CDISC Operating Procedure COP-001
Standards Development

Revision History

Date	Revision	Description	Author
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
1 May 2014	2.0	Enhancement to accommodate therapeutic area standards development	Rhonda Facile
15 July 2017	3.0	Adding QRS process, details about Education, release schedule, definitions of standards statuses and escalation policy.	Shannon Labout

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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 provide a high-level description of the principles, process and deliverables for the development of CDISC standards. CDISC standards development is an open, consensus-based process. Wide participation and collaboration with multidisciplinary reviews ensure quality and fitness for use, and encourage the most widely adopted production standards, which are provided openly via the CDISC website (www.cdisc.org). CDISC standards are harmonized through the BRIDG model to improve interoperability.

In addition to this COP, a process document, a process map and checklists have been developed to facilitate all CDISC standards development. The diagram below illustrates the relationship of these documents.

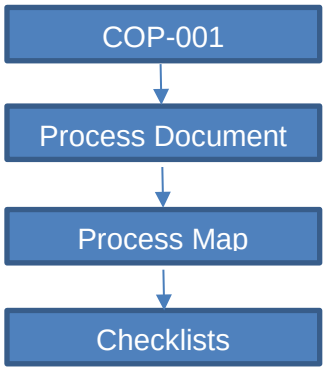

Diagram 1: COP-001, process document, process map, checklists

1.2 Definitions

CDISC Standard
A CDISC standard is any product (including specifications, user guides, implementation guides, models or schema) that has been developed, vetted and approved through the CDISC standards development process.

Draft Status
The proposed standard is in development by CDISC teams.

Provisional Status
The proposed standard has completed the CDISC standards development process and can be published, but some of the foundational standards components are not “final” (e.g., Controlled Terminology, biomedical concepts, draft domains).

Provisional standards may therefore be subject to change before they become final. Provisional standards are expected to be released as a final version once all components have been finalized. The use of provisional standards is encouraged but with an appropriate risk assessment.

Final Status
The standard has completed the CDISC standards development process and has been published for use.

1.5 Release Schedule

CDISC will maintain an open, transparent and predictable release schedule. “Provisional” status standards can be published when available for use.

When teams are ready to change the status flag from “Draft” or “Provisional” to “Final”, and CDISC publishes the standard as ‘Final’ on www.cdisc.org.

1.6 Standards Development Process Guidance

For detailed guidance on standards development, teams should review the CDISC Standards Development Process Guideline, process map and the accompanying checklists.

2 Authority

This CDISC Operating Procedure (COP) is approved by the CDISC President and CEO and should be followed by all those involved in developing CDISC standards, including CDISC staff, team/project leaders, CDISC consultants and representatives, standards reviewers and all volunteers participating on teams/projects or in user networks.

3 Process Overview

3.1 Stage 0: Scoping and Planning

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Publication	Standard Maintenance

The purpose of this stage is to ensure that the project is well defined with clear and achievable requirements and goals. The process typically includes background research, building a list of requirements, checking regulatory requirements and for TA projects, conducting a search of the public databases.

All CDISC Standards Development Projects require approval from the appropriate governance body and the CDISC Chief Standards Officer (CSO). After a project proposal is completed and approved, initial scoping and/or planning activities can start.

3.1.1 Process

- Perform background research and initial scoping
- Obtain approval from appropriate governance body for the scoping package

3.1.2 Deliverables

The deliverables for Stage 0 may include a requirements assessment, project charter and the scoping package.

3.2 Stage 1: Development of Biomedical Concepts

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Publication	Standard Maintenance

The purpose of this stage is to develop an approach for meeting the initial requirements and define in more detail the information that will comprise the proposed new or enhanced standard, including comparisons to existing standards. The process typically includes developing concept maps to facilitate semantic understanding of new information requirements where appropriate.

3.2.1 Process

- Collect remaining inputs and permissions
- Model and develop biomedical concepts
- Review concepts maps with clinical and/or relevant SMEs (if applicable)
- Refine information requirements
- Develop terminologies (including QRS)
- Obtain approval from appropriate governance body

3.2.2 Deliverables

The deliverable for Stage 1 is a list of biomedical concepts, and other relevant artifacts, such as concept maps or terminology requests.

Foundational standards may not require extensive modeling, but it is expected that applicable and appropriate modeling be performed.

3.3 Stage 2: Development of Draft Standards

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Publication	Standard Maintenance

The purpose of Stage 2 is to build on the draft list of biomedical concepts or content developed in Stage 1 and develop examples and metadata to enhance and finalize concepts. At the end of this stage, the draft document should be completed and contain all needed components in order to enable a thorough Internal Review.

