TMF Reference Model Steering Committee 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 Steering Committee ("TMF RM SC").

The TMF RM SC has been in place since 2014, before the TMF Reference Model Initiative ("TMF RM Initiative") became part of 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 TMF RM SC was originally established to provide strategic leadership for the TMF RM initiative; to manage and monitor the activities of the initiative, to ensure delivery of agreed objectives, to verify the project's coherence with established goals, and to manage relationships to relevant external initiatives.

2. Governing Policies

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 Committee 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

TMF RM SC members shall not use their position to promote their own organizations or to seek to gain business advantage directly because of their position or membership of the TMF RM Initiative. Information concerning project team members must be used solely for purposes related to the conduct of the project's 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. Responsibilities

The TMF RM SC has the following responsibilities:

Maintenance of the TMF RM Initiative Charter and the Steering Committee Charter	• Proposes changes to the charter and reviews change requests from initiative volunteers • Monitors adherence to the charters • Decides on changes and approves final charter
Oversight of the TMF RM content	• Decides to initiate reviews based on specific needs or events, in accordance with a change control model (see Deliverables section below) • Ratifies versions of the TMF RM approved by initiative volunteers for publication
Initiation of working groups	• Reviews & approves proposals for new working groups (proposals sourced from the Steering Committee or from initiative volunteers) • Clarifies the drivers for all working groups and the commercial implications of deliverables generated.
Oversight of working groups	• Reviews activities & progress of working groups to ensure appropriate progress is being made • Provides assistance/guidance to working groups as needed to resolve issues & mitigate risks • Provides feedback to working group and others (e.g., DRM Steering Committee), as necessary • Each working group should have a Steering Committee sponsor
Development & maintenance of the TMF RM Roadmap	• Evaluates the key priorities pertaining to the TMF RM • Maintains a roadmap of potential updates and extensions to the TMF RM Initiative, including an annual plan of deliverables • Tracks and communicates performance against the roadmap, revising as necessary
Communication & engagement with external activities of relevance to the TMF RM	• Establishes need for collaboration on relevant external initiatives • Directs and/or organizes active collaborations with external initiatives (via working groups, advisory boards, or other means) • Keeps volunteers appraised of external initiatives, information updates, etc.

Communication with CDISC Board	• Maintains communication about the TMF RM initiative with the CDISC Board through the Chair of the Steering Committee
Communication within and outside of TMF RM initiative	• Oversees communication about the TMF RM initiative to initiative volunteers and any third parties

4. Deliverables

TMF RM Initiative Charter	• A document that defines the rationale, scope, objectives, responsibilities, deliverables, timelines and participants of the TMF RM Initiative • Reviewed annually • Items deemed out of scope for the Steering Committee will be included in the TMF RM Initiative Charter
TMF RM Steering Committee Charter	• A document that defines the scope, responsibilities, deliverables, governance and participants of the TMF RM Steering Committee • Reviewed annually
TMF RM Strategy	• A plan that matches short-term and long-term goals with our deliverables in the TMF RM Initiative Charter. It helps reach consensus, help forecast activities and provides a framework to help plan and coordinate efforts • Reviewed annually or more frequently if needed due to industry demands
TMF RM Change Control Model	• A documented process for review, feedback and decision-making as it pertains to the content of the TMF RM. • Implementation of the change control model will be the responsibility of defined volunteers of the TMF RM Initiative, including the Steering Committee
TMF RM Repository	• To be established for all TMF RM Initiative documentation, including published Reference Model(s), working group documents (draft and final), steering committee documents (draft and final), membership lists (including committees, working groups, advisory boards) • Maintenance of the repository will be the responsibility of defined volunteers of CDISC and the TMF RM Initiative, including the Steering Committee

5. Membership

The Steering Committee will include functionally and geographically diverse clinical development perspectives. The committee will be comprised of a maximum of fourteen persons and will meet the following qualifications:

- Members' background or current employment must be associated with TMF management.
- Members must have a minimum three years TMF related experience
- Members must be aligned to one of the following stakeholder groups:
  - Corporate Sponsors (BioPharma/Device),
  - Clinical Research Organization (CRO)s,
  - Academic Sponsors (AROs),
  - Investigator Sites,
  - Other Vendors,
  - Consultants,
  - Recognized industry SMEs who are not included in the above list whose experience, knowledge, and demonstrated leadership is extremely relevant to current mission and objectives of the TMF RM Initiative.
- Each of the aforementioned stakeholder groups may have up to but no more than 50% of the total Steering Committee membership
- Each member must be employed by a unique business entity/organization, unless the Recognized Industry SME as described above.
- Nominations for membership on the Steering Committee will be accepted from TMF Reference Model Initiative members of at least 12 months standing.

Ad-hoc advisory boards may be assembled as needed to represent gaps in Steering Committee expertise and/or gaps not represented by working groups (for example non-commercial, devices, health authorities, geographic region, subject topic). In addition, the Steering Committee may identify additional project roles from time to time. Such positions will normally be open to project team members, with a vote of members taken where >1 member wishes to fill a position. These positions will not be Steering Committee positions and role-holders will have no Steering Committee voting rights, though they may be required to attend Steering Committee meetings.

All TMF RM SC members are expected to participate in all scheduled meetings as follows:

- A minimum 50% of the Steering Committee meetings over the previous year.
- A minimum 65% of the General TMF Reference Model meetings over the previous year.
- Note that 10% will be added to the SC member's percentages if they have run or had significant involvement in an initiative as decided by the Chair.

