Version Control Policy

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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

Version History

Version	Steering Committee Approval Date	Changes
1.0	19-Apr-2017	N/A

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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.

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. v1.0.0, v2.0.0, 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 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.

2.5 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).

2.6 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.