

Oasis eTMF Standard Technical Committee

10 October 2016

Meeting Minutes

1. Roll Call – Members and Observers Present

Troy Jacobson, [Forte Research Systems](#); Ayrat Sadreev, [SureClinical](#); Catherine Schmidt, [Sterling Bio](#); Zack Schmidt (Chair), [SureClinical](#); Trish Whetzel, [SureClinical](#) advisor; Lou Chappuie, individual; Aliaa Badr, [CareLex](#)

2. Approval of Minutes

No minutes were approved during this meeting.

3. eTMF Standard Update

The chair provided a summary of the work done so far in the Oasis eTMF Standard as follows:

- Final committee spec has been approved by OASIS, subject to what amounts to formatting edits.

Next steps:

- OASIS eTMF Standard Spec 1.0 to be voted on by TC at a special TC meeting vote, Oct 16 2016 at 9am-9.30am PDT
- Further public review is not needed
- Next step for consideration by the TC: submit spec for review by ISO standards committee for an ISO standard

4. New Business

No new business was proposed by the group.

Members can forward agenda items to Zack at zs@sureclinical.net.

Next Oasis eTMF TC meeting date is September 17th at 9am -9.30am PDT, special TC meeting to vote to publish OASIS electronic trial master file specification v1.0

Meeting adjourned at 9:20 a.m. PT

Minutes submitted by Zack Schmidt