

OASIS eTMF Standard TC

August 8 2016 meeting minutes

Main meeting: (9:05 am start)

Roll call - Zack Schmidt, SureClinical

Due to vacations, some people could not make the meeting today.

Agenda:

-Update

-OASIS Committee Spec Draft V3 vote

Background:

-The OASIS eTMF draft spec and schema final terms are back from review by National Cancer Institute (NCI). All eTMF standard terms have been reviewed, approved and published by the NCI's Enterprise Vocabulary Services (EVS) group. These terms have been incorporated into the OASIS eTMF draft spec.

Motion to vote approve the OASIS eTMF Standard TC's work:

Catherine Schmidt made a motion to accept the work of the TC as a definitive spec and release it for public review: "I move that the TC approve Electronic Trial Master File (eTMF) Specification Version 1.0 Working Draft 3 and all associated artifacts packaged together in:

<https://www.oasis-open.org/apps/org/workgroup/etmf/download.php/58617>

as a Committee Specification Draft and designate the Word version of the specification as authoritative. I further move that the Committee Specification Draft be released for a **15 day public review.**"

- The motion was seconded by Troy Jacobson.
- The motion was put to the floor for a vote by Chair Zack Schmidt.
- The motion was passed unanimously.

New Business -

- No new business at this time.

Present:

Troy Jacobson, Forte Research; Zack Schmidt, SureClinical; Airat Sadreev, SureClinical; Trish Whetzel, SureClinical; Catherine Schmidt, SterlingBio.