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
14 January 2019	4.0	Updating to include GGG role in development process	Amy Palmer
June 2019	4.1	Adding QRS addendum	Head of Standards
27 November 2023	4.2	Adding CORE addendum Adding Biomedical Concepts Addendum	Amy Palmer

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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).

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.

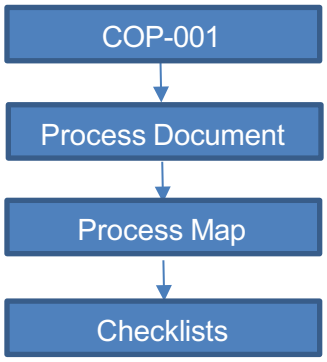

Diagram 1: COP-001, process document, process map, checklists

1.2 Definitions

CDISC Standard
A CDISC standard is any product (including but not limited to, specifications, user guides, implementation guides, models or schema, etc.) 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.

1.3 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.

1.4 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 Global Governance Group (GGG) approval for Internal Review (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

- 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 (if needed)
- Submit remaining/additional terminology requests
- Any normative content changes need to be reviewed by the GGG for approval to post for Public Review
- Submit public posting package to Publication Committee
- 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 document
- GGG reviews responses to Public Review comments
- Any normative content changes need to be reviewed and approved by the GGG. Submit additional terminology requests and complete other required activities as necessary (QRS)
- Send final document to copy editor for review
- GGG leads provide approval for publication
- Submit public posting package to Publication Committee for preparation 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 GGG Leads 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 on www.cdisc.org
- Communications Team announces availability of the new standard package

3.6.2 Deliverables

The deliverable for Stage 3c is the publication package, including complete metadata in SHARE and Education materials (if applicable).

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 Global Governance Group (GGG)

The CDISC Global Governance Group (GGG) is responsible for reviewing and approving all draft standards. This group 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 GGG meetings are open to any CDISC team member.

4.2 Escalation of Issues

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 CSO, or CSO's designee(s) will make a final decision should GGG not be able to reach one.

i. All issues should be resolved within the GGG, 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 the GGG wiki space
ii. 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
27 November 2023	CDISC, President and CEO	Dave Evans

COP-001 Standards Development Addendum QRS SDTMIG and ADaMIG Supplements

The development of QRS SDTMIG and ADaMIG Supplements will be developed following the CDISC Standards Development process outlined in COP-001. Due to the nature of these supplements (copyright permissions, terminology development rules, volume of supplements, concise structured text), there will be some modifications to COP-001 to address these differences. Listed below are the stages of development (Stage 0 to Stage 4) which specifically address the differences for QRS development for each stage.

Stage 0: Scoping and Planning

- Identification of a relevant QRS instrument and which version of the instrument will be developed. (Version choice and rationale for version selected will be in included in the QRS Supplement.)
- Copyright status is determined during Stage 0. The status (copyrighted instrument or public domain instrument) is documented in the QRS Supplement.
- Copyright permission documents are maintained within CDISC, including approved and non-approved permissions and are also noted on the CDISC QRS webpage.
- No scoping package is needed for QRS.

Stage 1: Development of Biomedical Concepts

- Development of biomedical concepts is not applicable for QRS Supplements.

Stage 2: Development of Draft Standards

- The development of QRS controlled terminology follows the QRS naming conventions for --TEST/--TESTCD and is reviewed and maintained by the QRS Controlled Terminology Subteam.
- The QRS SDTMIG or ADaMIG supplement is developed. If a CRF is received, this will be annotated with the --CAT/--SCAT--TEST/--TESTCD/--ORRES/--STRESC/--STRESN variables and any applicable supplemental qualifiers (non-standard) variables.
- The appropriate QRS Subteam (SDS or ADaM) will review and approve the draft supplement for movement to the Internal Review stage. The GGG is not required to review or approve the SDTMIG or ADaMIG QRS Supplements, although any modeling challenges can be elevated to the GGG for resolution.

Stage 3a: Internal Review

- The appropriate QRS Subteam will determine when a Supplement is ready for Internal Review as described in COP-001.
- Since the Supplements are short, structured, and concise documents, there may not be comments received during the Internal Review Stage. Reviewers are requested to indicate that the supplement

was reviewed when they had no comment. The lack of comments will not prevent the Supplement from progressing to the Public Review Stage.
- The Internal Review period for these supplements will be 14 days to accommodate a regulatory review.
- If regulatory review of a Supplement is requested, it may occur post Internal Review, but prior to Public Review.

Stage 3b: Public Review

- The appropriate QRS Subteam will determine when a supplement is ready for CDISC document Public Review.
- SDTMIG and ADaMIG QRS Supplements will be grouped in batches and posted for Public Review several times a year and are not subject to the November annual release schedule. The Public Review period for these Supplements will usually be 30 days.
- In the cases where CDISC did not receive permission to host the QRS Supplement on the CDISC website, Public Review of the Supplement may not occur.
- Since the Supplements are short, structured, and concise documents, there may not be comments received during the Public Review Stage. Reviewers are requested to indicate that the supplement was reviewed when they had no comment. The lack of comments will not prevent the Supplement from progressing to publication.

