


OASIS
Electronic Trial Master File Standard
Technical Committee

Meeting Agenda
Comment Review Period

January 26, 2015
9:00 – 10:00 AM PDT



Agenda

	Topic	Presenter
9:00 - 9:05	Call to Order	Zack
9:05 - 9:08	Roll Call (secretary: Cathy Schmidt)	Cathy
9:08 – 9:10	Approval of Jan 5 2015 minutes (Karen S)	All
9:10 – 9:15	Slates: W47 – W48	Zack
9:15 – 9:35	Optional: 12 final comment resolutions	All
9:35 – 9:55	eTMF TC Next Steps	Zack
9:55 – 10:00	New business & Next Meeting	All

Roll Call

Name	Company	Status
Jenny Huang	AT&T	Member
Jennifer Alpert Palchak	CareLex	Member
Aliaa Badr	CareLex	Member
Oleksiy (Alex) Palinkash	CareLex	Member
Beau Grignon	Forte Research Systems	Member
Troy Jacobson	Forte Research Systems	Member
Junichi Ishida	Fujitsu Limited	Member
Mead Walker	Health Level 7 (HL7)	Member
Lou Chappuie	Individual	Member
Sharon Elcombe	Mayo Clinic	Member
Robert Gehrke	Mayo Clinic	Member
Sharon Ames	NextDocs	Member
Prabhat Vatsal	NextDocs	Member
Rich Lustig	Oracle	Member
Lorie McClain	Oracle	Member
Michael Agard	Paragon Solutions	Member
Karen McCarthy Schau	Paragon Solutions	
Chris McSpirtt	Paragon Solutions	Member
Jamie O'Keefe	Paragon Solutions	Member
Fran Ross	Paragon Solutions	Member
Peter McNaney	Phlexglobal Ltd.	Member
Peter Alterman	SAFE-BioPharma Association	Member
Catherine Schmidt	SterlingBio	Member
Lou Chappuie	SureClinical	
Chris Ibell	SureClinical	Member
Ayrat Sadreev	SureClinical	Member
Zack Schmidt, Chair	SureClinical	Member
Trish Whetzel	SureClinical	Member
Jill Malayang	University of Michigan	Member

Use of Slates for Voting

- TC's often use Slates (vote on group of resolutions)
 - Slates posted and reviewed by TC **prior** to meeting (posted 12/23)
 - Slate announced, TC members 'pull' items to discuss
 - TC votes on items that remain on slate up for vote
 - TC then discusses items pulled from slate followed by vote
- Voting on comment response only, does not limit alterations to actual Spec, MV, Code
- Changes to be integrated in Spec, RDF/XML code, and MV spreadsheet and will be reviewed again by TC

Slate: W47

- Comments and Proposed Resolutions reviewed by Metadata vocab and spec workgroups

“Move to approve Comment Resolutions as written for Slate W47 which includes Comment Log reference numbers:

255.CSD1,744.CSD1,750.CSD1,749.CSD1,93.CSD1,263.CSD1,139.CSD1,140.CSD1,70.CSD1,109.CSD1,554.CSD1,555.CSD1,556.CSD1,110.CSD1,111.CSD1,112.CSD1,113.CSD1,552.CSD1,55.CSD1,551.CSD1,553.CSD1,146.CSD1,557.CSD1,558.CSD1,114.CSD1,234.CSD1,550.CSD1,71.CSD1,306.CSD1,329.CSD1,65.CSD1,332.CSD1,321.CSD1,333.CSD1,307.CSD1,331.CSD1,534.CSD1,212.CSD1”

Final Slate: W48

- Comments and Proposed Resolutions previously pulled for review. See Master comment spreadsheet – rows 152-170 (12 items):

“Move to approve Comment Resolutions as written for Slate W48, with the addition of comment: “All metadata will be described in a linked OASIS eTMF metadata spreadsheet for the specification.”

This applies to the following Comment Log reference numbers:

*101.CSD1, 104.CSD1, 102.CSD1, 102.CSD1, 99.CSD1,
100.CSD1, 95.CSD1, 96.CSD1, 97.CSD1, 64.CSD1,
49.CSD1, 138.CSD1, 141.CSD1*

Voting On Slates

- “I move to approve the comment resolutions for slates W47 – W48 as described in the Comment Log and listed in the meeting slides, with the exception that any references to individual names in the comments shall be removed prior to publication.”

Progress As Of Today

If all passed:

**100% DONE with Public Comment
Response!**

814 of 814 Comment Resolutions!



eTMF TC Next Steps

- Changes/edits from Comment Resolution work integrated into Specification (Aliaa)

Outstanding items:

- Add to spec:
 - Enhancements to Audit trail (Forte, SureClinical)
 - Universal content item portability (SureClinical Contribution)
- TC publish completed Comment Resolutions on OASIS
- TC review of updated/edited Specification
- Update Metadata Vocab spreadsheet
- Update RDF/XML code and validation
- Upon TC vote, publish revised eTMF Draft Specification (Spec, Code, Metadata) for public review of changes

New Business & Next Meeting

- New Business
 - Update on Investigator Site Files (Ibell)
 - Other?
- Upcoming TC Meetings (all 9am-10:30 PST unless otherwise agreed)
 - **February 9** secretary = ***Needed!***

Update on Investigator Site File data storage / Chris Ibell

Re: EMA request reference ASK-7128 - Investigator Site File data custody inquiry / Annex 11, inquiry from Chris Ibell

Dear Sir,

Thank you for your query regarding access to the TMF.

The entire TMF for the trial should be established at the beginning of the trial. In organising the TMF, it is essential to segregate some documents that are generated or held by the sponsor from those that are generated or held by of the investigator and vice versa. The documentation in the investigator site file will contain some source documents, for example, subject screening and identity logs and consent forms which shall remain under the sole control of the investigator due to data privacy regulations, unless the sponsor and the investigator are part of the same organisation.

The investigator TMF may be electronic, with the system either provided by the sponsor, a vendor or by the health care institution. A situation where all the site records are sent to the external sponsor for uploading onto an eTMF system, which the investigator then accesses via a portal, would potentially breach the data privacy requirement and give sole custody to the sponsor for source documents.

The sponsor and investigator(s) should consider the EMA GCP IWG Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials , as the considerations and recommendations will have applicability to source documents contained in eTMFs.

We hope this helps.

With kind regards,

- **European Medicines Agency, Thur 22 Jan, 2015**



Impact on OASIS eTMF work product in EMA regulated trials?