

QIBA FDG-PET/CT Tech Ctte Update Call

6 July 2012 at 9 AM CT (GMT-5)

Draft Call Summary

In attendance:

Ling X. Shao, PhD (co-chair)

Andrew Buckler, MS

David Clunie, MBBS

Barbara Croft, MD

Howard Higley, PhD

Martin Lodge, PhD

Lawrence MacDonald, PhD

Anne M. Smith, PhD

Rathan Subramaniam, MD

Daniel C. Sullivan, MD

John Sunderland, PhD

Valerie Treyer, PhD

John Wolodzko, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Agenda (Dr. Shao, moderator)

- 1) Review the action items that were generated from previous meeting(s).
- 2) Review the open issues/considerations to see where we are and if we can put them into actionable tasks.
- 3) Topics for discussion
 - a. Revisit the claim with respect to the latest Profile.
 - b. How to get the protocol reviewed before the release
 - c. Approach to addressing Public Comment needs further discussion

Discussion

- Review of action items from recent calls
- Latest version of Profile to be sent to the UPICT FDG-PET/CT Protocol Working Group as a courtesy
- Important to achieve consensus on outstanding issues in the next few weeks
- Group to review Dr. Lodge's draft version of the claim prior to the next call with the following in mind:
 - 1) Should the Claim focus on SUV max only, SUV mean, or both?
 - 2) Single site or multiple sites / multiple scanners?
 - 3) ROI – technique employed?

Assignments

- Dr. Wolodzko to prepare a list of pros and cons for three different phantoms for the next call
- Dr. Perlman to be asked to review consistency of definitions language and develop a strategy to share information cross QIBA Tech Cttes for future Profiles
- Drs. Lodge and Hoekstra to provide text for sections 6.4 and 6.5
- Dr. Yap is reviewing the Appendix
- Dr. Kinahan is reviewing the common data format mechanism relating to DICOM details as well as recalibration and change of measurements up to 10%
- Dr. Cole will email list of acronyms to Dr. Kinahan
- New action item: If targeting mid-August for Profile completion, FDA briefing document needs to be ready at same time

FDA Briefing Document

- Integration of Public Comments to coincide with FDA Review (as part of the Briefing Document)
- Dr. Higley suggested September as the target meeting date for FDA BQRT Review
- Profile may be sent as 1) in final form or 2) draft – marked as provisional
 - It is possible that there may not be sufficient time to address issues raised during the Public Comment phase prior to the FDA briefing

Next steps:

- Approach to addressing Public Comment needs further discussion
- Group to discuss Dr. Lodge's draft version of the claim on the next call, Friday, July 13th at 9 am CT.

Next call: To continue discussion of the Draft Claim at **9 am (CT) July 13th**.