TMF Reference Model Project

Project Charter & Scope

Support Provided by: Drug Information Association (DIA), specifically the Chairs and Members of the Document & Records Management (DRM) Community of the DIA

Background: The Purpose of the Trial Master File and Rationale for Our Project:

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. Prior to the creation of a TMF Reference Model, 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 is a highly inefficient way for our industry to work for many reasons:

- All academic and non-commercial trial sponsors, biopharmaceutical and device development companies, and contract research organizations (CROs) spend considerable amounts or time in defining and redefining the content and structure of the TMF for each of their clinical trials.
- The relative burden is very high on smaller companies that usually have limited document management expertise and limited financial resources.
- Records and information exchange between collaborating parties is extremely cumbersome and at times may prevent the transfer of TMF content or investigational product, or a joint venture from happening.
- Regulators consistently find different terminology and file structure between sponsors, creating inefficiency and a higher degree of variability during sponsor audits

This project was initiated in 2009 under the auspices of the 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 subsequent releases in February 2011, December 2011, June 2012 and June 2015.

Objectives

The TMF Reference Model project has two primary objectives:
- To develop and maintain the TMF Reference Model 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 Reference Model

To support these objectives, the project will maintain a roadmap which identifies activities that the project team will pursue. In addition, the project will maintain a website where relevant content can be accessed and shared.

Scope

The TMF Reference Model project is resourced by industry volunteers who devote time, as their schedule allows, to project activities. In addition, there are other industry groups – both inside and outside of the organization of the DIA – who have an interest in document and records management activities. It is therefore critical to keep the scope of the project focused, simple and achievable. The scope, is limited to delivering the two primary objectives described above. The project does not 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 project. With respect to the content domain for the TMF Reference Model, the project group shall consider the full TMF with all applicable functional areas involved in clinical research 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.

Operating Principles

TMF Reference Model project 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 should be technology neutral.
- may engage with sanctioned Standards Development Organizations and/or Regulatory Groups to optimize alignment and leverage existing industry standards.
- must explicitly address the applicable regulations and remain aligned with the defined eCTD structure
- will determine a sustainable method and format for dissemination of the model
- will initiate and oversee individual working groups within the project group to develop and deliver specific deliverables related to the TMF Reference Model

Whilst no records will be maintained of member participation or individual attendance at meetings, there is an expectation that members will try to engage with and participate in project activities as their schedule allows.

Participation

The project was created and supported under the auspices of the Drug Information Association (DIA) and is managed as a project of the Document and Records Management (DRM) Community. Any Community member may participate in the project. The TMF Reference Model project is governed by a Steering Committee who recognizes that the project's deliverables are of interest to the whole industry and the activities would benefit from engagement wider than the DIA membership. Therefore, in the same way that

non-DIA members can participate in DIA conferences and other DIA events, non-DIA members will also be permitted to participate in the activities of this project. However, non-members will not be able to benefit from DIA resources such as the online Community tools and will not be able to participate as a Steering Committee member.

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

Participants will be 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. As the project moves on, more active participation may be requested although never imposed.

A simple database will be maintained of project members. Other technology resources such as file-sharing and discussion boards may be used to facilitate and manage the work of the project team.

Governance

Project activities will be overseen by a Steering Committee, constituted per the Steering Committee Charter. Steering Committee members will be DIA members.

Code of conduct

This is a DIA DRM Community supported initiative and it is important that this group abides by the bylaws of the DIA. Therefore, the attention of participants is drawn to the non-commercial nature of this forum. 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 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.

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