



Release Notes v3.2.1

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Identification

Authors

Name	Organization
Joanne Malia	Regeneron Pharmaceuticals

Contributing Change Control Board Members

Name	Organization
Kelley Robinson	Odonate Therapeutics
Kristen Bretzius	Syneos Health
Gift-Tafadzwa Chareka	UZ-UCSF-Collaborative Research
JP Miceli	Advanced Clinical
Kate Santoro	bluebird bio
Laurel Ann Schrader	Transperfect Translation
Melissa Maberry	Veeva
Ashley Villa	Theradex Oncology
Katherine Firth	GSK
Allison Grosik	LMK Clinical Research Consulting
Carla Calitri	PRA Health Sciences
Mary Ann Brooks	Baxter Healthcare

Leila Ponce	Seattle Genetics
Jennifer Eberhardt	Sarepta Therapeutics
Noreen Bouchard	Astellas

Version History

Version	Steering Committee Approval Date	Changes
1.0	10FEB2021	N/A

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1 Introduction

These Release Notes relate to TMF Reference Model v3.2.1, the first maintenance update to TMF Reference Model v3.2. Version 3.2.0 was released in November 2020.

A maintenance release is defined as 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, as sub-artifacts are specific to a Company's needs and are not utilized globally
- Addition or modification of regulatory guidance references
- Correction of typographical errors

2 General Changes

The 3.2.0 version of the TMF Reference Model included extensive updates to the sub-artifacts column (column I). These recommendations, or suggestions, are intended to assist companies in more readily using the Zone > Section> Artifact taxonomy of the TMF Reference Model.

An inconsistency within the sub-artifacts has been raised as in some cases it appears that the sub-artifacts refer to individual documents whereas others may refer to general “buckets” of sub-artifacts along with individual documents.

The TMF Reference Model is a model and should be modified as needed by the companies using the model. It is recommended that companies need to select the sub-artifacts they want and may need to modify them to make them more applicable to their organization.

3 Maintenance Clarifications

Artifact Number	Artifact Name	Change
01.01.11	Debarment Statement	Trial level milestone updated to 02 Clinical Infrastructure Ready
01.03.01	Committee Process	Removed strike through
01.01.08	Monitoring Plan	Milestone added - 03 Site Live /Ready /Open for Enrolment
10.05.02	Tracking information	X added to country column
2.1.10	Report of Prior Investigations	RPI spelled out as Report of Prior Investigations
2.2.3	Informed Consent Form	Removed duplicate summary of change
3.1.2	Regulatory Authority Decision	Corrected wording to “conditional approval”