QIBA FDG-PET Biomarker Committee (BC) Call
07 September 2018 at 9 AM CT
Call Summary

In attendance:

John Sunderland, PhD (Co-Chair)	Edward Jackson, PhD	Eric Perlman, MD	**RSNA**
Scott Wollenweber, PhD (Co-Chair)	Martin Lodge, PhD	Mitsuaki Tatsumi, MD	Joe Koudelik
Chris Crisman, MBA	Jayant Narang, MD	Pierre Tervé, MS	Julie Lisiecki
Alex Guimaraes, MD, PhD	Nancy Obuchowski, PhD	Timothy Turkington, PhD	
Howard Higley, PhD	Amy Perkins, PhD	Richard Wahl, MD, FACR	

Moderator: Dr. Sunderland

Poster for RSNA 2018

- Discussion took place regarding whether or not the BC should submit a poster for the QIBA Kiosk at RSNA 2018
- If based on the 2017 poster, minimal updates would be required It was determined that the decision will be left to QIBA NM CC leadership
- Dr. Sunderland to follow up with Dr. Mozley for confirmation

Claim Confirmed Clinical Trial Efforts (Dr. Sunderland)

- An outline of a test-retest protocol has been written with preliminary statistical analysis to see how many subjects may be needed
- The estimated goal would be 100 to 120 subjects
- An application for funding has been submitted to the ACR Foundation; however, no decision has been made yet
- In the meantime, focusing on moving forward with protocol development seems prudent
- As external funding has not yet been achieved, BC leadership has considered an alternate plan which would involve a self-funded crowd-sourced trial managed by QIBA collaborating sites
- While the initial scan would have almost no cost (a standard-of- care scan), the follow up scans (within 7 days) would be the primary study cost
- It is estimated that 10 – 15 sites would be needed to distribute work equitably with 5-10 or so subjects per site
- Dr. Sunderland will follow up with QIBA academic sites to determine possible commitment, and the QIBA FDG BC at large to determine if there may be additional interested parties
- Site PIs that have volunteered to scan 10 subjects were as follows:
    1. Dr. Sunderland (University of Iowa)
    2. Dr. Subramaniam (University of Texas, Southwestern Medical Center)
    3. Dr. Lodge (Johns Hopkins University)
    4. Dr. Wahl (Mallinckrodt Institute of Radiology, Washington University)
    5. Dr. Kinahan (University of Washington)
- While not at a site, Dr. Perlman also volunteered his expertise in the following areas:
    - Case report forms
    - Reader manual
    - Operational workflow

Conformance

- In order to maintain trial rigor, it will be necessary to find a way to determine whether sites are QIBA conformant

- Sites would need to be audited for QIBA conformance on random subjects, though self-attestation will be used on the front end

- Data would be shared and compared to measure test/re-test repeatability
- An estimate for patient size for test / re-test scan might be needed, as statistical quality decreases as patient size increases

Conformance Mechanism

- Ongoing discussions are taking place between QIBA and ACR to explore the feasibility of a collaboration to work toward qualification, via a pilot program
- Dr. Wahl to contact Pamela Woodard (ACR Research Group) re: collaboration interest
- Follow-up will be needed regarding IRB requirements

Design

- Federally-funded clinical trials are required to have protocols posted on www.ClinicalTrials.gov; choosing wording carefully will be important, as whatever is added to the protocol must be reported
- It was decided that describing the multiple comparison method in broad terms would be best, e.g., the "Holmes method," etc.
- It is likely that RedCap will be used for trial management, as it is free to non-profit organizations and is regularly used by researchers

Inclusion Criteria

- Inclusion criteria for the proposed trial must be determined
- Those on the call agreed that they did not want to limit the trial to only one type of cancer, , though they remain flexible if ACR agrees to fund the trial with such a condition
- Patients with 5 maximum lesions vs. measuring the 5 hottest lesions per patient were debated, as the goal is to understand variability, not just as a function of size, but also a variety of sizes and a variety of SUVs (intensity)
- Review of the protocol with an eye for details will be needed in order to make certain that the language is clear and unambiguous
- A proposed deadline for having the trial design established would be RSNA 2018

Action Items:

- The next call will focus on the protocol and logistics for a proposed QIBA-led clinical trial
- Finalize a detailed protocol
- Develop checklist for conformance
- Develop case report forms (RedCap) and reader manual

Nuclear Medicine Schedule:

09/11	SPECT BC: TC^{99m} @ 2pm CT	**10/05**	FDG-PET BC	**10/31**	RSNA 2018 posters due
09/14	PET Amyloid BC	**10/09**	SPECT BC: TC^{99m} @ 2pm CT		
09/28	NM Coordinating Committee	**10/12**	PET Amyloid BC		
		10/19	I-123 Profile		
		10/26	NM Leadership – TBD		

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