# TMF Reference Model Initiative Charter

## 1. Purpose

The purpose of this Charter is to define the responsibilities, organizational structure and business processes associated with the CDISC TMF Reference Model Initiative ("CDISC TMF RMI").

The Trial Master File (TMF) contains those essential documents that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements. (ICH Guideline for Good Clinical Practice, E 6(R2), Section 8). All organizations who sponsor clinical trials have a responsibility to ensure a TMF is created and maintained for each clinical trial.

The TMF RMI (formerly known as "DIA TMF Reference Model") was started in 2009 under the auspices of the Drug Information Association (DIA) Special Interest Area Committee for Document Management (which has since become the Document and Records Management (DRM) Community). Its aim was to develop a taxonomy reference model for the TMF that any organization can use either as-is (without change), or as a starting point for enhancement of their current process. The first version of a TMF Reference Model was made available June 2010, with major and minor updates periodically. The TMF RM Initiative formally separated from the DIA in 2016 to be a stand-alone group.

In April 2022, The TMF RMI formally became part of Clinical Data Interchange Standards Consortium (CDISC), a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata.

The CDISC TMF RMI has established four pillars:

- Evolution: A new way to manage the CDISC TMF RM
  - Extend the granularity of the CDISC TMF RM
  - Expand the CDISC TMF RM to incorporate different types of studies and data
  - Implement better tools to manage, map and distribute the CDISC TMF RM
- Community: Continuity, good future vision and leadership
  - Strengthen community engagement to drive evolution
  - Safeguard the continuity of the CDISC TMF RM Leadership
  - Identify and encourage active working groups to produce deliverables.
- Formalization: Align and engage with Regulators
  - Implement a transparent governance process to establish the CDISC TMF RM as a formal, recognized, global standard

    - Secure formal recognition from the regulatory authorities as a standard for managing TMF content
    - Promote industry adoption of the Exchange Mechanism Standard
- Expansion: Information and expertise sharing
    - Rebrand to reflect the expanded activity
    - Produce best practices and documentation
    - Agree standardized TMF metrics both internally and externally

To support these objectives, the Steering Committee has maintained a roadmap which identifies activities that the Initiative may pursue. In addition, the team currently maintains a website (www.tmfrefmodel.com) where relevant content can be publicly and freely accessed and shared.

## 2. Governing Policies and Code of Conduct

CDISC is organized and shall at all times be operated exclusively for purposes within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the "Internal Code") and within the meaning of the Massachusetts General Laws Chapter 180, Section 4, as amended.

This Initiative operates in accordance with CDISC Bylaws, Policies, Charters (including this Charter) and will adhere to CDISC Operating and Internal Procedures where relevant.
https://www.cdisc.org/about/bylaws

Although it is acknowledged that the TMF taxonomy will ultimately need to integrate with commercially available products, and we welcome the participation of consultants and vendors, we remind all participants that this is not a forum for promotion of products, services, and companies and that such practice may result in the exclusion of offenders from the initiative.

Information concerning team members must be used solely for purposes related to the conduct of the Initiatives' activities. Membership information must not be used by any member for any other purpose e.g., personal reasons, commercial purposes, to seek or gain business, or to promote the member's own business and/or other interests.

## 3. Operating Principles

CDISC TMF RMI will

- Continue to extend the model as needed to enable innovation and process improvement within the industry.
- Be technology agnostic. Engage with regulators to optimize alignment and leverage existing industry standards.

Explicitly address applicable global regulations

- Determine a sustainable method and format for dissemination of the model and its related deliverables
- Initiate and oversee individual working groups to develop and deliver specific deliverables

related to the CDISC TMF RM
- Utilize a formal Change Control process to implement periodic updates to the CDISC TMF RM
- Promote information sharing and education of members and the industry.

## 4. Scope

The CDISC TMF RMI is resourced by industry volunteers who devote time, as their schedule allows, to specific activities. It has therefore been critical to keep the scope of the initiative focused, simple and achievable. The scope is currently limited to supporting the four pillars mentioned above. The Initiative does not currently concern itself with specific or individual TMF or GCP document management issues but is specifically limited to activities supporting the maintenance, , implementation, change management and utilization of the CDISC TMF RM.

The Steering Committee will determine which topics, issues or activities are considered to be within the scope of the initiative. With respect to the content domain for the CDISC TMF RM, the group shall consider applicable functional areas involved in clinical research and clinical investigations (for medical devices).

## 5. Membership

Any individual who has an interest in the CDISC TMF RMI is welcome to participate, whether from the pharmaceutical industry, industry groups (such as PhRMA, EFPIA or WSMI), biotechnology, healthcare, academia, government or international organizations, non-for-profit / NGO, consulting companies, or software / tools vendors. Participants must understand and accept that their company / organization name may be used by the group at the discretion of the person or persons in charge of communication.

There are two types of participants:

The Subscribers: Those who are subscribed to the CDISC TMF RM communications.

The Volunteers: A Volunteer is defined as someone who actively participates or has participated in a CDISC TMF RM sub-group, and plans to do so in the future. Volunteers will be required to follow the CDISC's code of conduct.

Volunteers are asked to author or review documents; participate in regular meetings or teleconferences; perform bibliographic or other types of research; present results and suggestions; or otherwise contribute to specific subgroups. There is an expectation that Volunteers will engage with and participate in activities as their schedule allows.

A record is maintained of Initiative subscribers and volunteers. Other technology resources such as file-sharing and discussion boards may be used to facilitate and manage the work of the teams.

The initiative publishes a data privacy statement and ensures personal data is handled in compliance with applicable data privacy requirements

## 6. Governance

Initiative activities will be overseen by the Steering Committee constituted per the Steering Committee Charter.

Changes to the CDISC TMF RM are managed by the Change Control Board in accordance with their Charter.

## 7. Authorization

This document has been approved and is in effect on this date:

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|---|---|
| Name | Chair of the CDISC TMF Reference Model Steering Committee |
| Date | January 22, 2023 |

## 8. Version History

| Type of Change | Date | Version |
|---|---|---|
| First issue of approved Project Charter | April 29, 2009 | V1.0 |
| Clarify scope of project. Include governance by Steering Committee. Provide for participation by non-DIA members. Use of membership information. Maintenance of project website. Simplify charter structure. | June 6, 2017 | V2.0 |
| Removal of affiliation with DIA and inclusion of the details associated with the move to being a CDISC Initiative. Change from Project to Initiative. Simplification of the Rationale. | June 24, 2022 | V3.0 |
| Conversion to CDISC format, inclusion of strategy objectives | January 12, 2023 | V4.0 |