

# Project Charter

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## Review, Testing, and Ratification of the eTMF Exchange Mechanism Standard, Version 1

Prepared by The Exchange Mechanism Standard Subgroup of the TMF Reference Model Group

04-MAY-2018

### Version History

Version	Date	Description of change
1.0	04-May-2018	Initial draft updated following TMF RM Steering Committee review.

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## Project Title

Review, Testing, and Ratification of the eTMF Exchange Mechanism Standard, Version 1

## Scope

The scope of the project is defined as follows:

- The scope of work for this project is to govern the review and testing process for Version 1 of the Specification.
- The scope of vendor reviewers for Version 1 is limited to companies that develop and sell eTMF products.
- The scope of this project excludes any work to create or review future versions.
- The scope of business cases for Version 1 will be defined in the Exchange Mechanism Standard Specification, which will be found on the Trial Master File Reference Model website <https://tmfrefmodel.com/> after its release.

## Objectives

The project team will work to achieve the following general objectives:

- Obtain ratification by the TMF Reference Model Steering Committee of the first version of the eTMF Exchange Mechanism Standard.
- Gain industry acceptance and commitment to using the standard.

Specific objectives in support of the general objectives include the following:

- Ensure the Specification and XML standards are reviewed and all questions and queries resolved.
- Ensure there is no conflict with the work of any other TMF RM subgroup.
- Achieve alignment with vendors' standard product offerings.
- Ensure that the standard meets business needs:
  - Ensure that business scenarios and related standard data sets are developed by sponsors and CROs.
  - Encourage vendors to develop product features to consume and/or generate the standard data sets.
  - Ensure that business scenarios are tested by vendors.

## Constraints and Assumptions

The volunteers who will perform the work of the project will typically have full-time work responsibilities that could conflict with their duties on the project.

Volunteers will provide estimates for time-to-completion of the tasks that are accurate and realistic within the context of their responsibilities to their employers.

## Risks and Issues

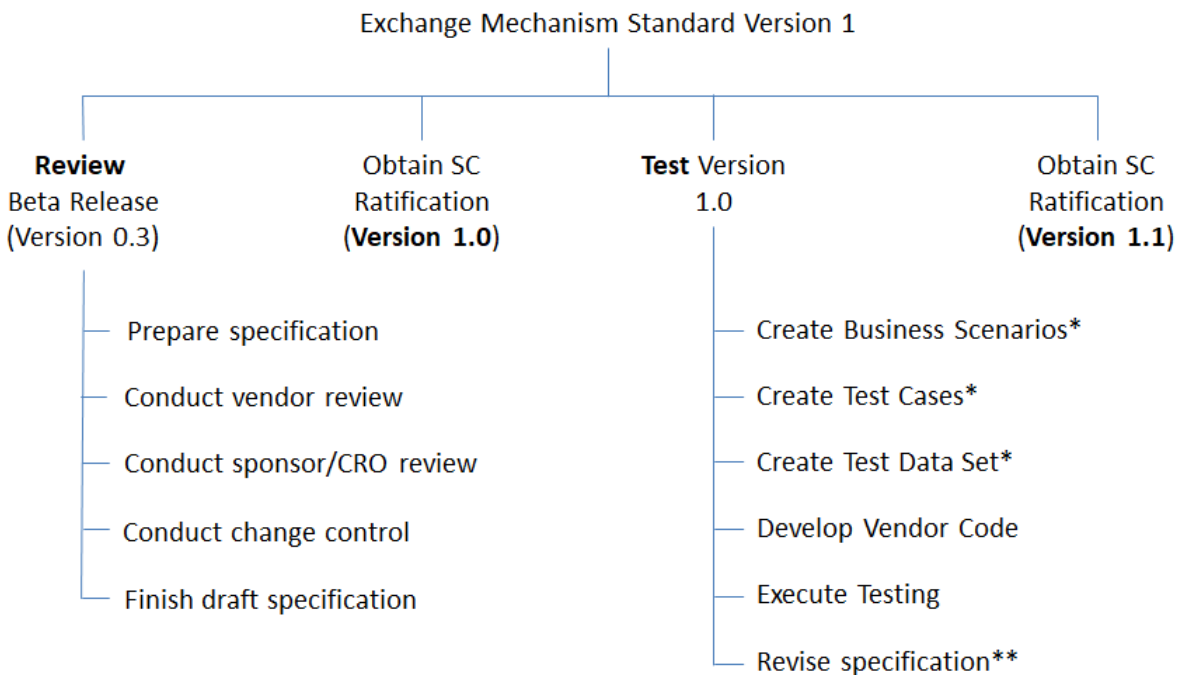
The following risks are known at this time:

- Significant rework could be required to satisfy the concerns expressed by reviewers.
- Managing scope could be challenging, given the diversity and large number of reviewers.
- A significant effort may be required to transfer existing knowledge to many new stakeholders.
- Some vendors may prefer other existing standards.

