



Published on OASIS (<https://www.oasis-open.org>)

---

# 45-day Public Review for Electronic Trial Master File (#eTMF) Specification Version 1.0 - ends August 8th

Submitted by pknight on Wed, 2014-06-25 02:59

**Type:**

Public Review

The OASIS Electronic Trial Master File (eTMF) Standard TC [1] members have recently approved a Committee Specification Draft (CSD) and submitted it for 45-day public review:

Electronic Trial Master File (eTMF) Specification Version 1.0  
Committee Specification Draft 01 / Public Review Draft 01  
20 June 2014

**Overview:**

In order to enable clinical trial stakeholders to rapidly achieve the benefits of interoperable electronic trial master file (eTMF) systems and technologies in life sciences, the OASIS eTMF Standard Technical Committee has developed a DRAFT eTMF system specification using an open architecture and technology neutral approach. As a proposed standard built upon standards, the OASIS eTMF Model specification includes the following components:

- Prose specification,
- Metadata Vocabulary based on a controlled vocabulary from the National Cancer Institute,
- Machine readable code using RDF/XML.

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 25 June 2014 at 00:00 GMT and ends 08 August at 23:59 GMT.

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.

URIs:

The prose specification document and related files are available here:

PDF (Authoritative):

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd01/etmf-v1.0-csprd01.pdf> [1]

HTML:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd01/etmf-v1.0-csprd01.html> [2]

Editable source:

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd01/etmf-v1.0-csprd01.doc> [3]

ZIP distribution file (complete):

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

<http://docs.oasis-open.org/etmf/etmf/v1.0/csprd01/etmf-v1.0-csprd01.zip> [4]

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/> [5]

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](https://www.oasis-open.org/committees/comments/index.php?wg_abbrev=etmf) [6]

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/> [7]

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 [2] applicable especially [3] 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

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

[5]

[2] <https://www.oasis-open.org/who/intellectualproperty.php> [8]

[3] <https://www.oasis-open.org/committees/etmf/ipr.php> [9]

<https://www.oasis-open.org/policies-guidelines/ipr#s10.3> [10]

Non-Assertion Mode

### **Additional info:**

Additional Public Review information provided by the TC:

OWL RDF/XML code:

- The namespace for the eTMF OWL RDF/XML code will change in future releases
- Code is draft only, not for production
- To view the eTMF OWL RDF/XML machine code, it's very helpful to use the free open source program Protégé. Protégé may be downloaded for free at: <http://protege.stanford.edu> [11]

OASIS eTMF Metadata Vocabulary Spreadsheet:

- Terms have been sourced from a wide variety of sources, including BRIDG, CareLex, Dublin Core, HL7, NCI, TMF Reference Model.
- Where possible, cross-reference terms are mapped to the TMF reference model.
- Items marked in pink highlight are terms that are in review by the OASIS eTMF Standard TC.

### **Associated TC:**

etmf

### **Deadline:**

Wed, 2014-06-25 - Fri, 2014-08-08

---

### **Links:**

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

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

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

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

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

[6] [https://www.oasis-open.org/committees/comments/index.php?wg\\_abbrev=etmf](https://www.oasis-open.org/committees/comments/index.php?wg_abbrev=etmf)

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

[8] <https://www.oasis-open.org/who/intellectualproperty.php>

[9] <https://www.oasis-open.org/committees/etmf/ipr.php>

[10] <https://www.oasis-open.org/policies-guidelines/ipr#s10.3>

[11] <http://protege.stanford.edu>