

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

17 January 2020 at 11 AM CT (new time)

Call Summary

In attendance:

Rathan Subramaniam, MD, PhD, MPH (Co-Chair)
Scott Wollenweber, PhD (Co-Chair)
Howard Higley, PhD
Paul Kinahan, PhD
Adriaan Lammertsma, PhD

Martin Lodge, PhD
Nancy Obuchowski, PhD
Amy Perkins, PhD
Eric Perlman, MD
Anne Smith, PhD

Ying Tang, PhD
Tim Turkington, PhD
Richard Wahl, MD
Jeff Yap, PhD

RSNA

Angela Colmone, PhD
Joe Koudelik
Julie Lisiecki

Moderator: Dr. Subramaniam

Call Time Change:

- The FDG-PET/CT BC unanimously agreed to change the call time to 11 am CT (on the 3rd Friday of the month)

Trial implementation progress:

- The FDG-PET BC would like endorsement from the National Clinical Trials Network (NCTN) at the National Cancer Institute (NCI) to include the Profile as a requirement or benchmark for FDG clinical trials.
- Drs. Kinahan and Subramaniam discussed including the checklist with a survey to upcoming NCTN clinical trial sites to assess real-world interest in implementing the Profile.
 - This could potentially be 50 – 70 sites in the US and Canada
- Dr. Turkington volunteered to provide technical support via email for questions regarding how to use the checklist and collect survey data, or assess feasibility
- It was also suggested that the team get in touch with the IROC nuclear medicine technologist in Pennsylvania
- Dr. Kinahan cautioned that no changes should be made to the actual qualification process as accrual is the most important, but suggesting collection of as much data as possible was encouraged
 - Dr. Kinahan to follow up with Dr. Boss (Director: ACR Imaging Core Laboratory) re: ECOG-ACRIN plans for upcoming head and neck trials; a t-con may be scheduled to discuss

Funding for an FDG-PET/CT Trial:

- Dr. Wahl suggested that Drs. Kinahan and Subramaniam put together a proposal for ECOG-ACRIN and draft/include a white “position” paper, laying out the reasons why this FDG-PET/CT trial should be funded, including some statistics from Dr. Obuchowski
 - This white paper may help influence the reviewers
- It may also be possible to piggy-back onto an existing lymphoma study
- In addition, drafting a standardized template / protocol beyond FDG that would include FDG and SPECT would be very helpful
 - If such a document were available, it could influence NCTN protocols and be applied to all NCTN trials
- Questions arose regarding why Profiles aren’t being used in this capacity
 - If a combination of the Profile plus checklist is needed, it might be helpful to do a gap analysis with the NCTN FDG protocol (if one exists) compared to the QIBA FDG Profile and create a document that would aim to address the missing details
 - Drafting a table based on all the items that are different will provide an at-a-glance reference
 - It might be easiest to write this document in a way that takes the burden off the user, i.e., “if you do this, you’ll comply.”
 - The goal is to provide a scanning protocol that meets QIBA requirements and is easy to adopt; implementing the full Profile may not be practical
 - Creating this document may require a new task force via several conference calls
- Eventually, Profiles for all the different radiotracers and isotopes may be helpful as well
- Dr. Turkington suggested reviewing the Profiles alongside a list of radiotracers and cancer types
- Dr. Turkington offered to create a draft document, leveraging similarities, as a starting point for the group, using “find” and “replace” for DOTATATE and other terms

- This draft document will be reviewed on the February BC call
- Dr. Turkington noted that the document will require more than “find” and “replace” edits, and that it would be very helpful to have a few more volunteers
- Dr. Subramaniam to follow up with Dr. Sunderland regarding an RO1 grant to fund a potential trial using SUVmax
- Dr. Subramaniam to invite Dr. Sunderland to act as PI) on this grant
- Dr. Kinahan to review the NCTN Profile and follow up with Dr. Boss

FDA Qualification Effort: (Dr. Higley)

- Dr. Subramaniam spoke with qualification staff at the FDA
- Drs. Higley, Jackson, Sullivan and Obuchowski corresponded last year re: an FDG-PET biomarker qualification effort; it was suggested that an FDG-PET test/retest study might be funded by fNIH under Dr. Sullivan’s leadership
- Coordinating with the fNIH to characterize novel T-cell imaging agents for repeatability would also be helpful
- An FDG-PET Lymphoma trial could potentially fund test-retest ancillary work
- FDA to explore PET Lymphoma (FDA) qualification efforts; some FDA encouragement has been received to put together a proposal re: drug development opportunities
- Funding has been allocated by the FDA for similar efforts in response to criticism regarding the slow pace of biomarker qualification efforts; so, it is important to take advantage of this opportunity
- CCS Associates (Drs. Higley, Kelloff, and Tang) are retained by the NCI gift fund to support fNIH biomarker qualification programs and indicated they’d be happy to help

QIBA FDG Grant Application [{RFA-FD-20-009}](#)

- Drug Development Tools Research Grants (U01 Clinical Trial Optional)
- **Application due date is March 17, 2020, by 11:59 Eastern Time**
- This opportunity became available on January 16th
- Due to the extremely tight turn-around time, movement must be quick to take advantage of this opportunity
- RSNA staff to prepare a Doodle poll for key leadership needed to draft a proposal
- If QIBA were to receive this funding, it would augment what the BC has been trying to accomplish with ACRIN 6678 and the 503 study

Continuing discussion items:

- RO1 proposal for a clinical trial with FDG-PET/CT
- NCTN trials
- SPECT/CT protocols needed for clinical trials
- Establishing quantitative parameters for new PET/CT radiopharmaceuticals in clinical practice
- Implementing the FDG-PET/CT Profile in multi-center trials

Nuclear Medicine Schedule: *The next scheduled QIBA calls will be as follows at 9 am CT unless otherwise noted:*

02/11	SPECT TC ^{99m} BC @ 2 pm CT
02/14	PET Amyloid BC
02/21	FDG-PET BC @ 11 am CT
02/28	NM Leadership – TBD
02/18	NM Q1 Coordinating Committee @ 1 pm CT

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