

Executive Summary

The Trial Master File Reference Model (TMF RM) Steering Committee recently developed four (4) strategic pillars to describe the strategy and direction of the TMF RM group. To implement these strategic pillars, it has become clear that affiliation with a formal organization will be necessary. The TMF RM Steering Committee evaluated a variety of organizations as a possible fit and found that the Clinical Data Interchange Standards Consortium (CDISC) aligned best with its principles and future strategy. The TMF RM Steering Committee recommends that the TMF Reference Model group affiliate with CDISC.

Overview

The TMF RM group began over 10 years ago. 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. Currently the TMF RM group is an independent group with no formal affiliation to any organization that is run by dedicated volunteers without any financial support or recognition by Regulatory Authorities.

The TMF RM currently has two primary objectives as outlined in the charter:

- To develop and maintain the TMF RM so that it remains aligned with regulatory requirements and the expectations of regulatory inspectors
- To develop supporting materials that assists in the understanding, interpretation, utilization, and adoption of the TMF RM

The TMF RM Steering Committee has received many requests to pursue worthy initiatives related to TMF management. Notably, requests to expand the model with more extensive metadata, the mapping of the model to other related models and standards, and development of additional guidance and training offerings. The TMF RM group does not have the structure or resources to reasonably complete many of these important initiatives. In discussing this situation, the TMF RM Steering Committee agreed to develop strategic objectives to help resolve the problem.

For several months in 2021, the TMF RM Steering Committee completed an exercise to identify the TMF RM group’s future strategy. ([TMF Reference Model General Meeting – Sep 2021](#)) The result is establishment of 4 strategic pillars to future-proof the group:



The implication of this strategy is that more support is needed to achieve the established strategic objectives.

TMF RM Steering Committee Position

To achieve the strategy, the TMF RM Steering Committee has unanimously agreed that the TMF RM group should affiliate with a formal organization.

The TMF RM Steering Committee established several criteria to aid in identifying organizations for affiliation. Those criteria are:

- TMF RM content remains under the TMF RM Steering Committee control
- TMF RM content remains freely available to the public
- TMF RM group must affiliate with a not-for-profit organization that
 - does not exclude any party involved, including vendors and technologists
 - has relationships and connections to regulatory authorities and standards organizations

The TMF RM Steering Committee conducted a review of multiple organizations (see [TMF Reference Model General Meeting – Dec 2021](#)) and has identified CDISC as the best fit to the TMF RM group affiliation principles.

CDISC's Mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. They are a global non-profit organization with more than 20 years developing and implementing clinical data standards.

Affiliation with CDISC provides the following benefits to the TMF RM group:

- CDISC is a Standards Development Organization formally recognized as by Regulatory Agencies (FDA, PMDA, NMPA, EMA)
- A formalized framework for a standards development lifecycle allowing for expansion of the model and further development of the eTMF exchange mechanism
- Better alignment and interchange with other clinical trial data standards both within CDISC and externally through CDISC's extensive network of collaboration partners
- Dedicated resources for the management and promotion of standards
- Technical resources to manage and deploy standards
- Publication and distribution of standards documentation and implementation guides
- Formalized training and certification on the CDISC standards
- Dedicated staff for events, education, membership and volunteers

While affiliation with CDISC will change the TMF RM group, the TMF RM Steering Committee is committed to continue to engage and leverage the community to drive the content and direction of the model.