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Call for Participation: OASIS Electronic Trial Master File (#eTMF) Standard TC

Submitted by censign on Mon, 2013-11-18 17:55
Type:
Call for Participation

A new OASIS technical committee is being formed. The OASIS Electronic Trial Master File (eTMF) Standard Technical Committee (TC) has been proposed by the members of OASIS listed in the charter below. The TC name, statement of purpose, scope, list of deliverables, audience, IPR mode and language specified in the proposal will constitute the TC's official charter. Submissions of technology for consideration by the TC, and the beginning of technical discussions, may occur no sooner than the TC's first meeting.

The eligibility requirements for becoming a participant in the TC at the first meeting are:

(a) you must be an employee or designee of an OASIS member organization or an individual member of OASIS, and

(b) you must join the Technical Committee, which members may do by using the Roster "join group: link on the TC's web page at [a].

To be considered a voting member at the first meeting:

(a) you must join the Technical Committee at least 7 days prior to the first meeting (on or before 09 December 2013); and

(b) you must attend the first meeting of the TC, at the time and date fixed below (16 December 2013).

Participants also may join the TC at a later time. OASIS and the TC welcomes all interested parties.

Non-OASIS members who wish to participate may contact us about joining OASIS [b]. In addition, the public may access the information resources maintained for each TC: a mail list archive, document repository and public comments facility, which will be linked from the TC's public home page at [c].

Please feel free to forward this announcement to any other appropriate lists. OASIS is an open standards organization; we encourage your participation.

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[a] https://www.oasis-open.org/apps/org/workgroup/etmf/ [1]

[b] See http://www.oasis-open.org/join/ [2]

[c] http://www.oasis-open.org/committees/etmf/ [3]

?CALL FOR PARTICIPATION?
OASIS eTMF Standard Technical Committee Charter

The charter for this TC is as follows.

(1) Proposal for OASIS Electronic Trial Master File (eTMF) Standard TC

(1) (a) Name of the TC

OASIS Electronic Trial Master File (eTMF) Standard Technical Committee (TC)

(1) (b) Statement of Purpose

The purpose of the OASIS eTMF Standard Technical Committee (TC) is to define machine readable formats for clinical trial master file content interoperability and data exchange to include:

1) An eTMF content classification model comprised of a standards-based vocabulary and content classification ontology;

2) A set of eTMF content classification rules and policies;

3) An eTMF Data Model and format for the interoperable exchange of electronic trial master file information for the clinical trials domain, whereby eTMF content can be exchanged through either cloud or physical media and viewed online or offline in web browsers.

Problem to be solved:

As clinical trial stakeholder organizations seek to move from paper-based record-keeping to electronic approaches, information interoperability, information standards and agency compliance are key factors in accelerating the safe delivery of therapies to patients globally.

In order to move clinical trial content from paper-based approaches to automated electronic content management systems (CMS), a standardized, machine-readable content classification system with a standards-based, controlled vocabulary is needed. For those with access to CMS systems, a method to exchange content via cloud services is needed. For those without access to CMS systems, a method to exchange, view and navigate content offline is needed. Today there is no standard that defines how eTMF data (content items such as documents, images, and record data) should be formatted for electronic exchange. To maximize interoperability, an open systems approach that is operating system independent, software application independent and computer language independent is required. Finally, any system must support government agency requirements that help raise the effectiveness, efficiency and safety of clinical trials, and must support long-term electronic archiving of content in standards-based formats.

(1) (c) Scope of Work

To facilitate a broader range of consensus and input, the work will be divided into two phases. In Phase one, the deliverable will focus on technical elements of the eTMF model, including the eTMF content model technical

specification, the eTMF content model schema and the eTMF data exchange model, as outlined below. In Phase two, efforts will be directed towards developing a standards-based controlled vocabulary for use with the standards defined in phase one for content modeling and data exchange.

Phase One Work ? eTMF Open Technology Platform - Goal of Draft Standard by June 2014:

1) We will gather, summarize and prioritize business and technical requirements from OASIS eTMF TC committee members, industry and academia for guidance in the creation of a clinical trial content exchange format. We will seek input during the initial stages of this work from key industry groups including, but not limited to, CareLex, clinical trial sponsors, Document & Records Management DIA Community, NCI Thesaurus, SAFE-BioPharma, technology vendors, and TransCelerate BioPharma. Input will be incorporated into the general statement of need.

2) The TC will create and deliver the core Content Management specification first. The team will work on the Core Technology Architecture followed by the Content Classification System numbering and naming requirements, including any necessary changes to core, followed by Core Metadata Vocabulary that is non-eTMF specific. Core Metadata Vocabulary shall support general metadata properties including: File properties, Basic audit trail properties, Classification properties, Business Process Modeling properties, Content Item properties; and Content Item Electronic and/or digital Signature related properties. The TC shall also focus on specifying Content Model File Format, Data Model File Format and Guidance for use, not precluding parallel work. The specification shall include standards-based metadata for interoperability, while maintaining the flexibility organizations need to adapt to business and government requirements.