6. Governing and decision-making process

The Steering Committee will meet at least monthly. A quorum is defined for decision-making at meetings to be 75%. The committee will come to decisions through majority vote. Decisions will be shared with a broader audience as appropriate.

7. Election and Leadership

Election

Steering Committee members will serve fixed three-year terms, with vacant positions opened up on expiry to self-nomination and voting by all registered members of the TMF RM Initiative. Vacancies will be filled by candidates receiving the highest number of votes cast. In the event that one of the stakeholder groups achieves 50% of the Steering Committee positions, further candidates from that stakeholder group will be disregarded and the remaining Committee Members selected in order of votes cast. Similarly, the Steering Committee must not comprise over 90% of members from a single geographic region (Americas, Europe, Asia-Pacific). In the event that one of these geographic regions achieves 90% of the Steering Committee positions, further candidates from that geographic region will be disregarded and the remaining Committee Members selected in order of votes cast. Nominees who fail to receive sufficient votes may subsequently join the Committee without a further election in the event of the resignation of an existing Committee member within six months of their nomination (see Resignations below).

Elections will be held once a year, around March. If a Steering Committee member does not meet the requirements for attendance, they will be asked to resign or they will not be eligible to stand again.

The membership roster for the Steering Committee will be maintained by the Secretary and will be posted to be is accessible to all TMF RM Initiative members

Change in Stakeholder Group

If a Steering Committee member changes employment, they are entitled to remain on the Steering Committee as long as their new role is in the Trial Master File space. If this change in employment results in one of the Stakeholder groups exceeding its allowable percentage, that is acceptable, and will be re-balanced at the next election.

Leadership

Three persons will fill leadership positions within the Steering Committee: Chair, Vice-Chair, and Secretary; as decided within the Steering Committee. The Chair and Vice-Chair will have already completed at least twelve consecutive months of office as a Steering Committee member.

Calls for nominations for Chair and Vice-Chair will be sent out in June of each year for all open positions. Nominees should submit a written statement describing their commitment to the leadership role and the goals of the team. Selection should be in September, and results announced at the US Interchange. Each

Steering committee member will vote for one candidate for each position and the candidate with the most votes will be selected. In the case of a tie, additional voting rounds will take place for the tied candidates, until one candidate receives more votes than the other remaining candidates. Each term will start on January 1st, with a total commitment of 2 years.

If a Chair steps down, a new one will be voted in for the remaining term. Past Chairs can stand for Chair again but not in a consecutive term.

The Chair will also be a CDISC Board Member for their term. It is the responsibility of the Chair to represent the views, perspectives and interests of the TMFRM SC in discussion at the CDISC Board of Directors meetings, which include annual face to face meetings as well as teleconferences.

The Chair is responsible for leading all TMFRM SC meeting activities, including face-to-face meetings, teleconferences and other similar events. In the event that the Chair cannot participate, the Vice-Chair will lead the activity, and if she or he is unavailable, this responsibility will fall to the Past-chair. If neither the Chair-elect nor Past-chair is available, the Chair will appoint a meeting leader.

Other Chair / Vice-Chair responsibilities include:

- Adhering to all relevant CDISC policies and procedures
- Modelling the principles of good conduct for volunteers
- Ensuring sanctioned project deliverables are completed
- Ensuring team meeting information to all active team members
- Ensuring Committee discussions are documented
- Ensuring adequate documentation and formal approval of the proceedings of the election process
- Reviewing the charter on an annual basis
- Encouraging attendance and participation of volunteers
- Actively participating in annual reviews of volunteer engagement and the assessment of active status with the CDISC Team Coordinator
- Escalating issues with volunteers to CDISC Heads of standards

Resignation

Should a member resign or become unable to complete an appointed term, the member may nominate a replacement from his/her organization to serve the remainder of the term. Nominations are subject to approval by the committee. If approval is not granted or no successor is nominated by the resigning Committee member, the vacant position will be filled by any Committee nominee who did not achieve sufficient number of votes to be elected to the Committee, as long as the prior election was within the prior six months, in order of votes cast at this election. The new Committee member will complete the remaining portion of the original term of office.

The requirement that no stakeholder group must fill more than 50% of the Committee positions and/or no geographic region may fill more than 90% of the Committee positions must be maintained. If the vacant position cannot be filled by either of these two processes, or if the previous election was more than six months ago, the position will be opened to nomination from the registered members of the TMF RM

initiative. In such circumstances, the person duly elected will serve the remainder of the original term of office if there is over one year remaining in that term. If there is one year or less remaining, the person duly elected will serve the remainder of the original term plus a full three-year term of office.

7 Authorization

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

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 Steering Committee Charter	March 19, 2014	V 1.0
Ivan Walrath has been replaced by Martin Thorley as representative for Pfizer on the TMF Reference Model Steering Committee; Change has been applied to the membership roster in the charter	March 31, 2014	V 2.0
Added language to Governance section describing process to be followed when Steering Committee members resign before completing their term.	April 3, 2014	v2.1
Section on member integrity added. Membership section updated to clarify the term lengths of elected members. Roster removed and location in TMF RM central location indicated as this changes frequently.	March 29, 2017	v3.0
Section on elections updated to include the scenario where voting results in >50% from one stakeholder group or >90% from a single geographic region (Americas, Europe, Asia-Pacific). Clarification added around resignation, term of office for replacements, and change in Stakeholder group.	November 27, 2017	V3.1
Include non-committee roles	March 29, 2019	V3.2
Added language around expected attendance at SC and General meetings	April 11, 2020	V 3.3
Conversion to CDISC format, updating of membership, amending to be in line with CDISC plans	January 22, 2023	V4