TRIAL MASTER FILE
TMF
REFERENCE MODEL

Version Control Policy

v1.1

Approval Date 14-FEB-2018

This document is freely distributable

Identification

Authors

Name	Organization	Title
Eldin Rammell	Rammell Consulting Ltd	Managing Director

Contributing Team Members

Name	Organization	Title
Lisa Mulcahy	Mulcahy Consulting, LLC	Principal Consultant
Karen Roy	Phlexglobal Ltd	Snr V-P, Client Solutions
Kathie Clark	Wingspan Technology	V-P, Product Management
Karin Schneider	Janssen R&D	Doc Mngt Enablement Head
Todd Tullis	Veeva Systems	Director, Product Management
Jamie Toth	Daiichi Sankyo	Director TMF Operations
Marie-Christine Poisson	Pfizer Inc	Head TMF Operations
Mike Czaplicki	GlaxoSmithkline	Clinical Documentation Operations Manager

Version History

Version	Steering Committee Approval Date	Changes
1.0	19-Apr-2017	N/A
1.1	14-Feb-2018	Requirement for version date to be in a specific format. Text added to clarify numbering of artifacts

Table of Contents

1 Introduction

This document describes the policy that will be followed by the TMF Reference Model Project to ensure all that the TMF Reference Model has appropriate version control.

2 Policy

2.1 Document dates

The author of the document will ensure that the date on which the document was created or revised is identified on the identification page and, when possible, is incorporated into the footer of the document, using the format dd-mmm-yyyy.

2.2 Version number

The author of the document will ensure the current version number is included on the identification page and, when possible, is incorporated into the footer of the document. The version number will also appear on the version history page. The first final approved version of a document will be version 1.0.

2.3 Numbering of revisions

Sequence-based identifiers will be used to indicate the significance of changes between releases of the TMF Reference Model. The Reference Model will use a three-sequence identifier as follows:

2.3.1 Major releases

The major number of the release (i.e. v**1**.0.0, v**2**.0.0, v**3**.0.0, etc) will be incremented when there is a substantial change in the content of the Reference Model which could cause incompatibility with the previous version and/or technical changes to implement the new version for electronic TMF solutions. Examples of changes that would require a major release include:

- Addition of artifacts
- Removal of artifacts
- Attribute deletions that are likely to cause incompatibility issues with prior versions

2.3.2 Minor releases

The first decimal number of the release (e.g. v3.**1**.0, v3.**2**.0, v3.**3**.0, etc) will be incremented when there is a substantial change in the content of the Reference Model but the change is

unlikely to cause incompatibility issues for those companies who have already adopted an earlier version. Examples of changes that would require a minor release include:

- Inclusion of an additional optional element to the Model e.g. milestones
- Changes to the alignment of artifacts with filing level (study, country and site)
- Attribute updates or attribute additions
- Attribute deletions that are unlikely to cause incompatibility issues

2.3.3 Maintenance releases

The second decimal number of the release (e.g. v3.0.**1**, v3.0.**2**, v3.0.**3**, etc) will be incremented when modifications are made in the Reference Model that have no significant impact on adoption or implementation of the Model. Examples of changes that would require a maintenance release include:

- Changes to the definition/purpose text that do not substantially modify the meaning e.g. additional text for clarification
- Inclusion or deletion of example sub-artifacts
- Addition or modification of regulatory guidance references
- Correction of typographical errors

2.4 Artifact Numbering

Every artifact in the TMF Reference Model is identified by an artifact number (e.g. 01.01.01) and a unique ID number (e.g. 001). To ensure ease of adoption of the TMF Reference Model between subsequent versions, the following principles will be followed for use of artifact number and unique ID number:

- If an artifact is **removed** from the TMF Reference Model, the corresponding artifact number and unique ID number will be removed from the Model and will not be used again in any future version of the Model. The version history and release notes will describe the consequent gap in artifact numbering and unique ID numbering.
- If an artifact is **added** to the TMF Reference Model, the new artifact will be assigned the next highest artifact number within the corresponding zone and section and the next highest unique ID number that has not been used previously in the Model. Artifact numbers and unique ID numbers that have previously been used will not be re-assigned.
- If an artifact is **moved** to a different section or to a different zone, the artifact will be assigned a new artifact number following the rule above for a new artifact. The unique ID number will remain the same.
- If any other property of an artifact changes (e.g. the artifact name), the artifact number and unique ID number will not change so long as the purpose and definition of the artifact remains substantially unchanged i.e. it is essentially the same artifact. If the change in properties is sufficiently significant that the artifact is considered a different artifact (e.g. a single artifact is split into two artifacts), the original artifact will be

considered to have been removed and one or more new artifacts created. In these circumstances, the rules above for removal and addition of artifacts will be followed.

2.5 Timing of changes

In an effort to minimize change impact, the updates to the TMF Reference Model will be bundled to reduce the number of releases. There are likely to be many factors that impact on the need to make changes but the following principles will apply:

There should be:

- no more than one Major release per year;
- no more than two Minor releases per year; and
- no more than four Maintenance Releases per year.

Apart from a complete review of the TMF Reference Model every other year, releases are demand driven, hence not on a set rollout schedule.

2.6 Documenting changes

A list of changes from the previous final document will be kept and included as a section in the new version. Where appropriate, this will include a rationale for the change(s).

2.7 Maintaining version history

The website administrator will be responsible for ensuring that new versions of the TMF Reference Model that have been approved by the Steering Committee are made available on the TMF Reference Model website (http://tmfrefmodel.com) in a timely manner and remain available and accessible.