3) We will create and deliver an eTMF Content Model format that fulfils the following requirements: 1) Is Machine Readable, 2) Is based on web-standards such as XML or RDF/XML, 3) Can be imported/exported to and from relational database systems, file systems, content management systems and simple web sites; and can be edited using any simple text editor; 4) Can be viewed from within any major web browser; 5) Contains the eTMF Content Model Ontology schema in machine readable form; 6) Can be represented as a machine readable ontology that is interoperable with other published ontologies such as NCI Thesaurus.

4) We will create and deliver an eTMF Data Model format that satisfies the following requirements: 1) Is Machine Readable, 2) Is based on web-standards such as XML or RDF/XML, 3) Can be imported/exported to and from relational database systems, file systems, content management systems and simple web sites; and can be edited using any simple text editor; 4) Can be viewed from within any major web browser; 5) Contains the eTMF Content Model Ontology schema in machine readable form; 6) Supports inclusion of pointers to documents and their associated metadata records; 7) Enables exchange of documents in any state between systems through either online or offline modes; 8) Defines the state of a content item (e.g., complete/incomplete and signed/unsigned); 9) Defines a core set of metadata for digital certificate signing (PKI x.509) of content items that defines details such as i) A link to the public key of a digital signer for identity verification; ii) digital signature time stamp details and other details as needed to validate the identity of a signer and the validity of a digitally signed content item.

Phase Two Work ? Controlled eTMF Vocabulary: Goal of Completion by December 2014

5) We will create a standards-based domain-specific eTMF controlled vocabulary for content classification. Terms will be sourced from published resources such as BRIDG, CareLex, Dublin Core, HL7, National Cancer Institute online NCI Thesaurus, TMF Reference Model v2.0, and other academic, government or non-profit sources of clinical trial terms. Terms that are deemed by the eTMF TC as core to the eTMF standard (and they are not part of any published vocabulary) will be submitted by the OASIS eTMF Standard TC for inclusion in NCI Thesaurus. Where possible, cross-references will be used to existing published sources. The content classification term definitions shall include relational links to online term definitions.

6) We will create a standards-based domain-specific eTMF controlled metadata vocabulary for content tagging. Metadata terms will be sourced from published sources such as BRIDG, CareLex, Dublin Core, HL7, National Cancer Institute online NCI Thesaurus, TMF Reference Model v2.0, and other academic, government or non-profit sources of clinical trial terms. Terms that are deemed by the eTMF TC as core to the eTMF standard (and they are not part of any published vocabulary) will be submitted by the OASIS eTMF Standard TC for inclusion in NCI Thesaurus. Where possible, cross-references will be used to existing published sources. The eTMF controlled metadata vocabulary term definitions shall include relational links to online term definitions.

The TC will accept as input the following public specification:

-CareLex Model Specification, V1.03, Published June 27 2013
http://carelex.org/downloads/ [4]

-CareLex eTMF Content Model Database, V 1.02, June 9 2013 - RDF/XML format (.OWL)
http://carelex.org/downloads/ [4] and http://purl.bioontology.org/ontology/CareLex [5]

-CareLex eTMF Content Model Spreadsheet, .XLS Format, V1.02, June 9 2013
http://carelex.org/downloads/ [4]

-TMF Reference Model
http://www.diahome.org/en-GB/News-and-Publications/Publications-and-Rese... [6]

- Other contributions will be accepted for consideration (without any prejudice or restrictions) and evaluated based on technical merit in so far as they conform to this charter and the IPR guidelines of the TC.

The TC will refine these initial contributions to produce OASIS standard specifications, including necessary supporting documentation.

The scope of the TC's work is limited to features defined in the input contributions and the following features and capabilities.

The features in scope for the TC have been divided into the following categories:

Phase One:

1. Core Technology Architecture

2. Content Classification System

3. Core Metadata

4. Content Model

4. Data Model

5. Guidance for Use

Phase Two:

Domain-specific eTMF controlled vocabulary for content classification.

Domain-specific eTMF controlled metadata vocabulary for content tagging.

