QIBA FDG-PET/CT Biomarker Committee (BC) Call
15 May 2020 at 1 PM CT (new time)
Call Summary

In attendance:			**RSNA**
John Sunderland, PhD (Co-Chair)	Howard Higley, PhD	Anne Smith, PhD	Joe Koudelik
Scott Wollenweber, PhD (Co-Chair)	Martin Lodge, PhD	Tim Turkington, PhD	Julie Lisiecki
Orest Boyko, MD, PhD	Alan Maurer, MD	Jeffrey Yap, PhD	
Carla Ferreira	Nancy Obuchowski, PhD		

Moderator: Dr. Sunderland

Profile Adoption – Next Steps

- Dr. Sunderland discussed how QIBA Leadership wants to encourage widespread use of the Profiles amongst pharma, CROs, the NCI Clinical Trials Network, and other organizations
- QIBA Leadership wants to demonstrate that there is value for various stakeholders in using the QIBA Profiles
- Conformance certifications and marks are available and will be used to promote QIBA globally
- There is greater involvement with the conformance process and in trying to get sites and manufacturers to conform to the Profiles via self-attestation or a more rigorous certification process, where sites provide evidence of conformance to QIBA reviewers or through an automated system
- Recent success with Invicro's London imaging site conformance was discussed and whether other CROs and industry partners would also be willing to apply for self-attestation or a more rigorous validated conformance

Industry Interest

- Dr. Sunderland asked BC industry members to consider whether there is value for manufacturers to advertise QIBA conformance with their various products, and if the conformance process is reasonable and achievable
    - Would manufacturers be willing to pay a fee?
    - What types of approvals would be needed?
- The ultimate question manufacturers will have is whether QIBA Conformance will help sell their products?
- Drs. Smith and Wollenweber both noted that any extra requirements would likely be seen as more costly and a possible hurdle to manufacturers in terms of "have-to-do" items
- Another hurdle is the lack of infrastructure in place for the more rigorous QIBA certified option
- Dr. Maurer noted that site qualification is taking place worldwide for PET/CT scanners and there is increasing interest in how to qualify scanners via quantitative metrics
    - A more streamlined and standardized site qualification method would be enthusiastically welcomed
    - If more industry standardization and greater availability of phantoms were possible, this would simplify qualification for clinical trials
    - Implementation of QIBA processes would be a major benefit/service within the clinical trial space

Vision for Harmonized Profile Templates

- A new user-friendly model might include separate Profiles or appendices to include all newly approved radiopharmaceuticals
- Updating the FDG-PET/CT Profile could include collaboration with EARL and SNNMI's Clinical Trials Network
- Dr. Sunderland has had preliminary discussions with Dr. Boellaard regarding the possibility of creating an International Standard
- Ideas are needed regarding appropriate format and how to accomplish this in an efficient manner Dr. Lodge suggested a new format altogether, such as an electronic, fluid, and ever-changing document with one-page summaries and links to more detailed information, in a "website" format for the Profile, utilizing more modular formatting
    - This would allow ease of reading and finding information quickly
    - Each radiopharmaceutical could be described in a separate appendix
    - Unchanged information could be summarized in separate chapters, using the UPICT headers

- Dr. Maurer noted that each radiopharmaceutical has different properties, requirements, etc., but having the ease to look up standards at one's fingertips would be very helpful
- Dr. Sunderland mentioned that 70-80% of text is common across the NM Profiles and isolating this text to make a Profile template would be useful
    - This might be referred to as the "core" document
    - A similar approach could be used for part of the Profiles that handle analysis software requirements
    - In this revision process, some of the Profile could be trimmed to make it easier to read
    - More checklist-type formatting with bullet points should also be incorporated
- Dr. Turkington suggested the current QIBA Approval Process is an impediment to progress and makes it difficult to update Profiles as new information becomes available
    - He believes QIBA Leadership needs to rethink the approval process and allow BCs to update Profiles without so many steps
- The goal is to make the document useful to many stakeholders, to make certain that it is accreditation-worthy, and could be used in clinical trials; application to patient care would be a secondary goal
- The goal will be to create a universal QIBA-UPICT-EANM-FDG template
    - Will need to perform a gap analysis for new tracers and biomarkers, such as PSMA and DOTATATE
    - Drafting a table based on all the items that are different will provide an at-a-glance reference

Nuclear Medicine Schedule: *The next scheduled QIBA calls will be as follows:*

05/19	NM Coordinating Committee @ 1 pm CT	**06/12**	PET Amyloid BC @ 9 am CT
05/29	NM Leadership @ 9 am CT – TBD	**06/19**	FDG-PET BC @ 1 pm CT
06/09	SPECT TC^{99m} BC @ 2 pm CT	**06/26**	NM Leadership @ 9 am CT – TBD

RSNA Staff attempt to identify and capture all committee members participating on WebEx calls. However, if multiple callers join simultaneously or call in without logging on to the WebEx, identification is not possible Call participants are welcome to contact RSNA staff at QIBA@RSNA.org if their attendance is not reflected on the call summaries.

Parties interested in joining the QIBA LinkedIn page for QIBA updates should visit: https://www.linkedin.com/company/rsna-qiba