

## QIBA CT Volumetry Biomarker Ctte (BC) Call

14 November 2016 at 11 AM CT

Draft Call Summary

In attendance:			RSNA:
Jenifer Siegelman, MD, MPH (Co-Chair)	Ravi Mankala, MS	Nicholas Petrick, PhD	Joe Koudelik
Rick Avila, MS	Nancy Obuchowski, PhD	Aria Pezeshk, PhD	
Andrew Buckler, MS	Michael O'Connor, PhD	Marthony Robins, PhD	
Matthew Fuld, PhD	Kevin O'Donnell, MASc	Daniel Sullivan, MD	
Marios Gavrielides, PhD	Eric Perlman, MD	Ying Tang, PhD	
Rudresh Jarecha, MBBS			

### Cancer Moonshot Initiative (Dr Sullivan)

- Dr. Sullivan mentioned that Dr. Roderic Pettigrew, NIBIB Director, recently requested mature QIBA Profiles for the Vice-President's [Cancer Moonshot Initiative](#), to be submitted by November 30, 2016
  - These Profiles may be considered for use as national imaging standards for research use in drug development and clinical care
- The FDG-PET/CT and CT Volumetry Profiles will be submitted as these are the most advanced Profiles to-date
- Dr. Sullivan cautioned that with the recent change in U.S. leadership, this program may be in jeopardy, but optimism was still high and QIBA leadership opted to proceed as originally planned

### CT Vol Profile Claim and Conformance Update (Mr. O'Donnell)

- Assessment procedures for sections 4.1 through 4.6 were discussed
- Sections 4.1-4.5 refer to required "Actor" performance to meet stated conformance, e.g., various components of the imaging workflow: scanner, technologist, physicist, Radiologist, analysis software, etc.
- Section 4.6 refers to the overall site, or whole-picture conformance
- Mr. O'Donnell pointed out that many loose-ends exist regarding the site qualification details, and assessment procedures were still needed to support the Profile claim
- A broad-sweeping statement regarding conformance for the entire chain (process) was not possible at this time, and the inclusion of text/caveats was suggested to make end-users aware of this limitation
- The actual need for a system test at the site level was debated
- There were varying points-of-view regarding how to address site conformance and the impact of not/including in the current Profile
- Concern was raised whether the Moonshot audience may be misled by the current claim language if site conformance was not assessed, i.e., clinical conformance would require an assessment procedure for section 4.6
- The use of Mr. Avila's phantom crowd-sourcing data was discussed in support of an overall site requirement
- Since changes cannot be made to the available science, a caveat describing Profile limitations was not deemed useful
- Both CT and FDG Profiles need testing to check key aspects underlying their claims
- To maintain on-time Profile release, it was suggested site assessment procedures could be addressed in a future Profile version
- Descriptive text added to the Executive Summary and the claim language stating the stage (Technically Confirmed) was deemed acceptable
- Since the Duke synthetic phantom was not ready for production, it was recommended to eliminate sections 4.3 – 4.4 and keep 4.6 (Dr. Perlman will draft strawman text)

### CT CC Profile Vote-to-Release Update

- The CT CC has voted to release the Profile for publishing with a 11/13 YES vote (0 No/Abstain)

#### **Action Items**

- Dr. Perlman to draft brief text outlining section 4 conformance assessment limitations
- Dr. Jarecha and Mr. Tervé working on feasibility checklists for each 'Actor' within the Profile
- Additional offline consensus opinions/feedback encouraged by Friday, Nov 18th

**Next Call:** TBD

\*There will be no BC calls on Monday, November 28<sup>th</sup> (RSNA 2016) *or* Monday, December 5<sup>th</sup>