



TMF Reference Model Initiative Charter

Definition of a TMF

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.

History

Prior to the creation of a TMF Reference Model (TMF RM), each organization had their own unique TMF structure as defined by their SOPs as no common model or taxonomy for organizing TMF documents existed. Many internal functions and third parties contribute to a TMF, each with processes and systems based on their own interpretation of the regulations. This was a highly inefficient way for our industry to work as it meant considerable effort for each organization and made TMF document exchange very cumbersome, and the Regulators had to deal with different structures and terminology.

The TMF Reference Model Initiative (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. With increasing reliance on the model by the clinical development industry, additional challenges motivated the initiative’s volunteers to seek a formal leadership structure, the Steering Committee, which has been in place since 2014. See the TMF RM Steering Committee Charter for more details.

In April 2022, The TMF RM Initiative 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.

Objectives

The TMF Reference Model Initiative has two primary objectives:

- To develop and maintain the TMF Reference Model so that it remains aligned with regulatory requirements and the expectations of Health Authority inspectors
- To develop supporting materials that assist in the understanding, interpretation, utilization, and adoption of the TMF Reference Model

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.



Scope

The TMF Reference Model initiative is resourced by industry volunteers who devote time, as their schedule allows, to specific activities. In addition, there are other industry groups who have an interest in document and records management activities. It has therefore been critical to keep the scope of the initiative focused, simple and achievable. The scope is currently limited to delivering the two primary objectives described above. The Initiative does not currently concern itself with general TMF or GCP document management issues but is specifically limited to activities supporting the maintenance, further development, implementation, and utilization of a TMF Reference Model. Examples of topics that are out of scope include:

- general processes for creation and management of TMF documents;
- content of documents, including processes for approval/signature;
- quality control (of individual document or the TMF as a whole);
- inspections and inspection readiness;
- paper document management, and
- document and records retention and archiving.

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 TMF Reference Model, the group shall consider the full TMF with all applicable functional areas involved in clinical research and clinical investigations for medical devices and will not include the Preclinical, Non-clinical, non-trial-specific Submission, and Chemical, Manufacturing & Controls (CMC) or non-trial-specific IP Manufacturing functional areas.

With the incorporation into CDISC, this scope will be expanding in accordance with recent strategy work.

Operating Principles

TMF Reference Model Initiative group:

- will continue to extend the model as needed to enable innovation and process improvement within the industry.
- will not endorse nor by design require any specific technology for application. It will be technology neutral.
- may engage with Regulatory Groups to optimize alignment and leverage existing industry standards.
- must explicitly address the applicable regulations
- will determine a sustainable method and format for dissemination of the model
- will initiate and oversee individual working groups within the group to develop and deliver specific deliverables related to the TMF Reference Model
- will utilize a formal Change Control process to implement periodic updates to the mode

Participation

Any individual who has an interest in the TMF Reference Model Initiative 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 TMF Reference Model communications.

The Volunteers: A Volunteer is defined as someone who actively participates or has participated in a TMF Reference Model 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

Governance

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

Code of conduct

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.

Version History

Type of Change	Date	Version
First issue of approved Project Charter	April 29, 2009	V 1.0
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	V 2.0
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