Stage 3c: Publication

- QRS Conformance Rules and individual education courses are out of scope for the QRS supplements.
- A final "quick" regulatory review of QRS supplements will be completed before publishing.
- Publication of QRS supplements is done on the QRS webpage for public access.

Stage 4: Standard Maintenance

- There are no additional considerations for QRS Supplements other than those listed in COP-001.
- If an issue is identified to the appropriate QRS Subteam (SDS or ADaM), it will be addressed with the appropriate change control process to the new updated version.

Authorization

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27 November 2023	CDISC, President and CEO	Dave Evans

COP-001 Standards Development Addendum CORE Rules Governance

The development of CORE rules will be developed following the CDISC Standards Development process outlined in COP-001. There can be multiple sources of CORE rules:

1. CDISC Models and Implementation Guides Conformance Rules
2. Regulatory requirements
3. Community-generated rules

Due to the nature of these of these various inputs, there will be some modifications to COP-001 to address the multiple sources of CORE rules. Conformance rules that are part of the CDISC Models and Implementation Guides are developed by the standards development teams along with the development of the various CDISC standards. They will follow COP-001 and will be developed simultaneously with the appropriate standard. The standards development teams develop the rule specifications. The CORE Rules Team uses these specifications to populate the CORE rule authoring tool with executable version of the rules.

The other two sources of CORE rules include regulatory requirements and community-generated rules. Listed below are the stages of development which specifically address the differences for these types of CORE rules development for each stage.

Throughout all stages of development, the CORE Rules Team is considered the governance body for machine-executable rules.

Stage 0: Scoping and Planning

- Identification and prioritization of regulatory and community-generated rules will be managed by the CORE Rules Team with input from CDISC Leadership Team.

Stage 1: Development of Biomedical Concepts

- Not applicable for CORE rules

Stage 2: Development of Draft Standards

- CORE rules are developed using a templated approach that specifies the rule condition and executable logic, scope of the rule, as well as any supporting documentation if applicable (i.e., regulatory requirements).

Stage 3a: Internal Review

- The CORE Rules Team will be responsible for performing an Internal Review and QC to confirm the executable rule logic, scope, that the rule works as expected and provides the correct output.
- The deliverable for Internal Review is a set of CORE Rules that have been entered in the yaml CORE Rules Authoring Tool, as well as positive and negative test data.

Stage 3b: Public Review

- Community-generated CORE Rules that are not explicitly part of the published CDISC Standards will be posted for a 30-day public review.
- Rules generated as a result of regulatory requirements will not be posted for Public Review, since CDISC does not develop these requirements. The rules will be available in the CDISC library. for review and feedback from the user-community. Any issues will be addressed as needed by the CORE Rules Team.

Stage 3c: Publication

- CORE Rules will be published in the CDISC Library.

Stage 4: Standard Maintenance

- CORE Rules will be updated and published periodically, depending on content volume.
- If an issue is identified and submitted to the CORE Rules Team, it will be addressed with the appropriate change control process in a future version.

Authorization

The document is authorized by:

Date	Title	Name
27 November 2023	CDISC, President and CEO	Dave Evans

COP-001 Standards Development Addendum Biomedical Concepts

The development of CDISC Biomedical Concepts (BCs) will be developed following the CDISC Standards Development process outlined in COP-001. Due to the nature of these BCs (e.g., informative content vs. normative content), there will be some modifications to COP-001 to address these differences. Listed below are the stages of development which specifically address the differences for BCs development for each stage.

Throughout all stages of development, the Data Standards BC Curation Team is considered the governance body for BC content.

Stage 0: Scoping and Planning

- Identification and prioritization of BCs will be managed by the BC Curation Team with input from CDISC Leadership Team.

Stage 1: Development of Biomedical Concepts

- Concept maps may be created to aid in the understanding of BCs during development but will not be required.
- If new terminology or standards are needed, their development will follow the appropriate existing development and governance process.

Stage 2: Development of Draft Standards

- BCs are developed using a templated approach that aligns with the BC and Dataset Specialization Logical Data Models and follows documented BC Principles and Curation Guidelines.

Stage 3a: Internal Review

- The BC Curation Team will be responsible for performing an Internal Review and executing structural and semantic data validation checks to confirm accuracy of all BC Packages.
- Data Science will provide tooling and edit checks for data validation activities.
- The deliverable for Internal Review is a set of BCs that will be loaded to CDISC Library as provisional content.

Stage 3b: Public Review

- The BC Curation Team review and disposition all Public Review comments.
- The BC Curation Team will approve the disposition of all Public Review comments.

Stage 3c: Publication

- Conformance Rules and individual education courses are out of scope for the BCs.
- BC content will be approved as final by the BC Curation Team and be publicly available through CDISC Library.

Stage 4: Standard Maintenance

- Final BCs will be updated and published periodically, depending on content volume.
- If an issue is identified and submitted to the BC Curation Team, it will be addressed with the appropriate change control process in a future version.

Authorization

The document is authorized by:

Date	Title	Name
27 November 2023	CDISC, President and CEO	Dave Evans