QIBA FDG-PET/CT Tech Ctte Update Call

20 July 2012 at 9 AM CT (GMT-5) Call Summary

In attendance:

Paul E. Kinahan, PhD (co-chair) Ling X. Shao, PhD (co-chair)

Keith Allberg

Michael M. Graham, MD, PhD

Howard Higley, PhD John Hoffman, MD Martin Lodge, PhD

Lawrence MacDonald, PhD

Eric Perlman, MD Anne Smith, PhD

Rathan Subramaniam, MD

Daniel C. Sullivan, MD Timothy Turkington, PhD John Wolodzko, PhD Brian Zimmerman, PhD

RSNA

Julie Lisiecki Madeleine McCoy

Discussion

- Group reviewed latest draft version of the claim and made minor edits:
 - Claim: If Profile criteria are met, then tumor glycolytic activity as reflected by the maximum standardized uptake value (SUVmax) can be measured from FDG-PET/CT with a within-patient coefficient of variation of 12% for evaluable tumors and using the same scanner.
 - Revised claim language circulated to group for review post-call, 7/20.
- Caveats also revised; to be discussed further on next call.
- Dr. Perlman reminded the group that the claim is dependent on specifications that are laid out in the Profile.
- SUVmax to be the definitive measurement.
- Dr. Wahl's references and UPICT protocol reference to be included in "evaluable tumors" in Appendix XX.

Assignments

- Group to review sections 6.4 and 6.5 on next call, (7/27)
- Group to review revised claim language prior to next call
- Dr. Cole will email list of acronyms to Dr. Kinahan
- Dr. Kinahan is reviewing the common data format mechanism relating to DICOM details (Appendix D)
- Dr. Kinahan to add draft phantom noise and resolution from UPICT to section 6.4
- Dr. Lodge to work on revised claim language section II
- Dr. Yap is reviewing the Appendix G.2
- New action item: If targeting mid-August for Profile completion, FDA briefing document needs to be ready at same time

Next steps:

Approach to addressing Public Comment needs further discussion

Next call: To continue discussion of the Draft Claim at 9 am (CT) July 27th.