will include statements indicating that the requirements have been met for producing the following for each standard model:
 - Consensus (Initial) Version
 - Harmonized Version
 - Review Version
 - Released (Production) Version 1.0
 - Testing
- Once the Board has signed off on these steps, the Released (Production) Version 1.0 will be made available along with the documentation listed in the first bullet of this section.

2.3 Stage III: Education and Support

After models are released, the Education Team will provide the appropriate training, which will be defined by the Education Strategy. This stage also includes responding to comments and questions about the model.

2.4 Stage IV: Standards Update and Maintenance

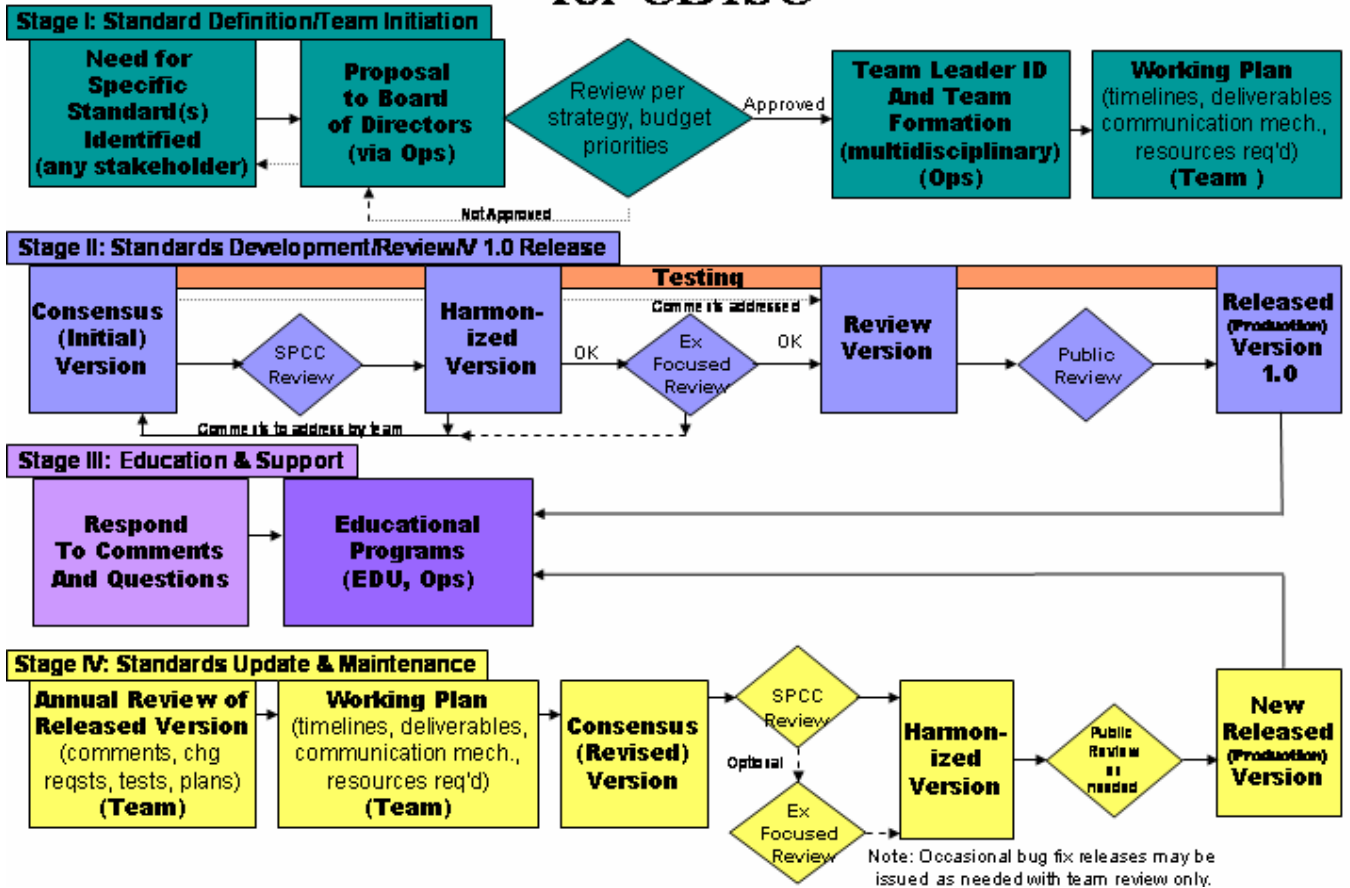
This stage refers to versions following Version 1.0. Each version should be reviewed at least once annually and updates of the models developed as deemed appropriate per the following steps.

- After a release of a final version, the team will be reconvened periodically to review the status of new or outstanding comments, change requests, test results, and future plans. A periodic assessment should be conducted of industry acceptance and implementation status. After each major release milestone, the team may be reconstituted with new members, although it is desirable for at least one half of the original members to remain active for at least a transition period of 3 months.
- The team will revise its charter annually and submit a new or revised plan to CDISC Operations and the Board of Directors.
- If changes to the model are required, the team will revise the model and prepare a Consensus (Revised) Version of the revised model. Some changes may be minor corrections to the standard or related documentation.
- The Consensus (Revised) Version will be submitted to the PSCC for review and approval together with a list of significant changes implemented since the last released version.
- Review by an external review committee will be optional, but the team is encouraged to solicit feedback from targeted individuals as much as possible.
- The team will publish the revised model as a Harmonized Version or as a Review Version with the approval of the PSCC. The version number should be incremented by .1 or 1 at the discretion of the team depending upon the degree of change from the previous release.
- The model should be posted on the public CDISC website for open review with a comment period of at least 30 days. The posting of this Review Version should be accompanied by an announcement via e-mail to the CDISC participant database. A press release is optional but should be issued for all major version releases.
- Occasional releases for minor corrections to the standard may be issued as needed with team review only.

2.5 Stage V: Accreditation of the CDISC Standards

At some point, CDISC models may reach a sufficient stage of maturity that they will benefit from a separate, more formal accreditation process by an independent Standards Development Organization, which would be envisioned as Stage V of the process. CDISC is currently working with HL7 to develop a RIM-compliant, overarching information model that can be used for building ANSI-standard HL7 messages.

Standards Development Process for CDISC



3 Authorization

This document has been authorized by:

Date	Representation	Name
1 January 2006	CDISC President	Rebecca Kush