

QIBA FDG-PET/CT Biomarker Committee (BC) Update Call

08 January 2016 at 9 AM CT (GMT-6)

Call Summary

In attendance:

<i>Rathan Subramaniam, MD, PhD (co-chair)</i>	Howard Higley, PhD	Amy Perkins, PhD	RSNA Joe Koudelik
<i>John J. Sunderland, PhD (co-chair)</i>	John Hoffman, MD	Eric Perlman, MD	Julie Lisiecki
<i>Scott Wollenweber, PhD (co-chair)</i>	Paul Kinahan, PhD	Pierre Tervé, MS	
Ishtiaq Bercha, MSc	Larry MacDonald, PhD	Timothy Turkington, PhD	
Ronald Boellaard, PhD	Nancy Obuchowski, PhD	John Wolodzko, PhD	
Terry Brown	Amy Perkins, PhD	Brian Zimmerman, PhD	

Moderator: Dr. Wollenweber

Discussion included:

Profile Checklist and Profile Updates

- Drs. Sunderland and Turkington provided an overview of the discussion at RSNA 2015's QIBA Breakout Session
- Results from the Phase II field test of the checklist have introduced needed changes for the Profile, version 1
- Dr. Turkington to draft language for proposed changes to the Profile
 - Edits will be reviewed by the co-chairs and scientific liaison prior to a new round of public comment for a possible version 2 release, utilizing the new QIBA Profile Template
 - It is hoped that much of this can be accomplished via email among the small group
- Any changes made to the Profile will have to be reflected on the Checklist
- Physician input/feedback still needed
- Items in need of update include:
 - any modifications based on the manufacturers' input
 - site feasibility notes
 - Three out of four PET CT scanner manufacturers have agreed to participate in the Checklist effort
 - The group remains hopeful that the fourth will join also
- Dr. Perlman will follow up with the Process Committee regarding versioning and public comment
- A democratic and efficient process for future updates must be established

Points for further discussion

- The QIBA Process Committee is reviewing the mechanism for change controls within QIBA Profiles
 - How changes are handled will depend on where the Profile is in its review cycle, e.g., "publicly reviewed," "technically confirmed," etc.
 - FDG-PET BC members believe that the current Profile, v1, is at the technical confirmation level now, due to completion of two phases of field testing
 - It was noted that a feasibility test is not the same as testing of the claim
- Details on how technical confirmation is achieved should be included in the Profile Appendix
 - This type of detail could help to define conformance standards
 - Future publication of the field testing process is under consideration for easy reference in documents
 - Any quantitative data that was collected in these efforts should also be tracked
 - Scans must be long enough to produce quality images but short enough to reduce noise
- Next challenge will be having imaging sites confirm Profile conformance (i.e., clinical conformance)
 - Funding from pharma and others would be needed to achieve this type of trial
 - Numbers within the field study would need adjustment for conformance with the claim
 - Dr. Obuchowski volunteered to tweak the field study for better claim conformance

Publications

- A high level summary of the FDG-PET Profile, v1, is available for reference from SNMMI
 - Graham MM, Wahl RL, Hoffman JM, et al. [Summary of the UPICT protocol for 18F-FDG PET/CT Imaging in Oncology Clinical Trials](#). *J Nucl Med*. 2015; 56(6):955-961. doi: [10.2967/jnumed.115.158402](#) PubMed Citation
- Another document detailing the group's efforts to update the Profile is under consideration for publication and may be submitted to either *JNM* or *Radiology* for consideration

- It is important to publish these updates for future Profile references
- Any additional documents to be published should indicate that changes to the current Profile will occur in the near future.

QIBA Nuclear Medicine BC Calls (Fridays, 9 am CT):

- Jan 22: SPECT BC
- Jan 29: TBD - Nuclear Medicine Combined BCs

SPECT Task Forces (Tuesdays at 2 pm CT):

pending availability of co-chairs:

- Jan 12: Quantitative and Image Analysis – *Drs. Miyaoka and Seiby*
 - Jan 19: Phantoms/ DRO Group – *Drs. Dickson and Zimmerman*
 - Jan 26: Clinical / Literature Review – *Dr. Seiby*
-