No issues have been identified.

## The Review Process

The following Work Breakdown Structure represents the major phases of the project:



\*Activities that could be done in parallel with the review

\*\*Revised specification will include addenda to clarify use cases and to list use cases for future consideration

Preparation for ratification of version 1.0 and version 1.1 of the Exchange Mechanism Standard by the TMF Reference Model Steering Committee will proceed as follows:

- Ratification of Version 1.0
  - The project team will resolve remaining outstanding comments on the existing draft specification and freeze the document as the Beta Release of the standard.
  - A Vendor Coordination Lead will conduct a review of the specification by vendors.
  - A Business Coordination Lead will conduct a review of the specification by sponsors and CROs.

- The project team will analyze comments and questions provided by vendor and sponsor/CRO reviewers and will determine what changes are required for Version 1.0.
- The project team will incorporate these changes into a draft specification which it will submit for ratification by the Steering Committee.
- The project team will ask the Steering Committee to publish the ratified draft as Version 1.0 of the Exchange Mechanism Standard Specification.
- Ratification of Version 1.1
  - Volunteer sponsor and CRO representatives will assist the project team in creating business scenarios on which to base test cases for testing the standard.
  - Volunteer sponsor and CRO representatives will assist the project team in creating the test cases.
  - Volunteer sponsor and CRO representatives will assist the project team in creating the set of data to be used in executing the test cases.
  - Each vendor will develop the version of code the vendor will use to execute testing.
  - Vendors will test the standard and document test results for the project team.
  - A Change Control Lead will follow a process to govern the review and approval of proposed changes resulting from analyses of test results.
  - The project team will incorporate approved changes into the specification for submission to the Steering Committee as Version 1.1 of the Exchange Mechanism Standard Specification.

## Milestones and Deliverables

The Project Management Lead will establish a project plan baseline no later than September 22, 2017. The plan will include a description of work activities, schedule, resource assignments, risk management plan, change control plan, and communications plan.

The team aspires to complete ratification of the standard before the 2018 DIA Annual Meeting. The following projections are subject to change when the project plan is baselined:

<b>Milestone</b>	<b>Projected Completion</b>
Review EMS Version 0.3	2018 Q2
Obtain Steering Committee Ratification of Version 1.0	2018 Q2
Publish Version 1.0	2018 Q2
Test EMS Version 1.0	2019 Q1
Create appendix with clarification of use cases supported under Version 1	2019 Q1
Create appendix listing use cases to be considered for future versions	2019 Q1
Obtain Steering Committee Ratification of Version 1.1	2019 Q1
Publish Version 1.1	2019 Q1

## Project Organization

The project sponsor is the TMF Reference Model Steering Committee.

The project core team has defined the roles of its members at <https://drive.google.com/open?id=1-ckKLVsxt5-Aeg3yBcjmXCTJNgaA8KI4SPec9i1z000>.

Reviewers of the Exchange Mechanism Standard may represent any of the following types of organizations:

- Vendor reviewers represent companies that offer a commercial eTMF product.
- Business reviewers represent any of the following entities:
  - Sponsor or CRO companies,
  - Industry consulting firms, or
  - Other TMF Reference Model project subgroups.

## Staffing Authority and Responsibilities

The Project Management Lead will conduct the following activities to maintain project team staffing:

- Facilitate the definition of team roles by current team members.
- Recruit and fill roles through a process that allows current team members to review candidates.

The Vendor Coordination Lead will be responsible for recruiting vendor reviewers.

The Business Coordination Lead will be responsible for recruiting business reviewers.

## Communication Plan

The Communication Plan identifies and describes each type of communication, its frequency, distribution media, audience, and the owner responsible for issuing each type of communication [https://drive.google.com/open?id=1\\_LnKe4f747VGFAPomw1uqSqGSYypciBCNtvZC4RpJA](https://drive.google.com/open?id=1_LnKe4f747VGFAPomw1uqSqGSYypciBCNtvZC4RpJA).

## Change Control Process

Processes for controlling changes to the standard will align with the TMF Reference Model Change Control process.

## Approvals

Work already begun by the Exchange Mechanism Standard subgroup may continue throughout the approval process. Approval of the Charter by the Co-Chairs and Project Management Lead will be sufficient to establish and execute a baseline project plan before receiving approval by the Steering Committee Chair. The Charter and project plan would be subject to change control if approval by the Steering Committee Chair were to become contingent on one or more proposed changes.

## Glossary

### List of Acronyms

Acronym	Definition
CRO	Clinical Research Organization
DIA	Drug Information Association
eTMF	An electronic implementation of a trial master file.
TMF	Trial Master File

### Terms and Definitions

Acronym	Definition
Standard	A formal document that establishes uniform engineering or technical criteria, methods, processes and practices.
Specification	An explicit set of requirements to be satisfied by a material, product, or service.