eTMF Exchange Mechanism

Release Notes r22.1

Approval Date 17-January-2022

Identification

Authors

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Version History

Version	Release Date	Change Requests
1.0	14-JUN-2018	Original version
19.1.5	30-MAY-2019	CR: 3, 4, 6, 7, 8, 9, 10
19.3.2	25-OCT-2019	CR: 11 and 12
22.1	21-JAN-2022	CR: 13

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6 Introduction

These Release Notes relate to changes and updates to the Specification for the eTMF Exchange Mechanism Standard (eTMF-EMS), with a minor release 22.1

A minor update is defined as a release, which has no substantial change to the specification, and the changes are unlikely to cause incompatibility issues with the previous releases of the EMS and/or 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.
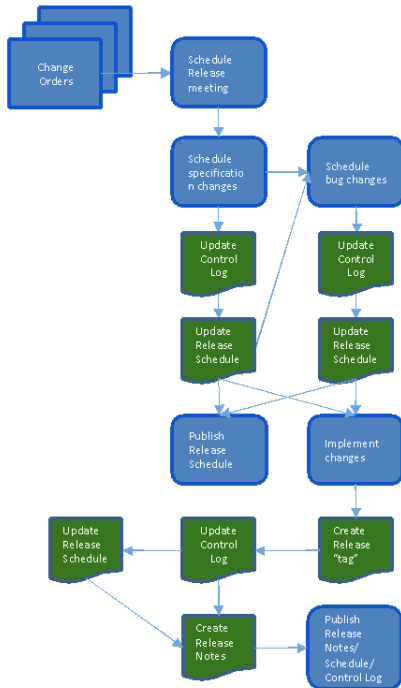
7 Context

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: 1.0.2 21-Jan-2022* https://tmfrefmodel.com/download/4329/.

8 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

9 EMS Release Plan for 2022

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
5/30/2019	Bug	19.1.5	19.1.5	1.0	5350831	19.1.5
10/25/2019	Bug	19.3.2	19.3.2	1.0.1	04acda7	19.3.2
1/21/2022	Major/Bug	22.1	22.1	1.0.2	52c1fff	22.1
2/4/2022	Bug	22.1.1				
2/18/2022	Bug	22.1.2				
3/4/2022	Bug	22.1.3				
3/18/2022	Bug	22.1.4				
4/1/2022	Bug	22.1.5				
4/15/2022	Major/Bug	22.2				
4/29/2022	Bug	22.2.1				
5/13/2022	Bug	22.2.2				
5/27/2022	Bug	22.2.3				
6/10/2022	Bug	22.2.4				
6/24/2022	Bug	22.2.5				
7/8/2022	Major/Bug	22.3				
7/22/2022	Bug	22.3.1				
8/5/2022	Bug	22.3.2				
8/19/2022	Bug	22.3.3				
9/2/2022	Bug	22.3.4				
9/16/2022	Bug	22.3.5				
9/30/2022	Major/Bug	22.4				
10/14/2022	Bug	22.4.1				
10/28/2022	Bug	22.4.2				
11/11/2022	Bug	22.4.3				
11/25/2022	Bug	22.4.4				
12/9/2022	Bug	22.4.5				

10 General and Bug Changes in the Release 22.1

The change request (CR) in this release is detailed in the table extracted from the EMS Change Control Log below.

CR#	Change Request Description	Link to the issue
13	Section 5.3.1: For Attribute ID change Attribute format to "Each dot-delimited component, x, y, or z, can have either one or two numeric digits. If there are two digits, the first digit can go from 1 to 9, and the second can go from 0 to 9. If there is one digit in the component, it can go from 0 to 9."	https://github.com/TmfRef/exchange-framework/pull/24