

## Oasis eTMF Standard Technical Committee

17 October 2016

### Meeting Minutes

#### 1. Roll Call – Members and Observers Present

Troy Jacobson, [Forte Research Systems](#); Peter Alterman, [SAFE BioPharma](#), Ayrat Sadreev, [SureClinical](#); Catherine Schmidt, [Sterling Bio](#); Zack Schmidt (Chair), [SureClinical](#); Trish Whetzel, [SureClinical](#) advisor; Lou Chappuie, individual.

#### 2. Approval of Minutes

Minutes from last meeting of Oct 10 2016 were discussed by Zack. First, the meeting minutes had an inaccuracy about the spec approval process. The statement "Final committee spec has been approved by OASIS..." was incorrect. The next step is that OASIS will set up the Special Majority Vote so that the TC can approve eTMF as an OASIS Committee Specification. Second, the meeting minutes stated that the next step for consideration by the TC: "submit spec for review by ISO standards committee for an ISO standard." Technically the process would likely be that OASIS will vote on the spec first, and then the TC can request that OASIS staff submit the spec as an ISO standard.

#### 3. eTMF Standard Update

The chair discussed the draft spec, and the need to take a vote.

- The chair thanked everyone who participated in the development of the spec.
- Peter Alterman made a motion as follows:

"I move to approve the Chair requesting that TC Administration hold a Special Majority Vote to approve Electronic Trial Master File (eTMF) Specification Version 1.0 contained in <[https://www.oasis-open.org/committees/document.php?document\\_id=59146&wg\\_abbrev=etmf](https://www.oasis-open.org/committees/document.php?document_id=59146&wg_abbrev=etmf)> as a Committee Specification. I further move that the TC affirm that changes have been made since the last public review, that the changes made are documented in <[https://www.oasis-open.org/committees/document.php?document\\_id=59147&wg\\_abbrev=etmf](https://www.oasis-open.org/committees/document.php?document_id=59147&wg_abbrev=etmf)> and that the TC judges these changes to be Non-Material in accordance with the definition in the OASIS TC Process (<http://www.oasis-open.org/policies-guidelines/tc-process#dNonmaterialChange>)."

- The motion was seconded by Lou Chappuie.
- The chair opened the floor for discussion, no objections were raised
- The chair asked for a vote of those objecting to the passage of the motion.
- No objections were raised and the motion passed.

#### 4. New Business

The chair asked if there was any new business. No new business was proposed by the group.

Meeting was then closed by the Chair, who thanked everyone for their assistance and participation in the work of the TC.

Next OASIS eTMF TC meeting date is November 14<sup>th</sup> at 9am -9.30am PDT; [details](#) on OASIS' website

Meeting adjourned at 9:15 a.m. PT

*Minutes submitted by Zack Schmidt*