Core Specification: eTMF Content Management Specification

1. General Requirements Statement of Need

2. Core Technology Architecture
2.1. Description of the Architecture
2.1.1. Web Standards support
2.1.2. Digital Signature support
2.1.3. Business Process model support
2.1.4. Export / Import formats

3. Content Classification System
3.1. Classification Categorization
3.1.1. Content Entities, Hierarchy and Numbering System
3.2. Metadata Definitions
3.2.1. Core Metadata
3.2.2. Domain specific Metadata
3.2.3. Rules For Use of Organization Specific Metadata
3.3. Content Model
3.3.1. Content Model Format
3.3.2. Content Model Exchange

4. Core Metadata and Content Type Term Sources
4.1. Core Metadata for eTMF content management
4.2. Content Type Term Sources

5. eTMF Data Model
5.1. eTMF Data Model Format
5.2. eTMF Data Model Viewing using Web Browsers
5.3. eTMF Data Model Exchange
5.4. Interoperability with the Content Management Interoperability Services (CMIS) standard
5.5. Supported Document and Record Exchange methods

6. Guidance for Use
6.1. Content Model Editing and Modification
6.2. Creating and submitting new Metadata vocabulary terms
6.3. Security considerations

Out of Scope

The following is a non-exhaustive list provided only for the sake of clarity. If some function, mechanism or feature is not mentioned here, and it is not mentioned as in-scope in the Scope of Work section, then it will be deemed to be out of scope.

The following items are specifically out of scope of the work of the TC:

* Adding classifications that are not related to the clinical trial regulatory document domain to the content model, data model, vocabulary or content type definitions;
* Extending beyond the scope described above
* Defining mechanisms for authentication, encryption, security, cross-origin access;
* Attempting to maintain backward compatibility with external applications, systems, schemas or models.
* Contributions to this TC which are out of scope for this charter may be accumulated and taken into consideration for potential development of a charter for another technical committee that may be created to address future extensions or modifications to the eTMF Standard.

(1)(d) List of Deliverables

The TC has the following set of deliverables for Version One of the Standard:

- OASIS standards track eTMF core content management specification (item 1 below) shall be completed by the TC within nine months after the initial TC meeting.

A list of all deliverables includes the following:

Phase One:

1. An eTMF Content Management Specification that includes: Architecture Diagram; eTMF Content Classification Ontology; Content Classification System Rules and Policies; Content Entities; Hierarchy and Numbering System; Core Metadata Definitions ; Core Metadata for File properties, Basic audit trail properties, Classification properties, Business Process Modeling properties, and Digital Signing and Content Item status properties; Content Model Format; Core eTMF Metadata for the clinical trials domain needed to classify content by study, by site, by country, by date; eTMF Data Model and file format information; eTMF Data Model Viewing and Exchange; and Guidance for Use: ; Editing Content Models and Security Considerations.

2. An eTMF Content Model format comprised of:
a) A core rules-based eTMF hierarchy with core content classification categories that support collection classification and sharing of regulatory documents;
b) An eTMF Content Model database delivered in machine readable format such as RDF/XML.
c) Core metadata that supports Section (1) (c) Scope of Work items 2, 3, 4 in from published sources including BRIDG, CareLex, Dublin Core, FDA, HL7, ICH and NCI Thesaurus and TMF Reference Model.

3. An eTMF Data Model specification and file format that allows interoperability:
1) Support for export of clinical trial study document and record content (documents such as ISO-32000 PDF and web-standards based images) to a universal digital container format (such as .ZIP 64) consisting of a package containing simple file folders and XML text files;
2) Export of the Content Model, documents and records using a machine readable format and contained in the universal digital container package;
3) eTMF Data Model documents and records shall be viewable in major web browsers.
4) eTMF Data Model and Content Management Interoperability Services (CMIS) standard integration points.
All other non-standards track and non-core deliverables within the scope outlined above will be delivered within

twelve months after the initial TC meeting.

Phase Two:

4. A domain-specific eTMF controlled vocabulary for content classification.

5. A domain-specific eTMF controlled metadata vocabulary for content tagging.

Maintenance

Once the TC has successfully produced the deliverables, the TC will enter into a maintenance mode. The purpose of the maintenance mode is to provide minor revisions to previously adopted deliverables, in order to clarify ambiguities, inconsistencies, and obvious errors. The maintenance mode will not functionally enhance a previously adopted deliverable or extend its functionality.

(1) (e) IPR Mode

This TC will operate under the OASIS Non-Assertion IPR mode. See https://www.oasis-open.org/policies-guidelines/ipr#s10.3 [7] mode as defined in the OASIS Intellectual Property Rights (IPR) Policy.

(1) (f) Anticipated Audience

The anticipated audience for this work includes:

* Vendors and service providers offering products that produce data services
* Vendors and application developers who consume data services
* Software architects who design, write, and deploy data producers and/or consumers
* End users implementing solutions that require an interoperable solution for exchanging clinical trial electronic content
* Regulatory agencies responsible for monitoring clinical trial regulatory compliance
* Clinical trial sponsors, clinical trial research organizations, consultants and industry stakeholders

(1) (g) Language

TC business will be conducted in English. The output documents will be written in (US) English.

