QIBA FDG-PET Biomarker Committee (BC) Call

05 October 2018 at 9 AM CT

Call Summary

In attendance:

John Sunderland, PhD (Co-Chair)
Rathan Subramaniam, MD, PhD, MPH (Co-Chair)
Hubert Beaumont, PhD
Howard Higley, PhD
Edward Jackson, PhD
Adriaan Lammertsma, PhD
Martin Lodge, PhD
Nancy Obuchowski, PhD
Amy Perkins, PhD
Eric Perlman, MD
Anne Smith, PhD
Mitsuaki Tatsumi, MD
Timothy Turkington, PhD
Richard Wahl, MD, FACR

RSNA
Joe Koudelik
Julie Lisiecki

Moderator: Dr. Sunderland

PET/MRI Update

- Drs. LaForest and Hope are conducting a preliminary test-retest study utilizing the QIBA FDG-PET/CT Profile to identify sections that might require modification
- The doctors are also performing their own related test-retest studies utilizing the Profile
- An update may be available by the next BC call on November 2nd

Claim Confirmed Clinical Trial Efforts (Drs. Subramaniam and Sunderland)

- Previously received comments from the ECOG-ACRIN Executive Committee will be used to formulate a response to the ACR Foundation by the end of next week
- Dr. Subramaniam asked for feedback from the group and will draft a letter this weekend for review by Drs. Jackson, Kinahan, Perlman, Rosen, Sunderland, and Wahl
- The three questions that need defense are as follows:
    1. Concerns regarding the challenge of patient accrual
    2. Suggestion to study a single cancer, rather than multiple types
    3. Significance of this QIBA study in light of the ACRIN 6678 study and its impact/findings
- Defenses for these concerns include:
    1. There are ten committed sites and 120 patients maximum would be accrued
    2. BC members would prefer not to limit the focus to a single cancer
        - In testing the Profile claim, the goal is to be as broad as possible but not to overstep what the claim can support
        - Need to consider how to address the impact of this on clinical practice
            - Noted was that the 6678 study focus was on lung cancer; the QIBA study would be more broad (4-5 cancer types)
            - It was noted that the majority of FDG imaging is used to look at response to therapy and understanding what true change means, which has tremendous clinical applications
            - FDA required 2+ clinical trials to assess BM validity

Other considerations

- Whether accessibility in the real world should be included was discussed
- Inclusion of patients that may not fit within normal parameters in order to use test-retest data
    1. This might be an exploratory option; would need to consult Dr. Obuchowski regarding powering the study

Inclusion Criteria TBD

- Suggestion to include 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)

NIBIB – New Leadership

- Dr. Bruce J. Tromberg, PhD has been selected to lead the National Institute of Biomedical Imaging and Bioengineering as of January 2019
- QIBA leadership will try to meet with Dr. Tromberg to gauge whether there may be continued interest in collaboration with QIBA and possible future support of efforts
- Dr. Wahl encouraged BC leaders to prepare a draft proposal including all real-world needed costs for a clinical trial, in the event that such a discussion may be welcome
    1. The estimated trial cost ranged from $250K to $1M (if support staff are needed)

Clinical Trial Task Forces

- Dr. Sunderland acknowledged that volunteer effort will be needed to organize a trial and asked for BC members to volunteer for one of the following 3 groups by responding to RSNA Staff: Jlisiecki@rsna.org:
    1. **Trial Logistics Group** (led by Dr. Perlman)
    2. **QIBA Conformance Group** (led by Dr. Sunderland)
    3. **Data Definition Final Design Group** (led by Dr. Subramaniam)
- Final protocols are anticipated to be complete by the RSNA Annual Meeting
- It is imperative that progress be made on the protocol definitions and trials design

***Radiology* Article Update**

- Substantial changes are still needed on revisions to the manuscript; no draft has yet been made available
- It would be ideal to have the manuscript ready for resubmission to *Radiology* no later than October
    - It is possible that the window of opportunity may have closed
- If not accepted by *Radiology*, other journal options will be considered, such as the *Journal of Nuclear Medicine* (*JNM)* or the *American Journal of Roentgenology* (*AJR)*
- Drs. Jackson, Wahl, and Subramaniam to follow up with Dr. Kinahan
- Dr. Subramaniam mentioned that a special molecular imaging-focused edition of AJR will be published in August 2019; however, a draft manuscript would be needed by January or early February at the latest

Profile Use

- Though a Profile and Checklist exist, it is not known whether groups are using them
- Some portions of the Profile have been used in Pharma trials, but no one knows for certain if the Profile has been used in its entirety
- On the next call, BC leaders would like to discuss how to encourage use of the Profile and the Checklist at clinical institutions

Action Items:

- All are asked to volunteer for Clinical Trial Task Forces by contacting RSNA Staff: jlisiecki@rsna.org
- The next call will focus on how to encourage Profile and Checklist use at clinical institutions
- Finalize a detailed trial design by the time of the RSNA Annual Meeting with a checklist for conformance
- Develop case report forms (RedCap) and reader manual

Nuclear Medicine Schedule:

10/09	SPECT BC: TC^{99m} @ 2pm CT	**11/02**	FDG-PET BC
10/19	I-123 Profile	**11/09**	PET Amyloid BC
10/26	NM Leadership – TBD	**11/13**	SPECT BC: TC^{99m} @ 2pm CT
10/31	RSNA 2018 posters due	**11/16**	I-123 Profile
		11/23	No calls

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