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# Electronic Trial Master File (#eTMF) Specification V1.0 published by the eTMF TC

Submitted by censign on Wed, 2016-11-16 15:22

**Type:**

TC Administration announcements

OASIS is pleased to announce the approval and publication of a new Committee Specification by the members of the OASIS Electronic Trial Master File (eTMF) Standard TC:

Electronic Trial Master File (eTMF) Specification Version 1.0  
Committee Specification 01  
25 October 2016

What is eTMF and why is it important?

Clinical trials are a critical part of the development and approval of medical treatments and devices. In order to enable clinical trial stakeholders to rapidly achieve the benefits of interoperable electronic trial master file technologies, the Technical Committee is developing the Electronic Trial Master File Specification using an open architecture and technology neutral approach. The specification describes details of an interoperable content classification system with rules, policies and procedures for how electronic content can be shared and customized for clinical trials.

This Committee Specification incorporates provides compatibility with TMF Ref Model V3. The 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.

This is an OASIS deliverable, completed and approved by the TC and fully ready for testing and implementation.

About the TC:

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.

URIs:

The prose specifications and related files are available here:

Editable source (Authoritative):

<http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/etmf-v1.0-cs01.docx> [1]

HTML:

<http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/etmf-v1.0-cs01.html> [2]

PDF:

<http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/etmf-v1.0-cs01.pdf> [3]

Schema document:

<http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/schema/OASIS-eTMF-Schema-...> [4]

Metadata vocabulary:

<http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/vocabulary/OASIS-eTMF-NCI...> [5]

Distribution ZIP file

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/cs01/etmf-v1.0-cs01.zip> [6]

Members of the OASIS Electronic Trial Master File (eTMF) Standard TC [1] approved this specification by Special Majority Vote. The specification had been released for public review as required by the TC Process [2]. The vote to approve as a Committee Specification passed [3], and the document is now available online in the OASIS Library as referenced above.

Our congratulations to the TC on achieving this milestone and our thanks to the reviewers who provided feedback on the specification drafts to help improve the quality of the work.

===== Additional references:

[1] OASIS Electronic Trial Master File (eTMF) Standard TC

<https://www.oasis-open.org/committees/etmf/> [7]

[2] Public reviews:

- 45-day public review, 24 June 2016:

<https://lists.oasis-open.org/archives/members/201406/msg00014.html> [8]

- Comment resolution log:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd01/etmf-v1.0-csprd01-comm...> [9]

- 15-day public review, 09 September 2016:

<https://lists.oasis-open.org/archives/members/201609/msg00003.html> [10]

- Comment resolution log:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02-comm...> [11]

[3] Approval ballot:

<https://www.oasis-open.org/committees/ballot.php?id=3003> [12]

**Associated TC:**

etmf

**Deadline:**

Wed, 2016-11-16 - Fri, 2016-12-16

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**Links:**

- [1] <http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/etmf-v1.0-cs01.docx>
- [2] <http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/etmf-v1.0-cs01.html>
- [3] <http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/etmf-v1.0-cs01.pdf>
- [4] <http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/schema/OASIS-eTMF-Schema-201610.xlsx>
- [5] <http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/vocabulary/OASIS-eTMF-NCI-Vocab-201607.xlsx>
- [6] <http://docs.oasis-open.org/etmf/etmf/v1.0/cs01/etmf-v1.0-cs01.zip>
- [7] <https://www.oasis-open.org/committees/etmf/>
- [8] <https://lists.oasis-open.org/archives/members/201406/msg00014.html>
- [9] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd01/etmf-v1.0-csprd01-comment-resolution-log.xls>
- [10] <https://lists.oasis-open.org/archives/members/201609/msg00003.html>
- [11] <http://docs.oasis-open.org/etmf/etmf/v1.0/csprd02/etmf-v1.0-csprd02-comment-resolution-log.xls>
- [12] <https://www.oasis-open.org/committees/ballot.php?id=3003>