



Release Notes v3.3.1

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Identification

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Version History

Version	Steering Committee Approval Date	Changes
3.3	31-MAR-2023	Updated definitions/artifacts to include mention of Device trials; Added ISO 14155 References
3.3.1	11-AUG-2023	Corrected typographical errors; clarified where to file co-monitoring visit reports

Table of Contents

1	Introduction	5
2	General Changes	6
3	Changes to Artifact Definitions	7
4	Changes to Document Level	8
6	New Sub-artifacts	9

1 Introduction

These Release Notes relate to TMF Reference Model v3.3.1, the first maintenance update to TMF Reference Model v3.3, which was released in March 2023.

A maintenance update is defined as modifications made to 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 General Changes

This maintenance release of the TMF Reference Model is intended to provide clarification for filing co-monitoring visit reports as well as correct typographical errors.

3 Changes to Artifact Definitions

Artifact 01.01.08 Monitoring Plan

Previous text	New text
<p>To describe how monitoring will be implemented during the trial, including strategy for source data verification and risk based monitoring (if applicable). Artifact can include any trial level evidence of plan execution including, but not limited to: plan, reports, checklists, etc. Note: Individual Monitoring Visit Reports are filed in zone 5.</p>	<p>To describe how monitoring will be implemented during the trial, including strategy for source data verification and risk based monitoring (if applicable). Artifact can include any trial level evidence of plan execution including, but not limited to: plan, reports, checklists, etc. Note: Individual Individual Monitoring Visit Reports are filed in zone 5.</p>
<p>Reason for change:</p> <p>To fix a typographical error</p>	

Artifact 01.04.04: Trial Team Evidence of Training

Previous text	New text
<p>To document completion of study-specific trial team training, including certification or evidence of training (attendance sheets). Includes EDC training. Does not include each individual's education, training and experience to perform his/her role. This should be documented in the company learning management system.</p>	<p>To document completion of study-specific trial team training, including certification or evidence of training (attendance sheets). Includes EDC training. Does not include each individual's education, training and experience to perform his/her role. This should be documentated documented in the company learning management system.</p>
<p>Reason for change:</p> <p>To fix a typographical error</p>	

4 Changes to Document Level

Not applicable

5 New Sub-artifacts

New Sub-artifacts identified in red.

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.	Reason for Change
05.04.05	Additional Monitoring Activity	Additional Monitoring Activity Non-Routine Visit Report Non-Routine Visit Report Confirmation Letter Non-Routine Visit Report Follow Up Letter Oversight Monitoring Visit Report Oversight Monitoring Visit Report Confirmation Letter Oversight Monitoring Visit Report Follow Up Letter Site Improvement Plan Co-Monitoring Visit Report	To clarify where co-visits are filed

6 Additional Changes

The following additional changes were made in order to correct typographical errors.

Artifact # or Item	Artifact/Item name	Change made	Reason for Change
05.03.02	Site Training Material	Sub-artifact correction – Device Maintenance Documents	Correct typographical error
Glossary	IIS	“D is dependent”	Correct typographical error