3.3.1 Process

- Define metadata modeling approach for new biomedical concepts with modeling experts
- Develop detailed metadata or specifications for standard, as appropriate
- Develop data examples consistent with metadata, as appropriate
- Develop draft standards document and review package
- Review package against the QC checklist
- Obtain Modeling Governance Committee approval (excludes QRS)
- Finalize draft standards document and package for Internal Review

3.3.2 Deliverables

The deliverable for Stage 2 is the draft standards review package.

3.4 Stage 3a: Internal Review

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Publication	Standard Maintenance

The purpose of the Internal Review is to ensure that all CDISC teams, collaborative groups and subject matter experts impacted by the draft standards have the opportunity to review the draft standard prior to Public Review.

3.4.1 Process

- Obtain approval from Modeling Governance Council for approval to post for Internal Review
- Post draft standard for Internal Review
- Perform fit for use testing (optional)
- Resolve issues and update draft standard
- Begin to develop education materials, including Public Review webinar
- Submit remaining/additional terminology requests
- Any normative content changes need to be reviewed by the Modeling Governance Council
- Submit public posting package to Publication Committee for approval to post
- Communications Team posts draft for Public Review

3.4.2 Deliverables

The deliverable for Stage 3a is the draft standards review package.

3.5 Stage 3b: Public Review

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Publication	Standard Maintenance

The purpose of the Public Review is to develop widespread consensus for the proposed standard by allowing for broad comment by the general public. Anyone interested may review and submit comments which must be reviewed and addressed by teams before proceeding to Stage 3c.

3.5.1 Process

- Collect public review comments
- Respond to public review comments and update the draft
- Submit additional terminology requests and complete other required activities as necessary (QRS)
- Any normative content changes need to be reviewed and approved by the Modeling Governance Council
- Submit public posting package to Publication Committee for final QC
- Send final document to Technical Writer for review
- Obtain Publication Committee approval for publication

3.5.2 Deliverables

The deliverables for Stage 3b are the standards document posting package, including electronic metadata as appropriate.

3.6 Stage 3c: Publication

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Publication	Standard Maintenance

At the conclusion of the Public Review the CDISC CSO will grant approval, and the new standard can be posted for implementation. This stage focuses on publishing and announcing the availability of the new standard.

3.6.1 Process

- Communications Team posts the standard for Public Review
- Communications Team announces availability of the new standard package
- Team Leader/Project Manager archives all documents

3.6.2 Deliverables

The deliverable for Stage 3c is the publication package, including complete Metadata in SHARE and Education materials.

3.7 Stage 4: Standard Maintenance

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Standard Maintenance

All clinical data standards are living documents that require periodic review and update as new biomedical concepts and issues are identified that require changes, additions or deletions to a published CDISC standard. The basic steps in this stage include monitoring feedback from user communities, providing training and updating the standards as needed. Changes to existing standards follow the same development process, starting at Stage 0 (scoping).

3.7.1 Process

- Monitor feedback and initiate new standards development projects as needed
- Deliver education materials, online and/or classroom training

4 Standards Development Governance

4.1 Modeling Governance Council

The CDISC Modeling Governance Council is responsible for reviewing and approving all draft standards. This council is composed of representatives from each of the foundational teams who have been empowered to review and approve modeling decisions on behalf of their team. The Modeling Governance Council meetings are open to any CDISC team member.

4.2 Escalation Policy

In cases where development teams recognize that a discussion is stalling, they can escalate the issue, within a reasonable timeframe, to ensure a resolution is reached. The CDISC Escalation Policy provides the mechanism for resolving disputes that may arise during standards development. The CDISC CSO, or in the event CSO is unwilling or unable to make the decision, CSO's designee, approved by CDISC President and CEO, will make a final decision should Modeling Governance Council not be able to reach one.

i. All issues should be resolved within the Modeling Governance Council, if possible
    a. Consensus is the goal for all decision making
    b. If consensus cannot be reached within a reasonable time frame, the issue should be escalated to the CSO
    c. Attempts to resolve issue should be documented in an Escalation Request Form

ii. The resolution will be documented on the Escalation Request Form

iii. All decisions made using the escalation process are final for the current version of the standard.

5 Authorization

The document is authorized by:

Date	Title	Name
21 July 2017	CDISC, President and CEO	David R. Bobbitt
1 May 2014	CDISC, President	Rebecca Kush
1 May 2014	CDISC, CTO	Wayne Kubick