



Trial Master File Reference Model

TMF Reference Model Steering Committee Charter

Background:

The TMF Reference Model Initiative (formerly known as “DIA TMF Reference Model”), started in 2009 by the DIA Document and Records Management Community, has been successful by several measures: volunteer participation, development and awareness of the model, and adoption of the model (among other measures). With increasing reliance on the model by the clinical development industry, additional challenges have motivated the initiative’s volunteers to seek a formal leadership structure.

Objective:

Provide strategic leadership for the TMF RM initiative; manage and monitor the activities of the TMF RM initiative, ensure delivery of agreed objectives, verify the project’s coherence with established goals, and manage relationships to relevant external initiatives.

Responsibilities:

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| Maintenance of the TMF RM charter and of the Steering Committee charter | <ul style="list-style-type: none">• 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 Reference Model content | <ul style="list-style-type: none">• 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 Reference Model approved by initiative volunteers for publication |



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| <p>Initiation of working groups</p> | <ul style="list-style-type: none"> • Reviews & approves proposals for new working groups (proposals sourced from the Steering Committee or from initiative volunteers) • Clarify the drivers for all working groups and the commercial implications of deliverables generated. |
| <p>Oversight of working groups</p> | <ul style="list-style-type: none"> • 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 |
| <p>Development & maintenance of the TMF Reference Model Roadmap</p> | <ul style="list-style-type: none"> • Evaluate the key priorities pertaining to the Reference Model • Maintain a roadmap of potential updates and extensions to the TMF Reference Model Initiative, including an annual plan of deliverables • Track and communicate performance against the roadmap, revising as necessary |
| <p>Communication & engagement with external activities of relevance to the TMF Reference Model</p> | <ul style="list-style-type: none"> • 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 apprised of external initiatives, information updates, etc |



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| Communication within and outside of TMF RM initiative | <ul style="list-style-type: none"> Oversees communication about the TMF RM initiative to initiative volunteers and any third parties |
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Deliverables:

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| TMF RM Initiative Charter | <ul style="list-style-type: none"> 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 TM Initiative Charter |
| TMF RM Steering Committee Charter | <ul style="list-style-type: none"> A document that defines the scope, responsibilities, deliverables, governance and participants of the TMF RM Steering Committee Reviewed annually |
| TMF RM Roadmap | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> A documented process for review, feedback and decision- making as it pertains to the content of the TMF Reference Model. Implementation of the change control model will be the responsibility of defined volunteers of the TMF Reference Model Initiative, including the Steering Committee |



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| TMF RM Repository | <ul style="list-style-type: none"> • To be established for all TMF Reference Model 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 the TMF Reference Model Initiative, including the Steering Committee |
| TMF RM Communications Plan | <ul style="list-style-type: none"> • Identify all stakeholder groups relevant to the TMF RM, channels to be used, and preferred frequencies of communication • Document Communication Plan • Reviewed annually |

Composition:

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 and be aligned to one of the following stakeholder groups: Corporate Sponsors (BioPharma/Device), CROs, Academic Sponsors (AROs), Investigator Sites, Other Vendors, Consultants
- 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
- It is not required, however highly recommended that each Steering Committee member is also a DIA member as we are using DIA infrastructure for communication and information sharing.
- 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



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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.

Governance:

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 Reference Model 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. At this time, current Steering Committee members will be assessed for the required meeting attendance:

- 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. The Chair will track all attendance

If a Steering Committee member does not meet these requirements, they will be asked to resign or they will not be eligible to stand again.



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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. Under normal circumstances, the Chair will have already completed at least one term of office as a Steering Committee member. Where more than one person offers to take a particular office, the office holder is voted on by a quorum of the Steering Committee.

Resignation

Should a member resign or become unable to complete an appointed term, the member may nominate a replacement from his/her organisation 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 Reference Model 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.

Member Integrity

Committee members shall not use their position to promote their own organisations or to seek to gain business advantage directly because of their position or membership of the TMF Reference Model



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project. 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.

Operations:

The Steering Committee will meet at least monthly. A quorum is defined for decision-making at meetings to be 75% with no more than 50% from any one of the stakeholder groups. The committee will come to decisions through majority vote. Decisions will be shared with a broader audience as appropriate.

Membership Roster:

The membership roster for the Steering Committee will be maintained by the Secretary and will be posted to the TMF Reference Model Document Library which is accessible to all TMF Reference Model Initiative members (<https://tmfrefmodel.com/resources/>).



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Version History

| Type of Change | Date | Version |
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| 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 Steering Committee and General meetings | April 11, 2020 | V 3.3 |