QIBA FDG-PET/CT Tech Ctte Update Call

08 June 2012 at 9 AM CT (GMT-5) Call Summary

In attendance:

Paul Kinahan, PhD (co-chair) Ling Shao, PhD (co-chair) Andrew Buckler, MS Martin Lodge, PhD Lawrence MacDonald, PhD Eric Perlman, MD Anne Smith, PhD Rathan Subramaniam, MD Valerie Treyer, PhD Timothy Turkington, PhD John Wolodzko, PhD Jeffrey Yap, PhD

RSNA Joe Koudelik Julie Lisiecki

Alternate meanings for Qualification discussed (Dr. Kinahan)

- Site Qualification Process (section 6.1.4) discussed including parameters and alternate meanings, such as:
 - o "Qualification" refers to FDA pathway; suggested use of "compliance" instead
 - \circ $\;$ Qualification means more testing / research vs. "accreditation" for clinical practice
 - Qualification refers to qualification of the scanner for quantitative purposes
- Separate accreditation from qualification and/ or a more general level of usage
 - Qualification: ongoing process of maintaining consistency / accuracy long-term over the course of a trial
 - Qualification: to be approved by body specific research study, or usage, which requires ongoing QA/QC and the collaborative involvement of CROs, ACRIN, CQIE, SNM-CTN, etc.
 - Accreditation: to be approved by body of broad clinical usage, regular ongoing QA/QC, e.g., ACR, CANNL
 - Compliance is what is necessary to meet the Profile claim
 - Sites shall maintain and document accreditation (ACR) or qualification (ACRIN, CQIE, SNM-CTN) status
 - a balance is needed between what is practically achievable while maintaining consistency and quality over time
 - \circ Sites should be accredited or qualified with measurements based on the ACR phantom
 - o Goal: for patients to be scanned on different systems with similar results
 - This is important, because even at one site, there can be variance on the same machine!
- Define what threshold levels performance has to achieve, focusing on clinical value
 - Don't want to make requirements/ parameters "too challenging," where they will not actually help to improve clinical practice, i.e., they cannot and should not be just a lofty "ideal" but rather something usable
- Targeting end of June for Profile to be cleaned up for Public Comment

SNM Meeting (week of June 9-13)

• Group will meet informally, Sunday June 10th, 4:30 pm ET, at the *Hotel Fountainbleau, Bleau Bar* in Miami Beach to discuss QIBA FDG-PET topics

Next steps:

- Meet at SNM meeting for those available (see above)
- Any comments to Dr. Kinahan, please: Kinahan@uw.edu

Next call: To continue discussion of the Profile at 9 am (CT) June 15th.