

QIBA FDG-PET/CT Tech Ctte Update Call

10 August 2012 at 9 AM CT (GMT-5)

Call Summary

In attendance:

Paul E. Kinahan, PhD (co-chair)

Ling X. Shao, PhD (co-chair)

Richard L. Wahl, MD (co-chair)

Andrew Buckler, MS

Patricia E. Cole, PhD, MD

Barbara Croft, MD

Howard Higley, PhD

John M. Hoffman, MD

Lawrence MacDonald, PhD

Neru Munshi, PhD

Eric Perlman, MD

Annette Schmid, PhD

Rathan Subramaniam, MD

Daniel C. Sullivan, MD

Scott D. Wollenweber, PhD

John G. Wolodzko, PhD

Brian E. Zimmerman, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Discussion

- Profile Claim language is being finalized
- ACRIN 6678 test-retest double baseline PET study results recently released and showed some discrepancy in relation to the QIBAPET claim.
- Concern voiced over possible confusion regarding the 33% difference in metabolic response in the QIBA claim vs. the 25% change found in the metabolic response for the ACRIN 6678 data
 - A follow-up phone call with the lead investigators is to be scheduled, preferably during one of the regular technical committee time slots.
 - Drs. C. Gatsonis, Wolfgang Weber, and B. Siegel to be invited to participate
- How to make the message more concordant or what type of explanatory detail may be needed must be decided prior to release of the Profile for Public Comment phase
 - Dr. Higley asked that the SNM abstract be distributed: "Assessing Significant Changes in FDG-PET Data in Oncology Clinical Trials."
 - All inquiries regarding the data should be directed to Dr. Alex de Crespigny, at Genentech: decrespigny.alex@gene.com.
 - Of note, the data presented was originally based on clinical trial data and was not originally conceived as a test-retest study
- Remaining action items to be focus of next technical committee call, August 17th.

Assignments

- Dr. Cole to email list of acronyms to Dr. Kinahan
- Dr. Kinahan is reviewing the common data format mechanism relating to DICOM details (Appendix D)
- Dr. Kinahan will combine Dr. Lodge's summary table with Dr. Higley's references.
- Dr. Lodge to work on revised Claim language – section II
- Dr. Yap is reviewing the Appendix G.2
- 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, along with resolving the ACRIN 6678 test-retest results in relation to the claim.

Next call: Discussion of remaining action items, **9 am (CT) August 17th**.