(2) Non-normative information regarding the startup of the TC

(2) (a) Similar or Applicable Work

The CareLex eTMF Reference model. The CareLex eTMF Reference Model submitted for initial consideration utilizes the following:

* W3C's XML, RDF/XML and OWL Semantic technologies
* The TMF Reference Model, a public domain list of content types for the clinical trials area
* Public domain Metadata vocabularies from HL7, the National Cancer Institute, and Dublin Core
* ISO 32000 PDF specification

Other Applicable Works for Reference:

*US Code of Federal Regulations, 21CFR11, Electronic Records, Electronic Signatures
*ISO 32000 / PAdES specification

*SAFE-BioPharma published standards for digital signatures
*FDA guidelines for digital signatures:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf [8]
*European Commission Directive 2001/83
*EMA Reflection paper on GCP compliance in relation to trial master files, Feb 1, 2013
*European Commission Directive 2005/28

(2) (b) Date, Time, and Location of First Meeting

The first meeting of the OASIS eTMF TC is tentatively scheduled for Monday December 16, 2013 from 9 AM PT to 10.00 PM Pacific Time. This meeting will be conducted via teleconference call and web screen sharing.

(2)(c) On-Going Meeting Plans & Sponsors

It is anticipated that the eTMF TC will meet via teleconference every other week for 60 minutes at a time determined by the TC members during the TC's first meeting. It is anticipated that the eTMF TC members will not be required to attend face-to-face meetings. The eTMF TC may change the time, frequency and dates of meetings.

Sponsorship for the meetings will be circulated among the members.

(2)(d) Proposers of the TC

Proposers of the eTMF Standard Draft Charter:

Zack Schmidt, info@SureClinical.com [9], SureClinical

Trish Whetzel, PhD, twhetzel@SureClinical.com [10], SureClinical

Aliaa Badr, abadr@CareLex.org [11], CareLex

Oleksiy Palinkash, opalinkash@CareLex.org [12], CareLex

Jennifer Alpert Palchak, jalpert@CareLex.org [13], CareLex

Catherine Schmidt, info@sterlingbio.com [14], Individual member

Louis Chappuie, lchappuie@gmail.com [15], Individual member

Peter Alterman, PhD, PAlterman@safe-biopharma.org [16], SAFE-Biopharma

(2)(e) Statements of Support

"I, Zack Schmidt, info@SureClinical.com [9], as OASIS primary representative of SureClinical, confirm our support for this charter and endorse our proposers listed above as named co-proposers.

"I, Aliaa Badr, abadr@CareLex.org [11], as OASIS primary representative of CareLex, confirm our support for this charter and endorse our proposers listed above as named co-proposers.

"I, Peter Alterman, PhD, PAlterman@safe-biopharma.org [16], as OASIS primary representative of SAFE-Biopharma, confirm our support for this charter and endorse our proposers listed above as named co-proposers.

(2)(f) TC Convener

The TC Convener for the first meeting will be Zack Schmidt from SureClinical

(2)(g) Affiliation to Member Section

None

(2)(h) Initial contributions:

CareLex Model Specification, V1.03, Published June 27 2013
http://carelex.org/downloads/ [4]

CareLex eTMF Content Model Database, V 1.02, June 9 2013 - RDF/XML format (.OWL)
http://carelex.org/downloads/ [4] and http://purl.bioontology.org/ontology/CareLex [5]

CareLex eTMF Content Model Spreadsheet, .XLS Format, V1.02, June 9 2013
http://carelex.org/downloads/ [4]

TMF Reference Model v2.0 published June 25 2012

Associated TC:
etmf
Deadline:
Mon, 2013-11-18 - Mon, 2013-12-16

Links:
[1] https://www.oasis-open.org/apps/org/workgroup/etmf/
[2] http://www.oasis-open.org/join/
[3] http://www.oasis-open.org/committees/etmf/
[4] http://carelex.org/downloads/
[5] http://purl.bioontology.org/ontology/CareLex
[6] http://www.diahome.org/en-GB/News-and-Publications/Publications-and-Research/EDM-Corner.aspx
[7] https://www.oasis-open.org/policies-guidelines/ipr#s10.3
[8] http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf
[9] mailto:info@SureClinical.com
[10] mailto:twhetzel@SureClinical.com
[11] mailto:abadr@CareLex.org
[12] mailto:opalinkash@CareLex.org
[13] mailto:jalpert@CareLex.org
[14] mailto:info@sterlingbio.com
[15] mailto:lchappuie@gmail.com
[16] mailto:PAlterman@safe-biopharma.org