



# CDISC Operating Procedure CDISC-COP-001 Standards Development

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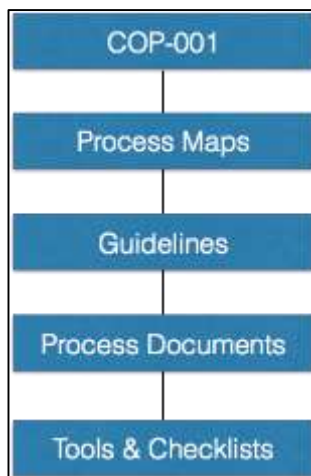
# CDISC Operating Procedure CDISC-COP-001 Standards Development

## 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 Foundational and Therapeutic Area (TA) standards. CDISC standards development is an open, consensus-based process. Wide participation and collaboration with multidisciplinary reviews are sought throughout this process to ensure quality and fitness for use, and to encourage the most widely adopted production standards, which are provided openly via the CDISC website ([www.cdisc.org](http://www.cdisc.org)). CDISC standards are harmonized through the BRIDG model to improve interoperability.

In addition to this COP, process flow charts, guidance documents, tools and checklists have been developed to facilitate all CDISC standards development projects, and are made available to project upon project teams upon approval. The diagram below describes the relationships of these documents.



*Diagram 1: COP, process maps, guidelines, process documents, tools and checklists*

### 1.2 Definitions

A CDISC data standard is any product (including specifications, user guides, implementation guides, models or schema) provided by CDISC that describes representation of clinical (or non-clinical) research data and has been properly developed, vetted and approved through the CDISC process.

“Foundational standards” is the term used to refer to the suite of CDISC standards to support the non-clinical and clinical process, including the clinical study protocol (Protocol), design (Study Design), data collection (CDASH), laboratory work (Lab), analysis (ADaM), and data tabulation (SDTM and SEND). See <http://www.cdisc.org/standards> for more information on each of these clinical data standards.

“Therapeutic Area standards” describe core clinical concepts for a particular condition or disease area and how they can be expressed through CDISC foundational standards (e.g. the SDTM, CDAST, ADaM, etc.) See <http://www.cdisc.org/therapeutic> for more information on therapeutic area data standards.

A CDISC standard is released as "Final" once it has completed the CDISC public review process with all comments resolved and is made available for full use by the user community.

A CDISC standard is released as "Provisional" when it has completed the CDISC public review process with all comments resolved and is made available for initial use by the user community, but may contain or be dependent upon some related or component parts (e.g., Terminology, draft domains) that are still undergoing further development or review separately, and are thus at some risk for change before they become final. Provisional standards are expected to be released as a final version once all individual component parts have been finalized.

### **1.3 Process Details**

For detailed guidance on standards development, teams should review the appropriate foundational or TA standards development process document and the accompanying tools (checklists, software, instructions).

Standards development process maps, guidelines and tools are available on the CDISC portal in “Teams Projects” links.

It is important that communication with all appropriate parties takes place during each step of the process. A checklist for this purpose is also available for project managers/teams.

### **1.4 Background**

This updated version of COP-001 is based on the previous COP-001 version 1.1 and incorporates enhancements to build in additional quality, efficiency and controls for development of all CDISC standards and address the challenges of developing many therapeutic area standards in a short period of time.

## **2 Authority**

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

## **3 Process Overview**

This diagram below provides an overview of the high-level CDISC Standards Development process. Each step will be explained in more detail in subsequent sections.

