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Electronic Trial Master File (eTMF) Specification V1.0 public review ends September 23rd

Submitted by censign on Thu, 2016-09-08 22:01

Type:

Public Review

The OASIS Electronic Trial Master File (eTMF) Standard TC members [1] have produced an updated Committee Specification Draft (CSD) and submitted this specification for 15-day public review:

Electronic Trial Master File (eTMF) Specification Version 1.0
Committee Specification Draft 02 / Public Review Draft 02
08 August 2016

Specification Overview:

The OASIS eTMF Specification publishes details of an interoperable content classification system with rules, policies and procedures for how electronic content can be shared and customized for clinical trials. Machine readable, open standards-based technologies are used in a vendor neutral approach.

This version incorporates over 800 comments from previous public review and provides compatibility with TMF Ref Model V3. TMF Ref Model terms have been reviewed, assigned controlled vocabulary IDs and have been published by the National Cancer Institute's Enterprise Vocab Services for free use in this work by any organization.

We welcome industry feedback and participation in the refinement of this proposed standard.

TC Description:

The Oasis eTMF Standard Technical Committee is chartered to define open technologies for clinical trial master file content interoperability and data exchange that will enable safe and rapid delivery of drug and device therapies globally.

For more information, see the TC Charter and FAQ.

Public Review Period:

The public review starts 09 September 2016 at 00:00 UTC and ends 23 September 2016 at 11:59 UTC. The specification was previously submitted for public review [2]. This 15-day review is limited in scope to changes made from the previous review. Changes are highlighted in the red-lined copy of the spec at <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02-DIFF...> [1].

This is an open invitation to comment. OASIS solicits feedback from potential users, developers and others, whether OASIS members or not, for the sake of improving the interoperability and quality of its technical work.

Reviewers may provide comments directly from the comment-tag version of document. The file

[etmf-v1.0-csprd02-COMMENT-TAGS.html](#)

contains the HTML version of the draft with a [?\[comment?\]?](#) link next to each section heading. Clicking on this link will launch your email application and begin a message to etmf-comment@lists.oasis-open.org [2] with the specific section number and title in the subject line. Simply enter your comment and click send.

Note that you must be subscribed to the comment mailing list before sending feedback. Instructions on how to subscribe can be found at https://www.oasis-open.org/committees/comments/index.php?wg_abbrev=etmf [3].

URIs:

The prose specification document and related files are available here:

Editable source (Authoritative):

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02.docx> [4]

HTML:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02.html> [5]

HTML with in-line commenting:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02-COMM...> [6]

PDF:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02.pdf> [7]

Schema:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/schema/OASIS-eTMF-V3-S...> [8]

Vocabulary:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/vocabulary/OASIS-eTMF-...> [9]

ZIP distribution files (complete):

For your convenience, OASIS provides a complete package of the prose specification and related files in a ZIP distribution file. You can download the ZIP file here:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02.zip> [10]

Additional information about the specification and the OASIS Electronic Trial Master File (eTMF) Standard TC can be found at the TC's public home page:

<https://www.oasis-open.org/committees/etmf/> [11]

Comments may be submitted to the TC by any person through the use of the OASIS TC Comment Facility which can be used by following the instructions on the TC's "Send A Comment" page, or directly at:

https://www.oasis-open.org/committees/comments/index.php?wg_abbrev=etmf [3]

Comments submitted by TC non-members for this work and for other work of this TC are publicly archived and can be viewed at:

<https://lists.oasis-open.org/archives/etmf-comment/> [12]

All comments submitted to OASIS are subject to the OASIS Feedback License, which ensures that the feedback you provide carries the same obligations at least as the obligations of the TC members. In connection with this public review of "Electronic Trial Master File (eTMF) Specification Version 1.0", we call your attention to the OASIS IPR Policy [3] applicable especially [4] to the work of this Technical Committee. All members of the TC should be familiar with this document, which may create obligations regarding the disclosure and availability of a member's patent, copyright, trademark and license rights that read on an approved OASIS specification.

OASIS invites any persons who know of any such claims to disclose these if they may be essential to the implementation of the above specification, so that notice of them may be posted to the notice page for this TC's work.

===== Additional references:

[1] OASIS Electronic Trial Master File (eTMF) Standard TC
<http://www.oasis-open.org/committees/etmf/> [13]

[2] Previous public reviews:

45-day public review, 24 June 2016:

<https://lists.oasis-open.org/archives/members/201406/msg00014.html> [14]

- Comment resolution log:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd01/etmf-v1.0-csprd01-comm...> [15]

[3] <http://www.oasis-open.org/policies-guidelines/ipr> [16]

[4] <http://www.oasis-open.org/committees/etmf/ipr.php> [17]

<https://www.oasis-open.org/policies-guidelines/ipr#Non-Assertion-Mode> [18]

Non-Assertion Mode

Associated TC:

etmf

Deadline:

Thu, 2016-09-08 - Fri, 2016-09-23

Links:

[1] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02-DIFF.pdf>

[2] <mailto:etmf-comment@lists.oasis-open.org>

- [3] https://www.oasis-open.org/committees/comments/index.php?wg_abbrev=etmf
- [4] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02.docx>
- [5] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02.html>
- [6] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02-COMMENT-TAGS.html>
- [7] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02.pdf>
- [8] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/schema/OASIS-eTMF-V3-Schema-201607.xlsx>
- [9] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/vocabulary/OASIS-eTMF-V3-NCI-Vocab-201607.xlsx>
- [10] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02.zip>
- [11] <https://www.oasis-open.org/committees/etmf/>
- [12] <https://lists.oasis-open.org/archives/etmf-comment/>
- [13] <http://www.oasis-open.org/committees/etmf/>
- [14] <https://lists.oasis-open.org/archives/members/201406/msg00014.html>
- [15] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd01/etmf-v1.0-csprd01-comment-resolution-log.xls>
- [16] <http://www.oasis-open.org/policies-guidelines/ipr>
- [17] <http://www.oasis-open.org/committees/etmf/ipr.php>
- [18] <https://www.oasis-open.org/policies-guidelines/ipr#Non-Assertion-Mode>