1. **Roll Call – Members and Observers Present** (alpha order)

Michael Agard, [Paragon Solutions](http://www.consultparagon.com/); Jennifer Alpert Palchak, [CareLex](http://carelex.org); Sharon Ames, [NextDocs](http://www.nextdocs.com/); Aliaa Badr, [CareLex](http://carelex.org); Lou Chappuie, individual; Troy Jacobson, [Forte Research Systems](http://forteresearch.com/); Rich Lustig, [Oracle;](http://www.oracle.com/us/industries/health-sciences/overview/index.html) Alex Palinkash, [CareLex](http://carelex.org); Ayrat Sadreer, [SureClinical](http://sureclinical.com/); Catherine Schmidt, [SterlingBio](http://www.sterlingbio.com/); Zack Schmidt, [SureClinical](http://sureclinical.com/).

Leave of Absence: Peter Alterman

1. **Approval of Minutes**

*Motion:* Michael moved the TC to adopt the 6-13-14 and 6-20-14 meeting minutes, and Lou seconded the motion. The minutes were unanimously approved.

1. **Draft Specification Status**

Zack provided an update on the Draft Specification. The document has been published and available for public comment. There were lessons learned regarding some OASIS rules on formatting, but other than that the posting of the Specification and other documents was a success.

1. **Outreach Initiative**

Zack reviewed the upcoming outreach initiatives. OASIS has offered help with articles, webinar briefings and editorial outreach. Jennifer explained that in addition to education the purpose of the outreach is to spur public review comments. Carelex will be managing the comments as they come in and it will be overwhelming if the comments come in all at the end and could create a delay in the response to the submitter.

There was discussion around the content of the outreach and the need to target the content to the audience. The attendees agreed that there should be 2 sets of content: one technical and one non-technical. Zack will create the technical slides and Jennifer the non-technical and present back to the TC for input by the end of the week.

The webinars are not scheduled yet.

Sharon and Jennifer are meeting with Karen Roy from the TMF RM tomorrow to discuss the outreach approach for the RM group.

Michael voiced concerned regarding the potential to getting a lot of noise in the comments if reviewers do not have a clear understanding on how to comment. Zack and Jennifer agreed that there should be some direction in the content regarding how to provide valuable feedback.

Jennifer to circle back with Michael and Sharon this week for a review of the slide content.

Jennifer had provided via email the TC information about the public review of the documents. She asked that we all share with our TMF community forums or to anyone in the clinical arena who has an interest in interoperability.

1. **Scope of the Technical Standard**

There was a discussion on the scope of the standard. Sharon voiced concern that the scope is not clearly defined. Should it be only for Sponsor/CRO Trial Master Files or should it also include on-site Investigator Site File? The attendees agreed that the scope should not be limited to only the

Sponsor/CRO and should include the ISF, however, with the understanding that regulations regarding PHI or PII e.g. HIPAA, must be observed.

Zack confirmed that there is a statement referencing the need to follow HIPAA Regulations in the Specification document. Sharon suggested that statement be revised to include more global terms since HIPAA is US only. The TC can take action on this during the review process.

Zack suggested that perhaps a metadata term be added to the vocabulary to denote when a record contains PHI or PII data. No action needed, only a conversation point.

1. **Other Business**

Sharon asked how the documentation on the OASIS TC is updated. She noticed that she is not classified as voting member. There is an attendance tracker on the TC site that is blank.

Jennifer will review and update the documents as needed. The Roll Call document is used in place of the attendance tracker. She will post the updated Roll Call document. She corrected Sharon’s status to be a voting member during the meeting.

Zack thanked everyone for their attendance and adjourned the meeting.

Meeting adjourned at 9:52 a.m. PT

*Minutes submitted by Sharon Ames*