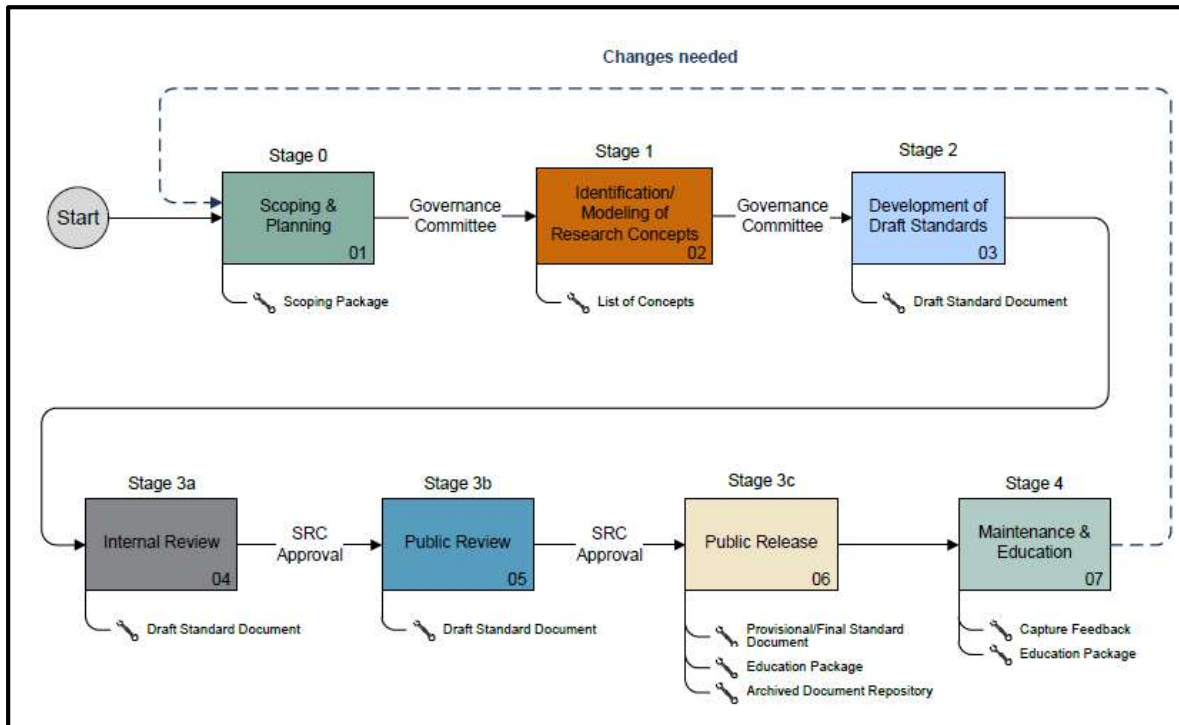


Diagram 2: Standards Development Process Map

### 3.1 Stage 0: Scoping and Planning

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

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, the building of a list of requirements, a check of the regulatory requirements and for TA projects a search of public databases.

All CDISC Standards Development Projects (i.e. Therapeutic Area and Foundational standards development projects) require approval from the appropriate governance body (for example, the Therapeutic Area Program Steering Committee (TAPSC), the CDISC Chief Technology Officer (CTO) and/or another CDISC Executive Operations leader, or team leaders for smaller maintenance projects). After a project proposal is completed and approved, initial scoping and/or planning activities can start. The duration for the Scoping and Planning stage may vary depending on the team, however for TA development projects the target is approximately 6 weeks.

#### 3.1.1 Process

- Perform background research and initial scoping
- Obtain approval from appropriate governance body for the scoping package
- Conduct a lessons learned meeting at the end of scoping stage, as appropriate

### 3.1.2 Deliverables

The deliverables for Stage 0 are the requirements assessment, project charter and the scoping package.

## 3.2 Stage 1: Identification/Modeling of Research Concepts

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

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 concepts and start to build the standards document
- Review concepts maps to be included in the standard with clinical SMEs
- Refine information requirements
- Assess terminology needs (including questionnaires) and begin work on developing terminologies that fit within existing standards
- Update project plan and charter

### 3.2.2 Deliverables

The deliverable for Stage 1 is a draft standard document, 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 information 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	Identification/ Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

The purpose of this process step is to build on the draft list of 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 or external review.

The duration for the Development of Draft Standards stage may vary depending on the team, however for TA development projects the target is approximately 10 weeks.

