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 Elcombe, [Mayo Clinic](http://www.mayoclinic.org/); Ishida Junichi, [Fujitsu Limited](http://www.fujitsu.com/us/); Troy Jacobson, [Forte Research Systems](http://forteresearch.com/); Alex Palinkash, [CareLex](http://carelex.org); Fran Ross, [Paragon Solutions](http://www.consultparagon.com/); Ayrat Sadreev, [SureClinical](http://sureclinical.com/); Zack Schmidt, [SureClinical](http://sureclinical.com/); Trish Whetzel, , [SureClinical](http://sureclinical.com/) advisor.

Ishida Junichi from Fujitsu Limited was welcomed as a new member.

1. **Approval of Minutes**

The July 7, 2014 meeting minutes will be posted Wednesday for future approval.

1. **Public Review Promotion & Update**

August 8, 2014 is the Public Comment deadline. A number of promotional activities have been executed. Let Jennifer Alpert Palchak know of any other promotional activities for tracking purposes.

1. **Public Review Update**

Comments from industry and regulatory groups have been received. The information will also be presented to the FDA data standards group at CDER.

1. **Public Comment TC Process**

The public comment TC process includes: Receiving and acknowledging each comment, recording the comment, reviewing and resolving, and posting the resolutions. The TC agreed that it is reasonable to utilize a spreadsheet rather than JIRA to document the issues as the JIRA Comments cannot be turned off – resulting in multiple e-mails to the TC members.

1. **TC Comment Review**

Jennifer Alpert Palchak recommended that three subgroups be identified to manage public comments: Specification, Metadata Vocabulary, and Technical. There was a desire to review the current comments prior to identifying a process for managing them. The group agreed on the following action:

1. Jennifer Alpert Palchak will post the spreadsheet containing the comments to date.
2. TC members will e-mail Jennifer Alpert Palchak and Zack Schmidt by Monday, July 28 to either:
3. indicate support for two review groups: Metadata Vocabulary group (with Core Metadata as a subgroup), and Specification group; the two groups would meet simultaneously during the August 4 TC time period and bring proposals to the whole TC at its August 18 meeting
4. or propose an alternative strategy.
5. **TC Comment Resolution**

The workgroups would review the comments and recommend resolutions to the TC. The TC will discuss and agree on resolutions. The TC may vote on ‘slates’ of resolutions.

1. **New Business**

Comments will be posted and TC members will need to e-mail yes/no to the workgroup strategy providing an alternate proposal if not approving the workgroup strategy.

1. **Proposed Meeting Agenda for August 4 and August 18 meetings (dependent upon comment resolution strategy):**
* Draft Agenda for August 4 (Workgroups) OR Full TC:

–Roll call

–Begin Workgroups to review CSD Public Review Comments

–New business

* Draft Agenda for August 18 (TC Meeting):

–Roll call

–TC review of Workgroup recommendations

–New business

**Action Items from this meeting:**

1. All TC members: review Comments Log to date which will be posted on OASIS eTMF TC site. Then VOTE (yes/no) whether you agree to have the two workgroups (Metadata Workgroup & Specification Workgroup) meet on 8/4 in place of the TC to begin reviewing comments and develop 'proposed resolutions' for the TC to vote on at a later date. If voting no, please provide alternative approach to comment review. Email your vote by Monday 7/28 to: etmf@lists.oasis-open.org and cc: jalpert@carelex.org

B. Members with issues for the TC to address are asked to please post them to the eTMF TC Issues List in preparation for meetings.

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

Meeting adjourned at 9:54 a.m. PT (12:54 ET)

*Minutes submitted by Sharon Elcombe*