eTMF Exchange Mechanism

Release Notes r19.3.2

Approval Date 25-Oct-2019

Identification

Authors

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Version History

Version	Release Date	Change Requests
19.3.2	25-OCT-2019	CR: 11 and 12

Table of Contents

1 Introduction

These Release Notes relate to changes and updates to the Specification for the eTMF Exchange Mechanism Standard (eTMF-EMS), with a minor release 19.3.2.

A minor update is defined as a release, for which there is no substantial change to the specification, and the changes are unlikely to cause incompatibility issues with the previous releases of the EMS and/or there are no significant technical changes to implement the update for electronic TMF solutions.

Examples of changes that would require a minor release include:
- Bug changes
- Changes to the alignment of artifacts with filing level (study, country and site)

This minor release also includes maintenance changes, defined as no significant impact on adoption or implementation of the Specification. Examples of changes that would require a maintenance release include:
- Exchange process
- eTMF Exchange agreement
- Correction of typographical errors

An outline of the release process and release plan are detailed under sections 3 and 4 and the link to the changes incorporated in the current release are under section 5.
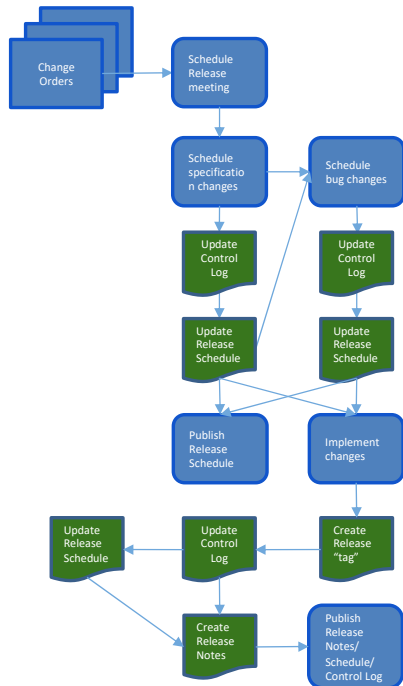
2 Context

The specification of the eTMF Exchange Mechanism Standard was created to bridge an existing gap by enabling easy transfer of eTMF documents between key stakeholders. The specification is an organic document that will go through changes to improve the exchange process and comply with evolving standards. Details on scope and purpose of the EMS can be found in *Specification for the eTMF Exchange Mechanism Standard (eTMF-EMS) Version: 1.0.1 25-Oct-2019*, https://tmfrefmodel.com/resources

3 EMS RELEASE PROCESS

A layout of the release steps:

Release Process

- **Schedule release meeting**
  - If there is no or few Change orders this can be done by email
- Schedule specification changes
  - Negotiate when different specification changes should be implemented
- Schedule bug changes
  - Negotiate when different bug changes should be implemented
    - There is no need to hold a bug to a later release, as there is no requirement for a vendor to take a release. Testing can be bulk.
  - Assign change to develope.
- **Implement changes**
  - Implement specification changes
  - Implement XML/XSD changes
    - If specification changes are made, wait for approval
    - Create Release "tag"
    - Update Control Log and Release Schedule
- **Create release notes**
  - Include changes, known issues and link to Release Schedule
  - Afer review publish Release Notes, Schedule and Control Log

4 EMS Release Plan for 2019 (missing GitHub hash)

Bug release date	Release type	Development name	XSD version	Specification version	Github hash	Release version
6/14/2018	Initial		1.0	1.0	1124ec3	1.0
6/21/2018	Bug		1.0.01	Pending	9b6e259	1.0.01
1/11/2019	Bug	18.4.1				No release
1/25/2019	Bug	18.4.2				No release
2/8/2019	Bug	18.4.3				No release
2/22/2019	Bug	18.4.4				No release
3/8/2019	Bug	18.4.5				No release
3/29/2019	Major/Bug	19.1				No release
4/12/2019	Bug	19.1.1				No release
4/24/2019	Bug	19.1.2				No release
5/6/2019	Bug	19.1.3				No release
5/18/2019	Bug	19.1.4				No release
5/30/2019	Bug	19.1.5	19.1.5	1.0	5350831	19.1.5
6/28/2019	Major/Bug	19.2				No release
7/12/2019	Bug	19.2.1				No release
7/26/2019	Bug	19.2.2				No release
8/9/2019	Bug	19.2.3				No release
8/23/2019	Bug	19.2.4				No release
9/6/2019	Bug	19.2.5				No release
9/27/2019	Major/Bug	19.3				No release
10/11/2019	Bug	19.3.1				No release
10/25/2019	Bug	19.3.2	19.3.2	1.0.1	04acda7	19.3.2
11/8/2019	Bug	19.3.3				
11/22/2019	Bug	19.3.4				
12/6/2019	Bug	19.3.5				
12/27/2019	Major/Bug	19.4				
1/10/2020	Bug	19.4.1				
1/24/2020	Bug	19.4.2				
2/7/2020	Bug	19.4.3				
2/21/2020	Bug	19.4.4				
3/6/2020	Bug	19.4.5				
3/27/2020	Major/Bug	19.5				

5   General and Bug Changes in the Release 19.3.2

All change requests (CR) in this release are detailed in the table extracted from the EMS Change Control Log below.

CR#	Change Request Description	Link to the issue
11	Schema should have the ability to contain several <SIGNATURE> tags per <FILE> tag Currently, the <FILE> tag may have only one <SIGNATURE> tag. An option is necessary to allow multiple <SIGNATURE> tags, that is one tag for each time a file is signed. Please see #21	https://github.com/TmfRef/exchange-framework/issues/20
12	Interim version for testing, involving the following changes: • Section 5.3.3: Removed the attribute CHKSUMSTD. • Section 5.3.5: Capitalized the initial character of every allowed value of AUDITENTRYTYPE in order to be consistent with the allowed value formats of other attributes. • Section 2: Changed: ● Exchange.xsd ○ Schema for validation of XML format (currently in development) to: ● Exchange.xsd ○ Schema for validation of XML format and added a hyperlink to "Schema for..." pointing to the 1.0.1 version of the XML schema in GitHub.	https://docs.google.com/document/d/1HoWSullCENxEUdr3R8is8qXZSOSXG__GpDs5jDWkYG4/edit#