### 3.3.1 Process

- Define metadata modeling approach for new 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 SRC QC checklist (resolving discrepancies if applicable)
- Finalize draft standards document and package for internal review with approval of team leaders
- Conduct Project Review meeting with modeling experts, as needed

### 3.3.2 Deliverables

The deliverables for Stage 2 are the draft standards document review package.

## 3.4 Stage 3a: Internal Review

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

The purpose of the Internal Review is to ensure that all relevant CDISC teams, collaborative groups and subject matter experts involved in or impacted by the draft standards have the opportunity to review the new standards prior to public review of the draft standards. The duration of the Internal Review stage may vary depending on the team, however for TA development projects the target is approximately 6 weeks.

### 3.4.1 Process

- Post draft standard for internal review
- Resolve comments and update draft standard for public review
- Begin to develop education materials, including introductory webinar
- Submit remaining/additional terminology requests
- Submit public posting package to SRC for public review
- Resolve issues noted by SRC
- Post package for public review

### 3.4.2 Deliverables

The deliverables for Stage 3a are the public review posting package, posting announcements and the standards education package.

### 3.5 Stage 3b: Public Review

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

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. The duration of the Public Review stage may vary depending on the team, however for TA development projects the target is approximately 10 weeks.

#### 3.5.1 Process

- Collect public review comments
- Respond to public review comments and update package
- Submit additional terminology requests or complete other required activities as necessary
- Submit provisional/final version and a listing of all comments with dispositions to SRC
- Resolve issues noted by SRC
- Obtain SRC approval for public release

#### 3.5.2 Deliverables

The deliverables for Stage 3b are the standards document posting package including the production or provisional version of the standards document and electronic metadata as appropriate.

### 3.6 Stage 3c: Public Release

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

At the conclusion of the Public Review, and after all comments have been addressed, and the SRC and the CDISC CTO have granted approval, the new standard can be posted for implementation. This stage focuses on preparing the package and announcing the availability of the new TA standard.

#### 3.6.1 Process

- Post package for implementation
- Announce availability of the new standard package
- Archive all documents
- Conduct lessons learned meeting

### 3.6.2 Deliverables

The deliverables for Stage 3c are the standards document document and the Lessons Learned Report.

## 3.7 Stage 4: Maintenance and Education

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

All clinical data standards are living documents that require periodic review and update as new constructs 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 or extending the standards as needed. If significant changes or additions are noted, the team returns to Stage 0 of the standards development process, or directly to Stage 1 or 2 for less extensive updates.

### 3.7.1 Process

- Monitor feedback and initiate new standards development projects as needed
- Complete, announce and deliver education materials, online or classroom training, as appropriate
- Market online courses and provide training

### 3.7.2 Provisional Releases

If there are any remaining provisional dependencies then they must be resolved and the document modified as necessary. This new version must be submitted package to CTO for permission to post as final.

- CTO reviews package and consults SRC as needed to verify that all provisional issues are appropriately
- Obtain approval from CDISC CTO to change state to final

### 3.7.3 Education

All published CDISC standards should have a training package developed in collaboration with the education team that is available as soon after publication of the standard.

## 4 Standards Development Governance

All draft, provisional and final standards must be approved by the Standards Review Council (SRC) which is responsible for reviewing and approving all draft standards prior to publication and posting on the CDISC website.

Primary responsibility for the development of CDISC standards The CDISC Chief Technology Officer (CTO) has primary responsibility for ensuring that CDISC standards are developed consistent with this COP.

For most Foundational Standards projects, governance of specific standards products is provided by team leads and the CTO; however, in some cases governance may be provided by an external body, such as the CFAST Therapeutic Area Program Steering Committee (TAPSC) and working with the CFAST Scientific Advisory Committee (SAC).



## 5 Authorization

The document is authorized by:

Date	Title	Name
1 May 2014	CDISC, President	Rebecca Kush
1 May 2014	CDISC, CTO	Wayne Kubick