



**CDISC Operating Procedure COP-020
Trial Master File (TMF) Standards
Development**

Revision History

Date	Revision	Description	Author
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CDISC Operating Procedure CDISC-COP-020 TMF 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 Trial Master File (TMF) standards. CDISC TMF 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 standards, which are provided openly via the CDISC website (www.cdisc.org).

In addition to this COP, a process document has been developed to facilitate all CDISC TMF standards development.

1.2 Definitions

CDISC TMF Standard

A CDISC TMF standard is any product (including but not limited to, new or updated artifacts or sub-artifacts, terminology, exchange mechanism updates, etc.) that has been developed, vetted and approved through the CDISC TMF standards development process.

Draft Status

The proposed TMF standard is in development by CDISC teams.

Final Status

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

1.3 Release Schedule

CDISC will maintain an open, transparent and predictable release schedule.

1.4 Version Number

A sequence-based, unique identifier used to indicate the significance of changes between releases of the TMF Reference Model. For detailed guidance on versions, teams should review the CDISC TMF Standards Development Process Guideline.

1.5 Standards Development Process Guidance

For detailed guidance on TMF standards development, teams should review the CDISC TMF Standards Development Process Guideline.

2 Authority

This CDISC TMF Operating Procedure (COP) is approved by the CDISC President and CEO and should be followed by all those involved in developing CDISC TMF 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 2a	Stage 2b	Stage 2c	Stage 3
Scoping & Planning	Development of Draft TMF Standards	TMF Community 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.

All CDISC TMF Standards Development Projects require approval from the appropriate governance body.

3.1.1 Process

- Review proposed changes and performs initial scoping
- Make an initial determination on the Version Number
- Obtain approval from TMF RM Steering Committee (SC) for the scoping package

3.1.2 Deliverables

The deliverable for Stage 0 is the scoping package.

3.2 Stage 1: Development of Draft TMF Standards

Stage 0	Stage 1	Stage 2a	Stage 2b	Stage 2c	Stage 3
Scoping & Planning	Development of Draft TMF Standards	TMF Community Review	Public Review	Publication	Standard Maintenance

The purpose of Stage 1 is to define in more detail the information that will comprise the new or enhanced TMF Standards. At the end of this stage, the draft document should be completed and contain all needed components in order to enable a thorough TMF Community Review.

3.2.1 Process

- Review and refine proposed changes and develop terminologies, if applicable.
- Finalize proposed changes
- Develop draft TMF standards document and review package
- Submit terminology requests
- Make a final determination on the Version number
- Obtain TMF Steering Committee (SC) approval for TMF Community Review
- Finalize draft TMF standards document and package for TMF Community Review

3.2.2 Deliverables

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

3.3 Stage 2a: TMF Community Review

Stage 0	Stage 1	Stage 2a	Stage 2b	Stage 2c	Stage 3
Scoping & Planning	Development of Draft TMF Standards	TMF Community Review	Public Review	Publication	Standard Maintenance

The purpose of the TMF Community Review is to ensure that all CDISC TMF members impacted by the draft TMF standards have the opportunity to review the draft TMF standards prior to Public Review.

3.3.1 Process

- Post draft TMF standard for TMF Community Review
- Resolve issues and update draft TMF standard
- Develop education materials, including Public Review webinar (if needed)
- Obtain TMF SC approval for public posting package if major changes from TMF Community review are identified
- Submit public posting package to Publication Committee
- Communications Team posts draft for Public Review

3.3.2 Deliverables

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

3.4 Stage 2b: Public Review

Stage 0	Stage 1	Stage 2a	Stage 2b	Stage 2c	Stage 3
Scoping & Planning	Development of Draft TMF Standards	TMF Community Review	Public Review	Publication	Standard Maintenance

The purpose of the Public Review is to develop widespread consensus for the proposed TMF standards 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 2c.

3.4.1 Process

- Collect Public Review comments
- Respond to Public Review comments and update the draft document
- Review responses to Public Review comments
- Any normative content changes need to be reviewed and approved by the TMF CCB
- Submit additional terminology requests and complete other required activities as necessary
- Send final document to TMF SC for review
- Send final document to copy editor for review
- CCB lead(s) provide approval for publication
- Submit public posting package to Publication Committee for preparation for publication

3.4.2 Deliverables

The deliverables for Stage 2b are the TMF standards document posting package

3.5 Stage 2c: Publication

Stage 0	Stage 1	Stage 2a	Stage 2b	Stage 2c	Stage 3
Scoping & Planning	Development of Draft TMF Standards	TMF Community Review	Public Review	Publication	Standard Maintenance

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

3.5.1 Process

- Communications Team posts the standard on www.cdisc.org
- Communications Team announces availability of the new TMF standards package

3.5.2 Deliverables

The deliverable for Stage 2c is the publication package.

3.6 Stage 4: Standard Maintenance

Stage 0	Stage 1	Stage 2a	Stage 2b	Stage 2c	Stage 3
Scoping & Planning	Development of Draft TMF Standards	TMF Community Review	Public Review	Publication	Standard Maintenance

All TMF standards require periodic review and update as new concepts and issues are identified that require changes, additions or deletions to a published CDISC TMF standard. The basic steps in this stage include monitoring feedback from user communities, reviewing the output from TMF working groups, monitoring regulatory updates and updating the TMF standards as needed. Changes to existing TMF standards follow the same development process, starting at Stage 0 (scoping).

3.6.1 Process

- Monitor feedback and initiate new TMF standards development projects as needed
- Deliver education materials

4 Standards Development Governance

4.1 TMF Steering Committee (TMF SC)

The CDISC TMF Steering Committee (TMF SC) is responsible for reviewing and approving all draft TMF standard scoping packages and has high level oversight of activities relating to changes to the TMF Reference Model. This group is composed of representatives voted in by the TMF Community.

4.2 TMF Change Control Board (TMF CCB)

The CDISC TMF Change Control Board (TMF CCB) is responsible for creating the scoping package for each release and reviewing, triaging and approving all draft TMF standards. This group is composed of subject matter experts who have been empowered to review and approve changes to the TMF Reference Model. The CCB has the overall responsibility for managing and maintaining the TMF Reference Model.

4.3 Escalation of Issues

In cases where the CCB recognizes that a discussion is stalling, they can escalate the issue, within a reasonable timeframe, to ensure a resolution is reached to the CDISC TMF SC. If the issue cannot be resolved by the TMF SC, the final decision will be made by the CDISC Chief Standards Officer.

- i. All issues should be resolved within the CCB, 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 TMF SC
 - c. If the issue cannot be resolved by the TMF SC, the final decision will be made by the CDISC Chief Standards Officer
 - d. Attempts to resolve issue should be documented in the CCB 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
26-MAR-2025	Chief Standards Officer	Peter Van Reusel