QIBA CT Volumetry Biomarker Ctte (BC) Call 12 March 2020 at 11 AM (CT) Call Summary

In attendance

Ehsan Samei, PhD (Co-Chair) Jenifer Siegelman, MD, MPH (Co-Chair) Maria Athelogou, PhD Hubert Beaumont, PhD Jocelyn Hoye, PhD James Mulshine, MD Nancy Obuchowski, PhD Kevin O'Donnell, MASc Nicholas Petrick, PhD Ying Tang, PhD **RSNA** Joe Koudelik Julie Lisiecki

Moderator: Dr. Samei

Simulated Lesion Study Discussion:

- Dr. Hoye has been working with simulated 10 mm solid lesions and has expanded testing to include various lesion sizes
- She is looking at LUNG-RADS related to the risk of malignancy and is re-writing simulations for new size benchmarks as follows: 3 mm; 6 mm; 10 mm; 15 mm
- The team is considering adding another category of larger-sized lesions and increasing the upper range
- The 3 6 mm lesions would be of interest to the Small Lung Nodule BC, whereas the 10 100 mm lesions sizes, with breakpoints at 35 and 50 mm would be of greater interest to the CT Advanced Disease Profile
- Parameters in the Small Lung Nodule Profile could be tweaked to match volume in the CT Advanced Diseased Profile
 - o Another call will be scheduled to review the additional simulation test results
 - The Profile Change Proposal depends on these results
- It is not yet clear how to get test-retest data to move to Claim Confirmed (Stage 4)

Partnership with Dr. Beaumont:

- Dr. Beaumont is working with a French cancer center, and they have agreed to make measurements onsite with clinical data to better assess the phantom
- It may be possible to design a study with phantom testing, using an alternative phantom, as the one required by the CT-ADV Profile is not available
- If this may be possible, the following are required:
 - A uniformity section
 - An edge resolution section
 - Calculation of modulation transfer function (MTF) 50 values based on phantom edges
- The group believes this is a feasible solution since the Profile does not require the ACR phantom; any equivalent that meets minimum criteria is acceptable
- Dr. Siegelman suggested drafting a Google document that lists phantoms that are acceptable to be linked to the Profile for reference
- Dr. Beaumont indicated that his colleagues are willing to make the prescribed measurements and to follow the subject handling requirements outlined in the Profile
- They intend to use a CATPHAN phantom, which will allow for scanning and collection of DICOM data to check conformance by providing sample sizes and measurements
- Mr. O'Donnell recommended using a requirements checklist for the actors, along with validation of any segmentation tool used, i.e., automated vs. semi-automated, or fully manual
- Some of the tools are:
 - LIFX fully manual
 - o GE
 - Median Technologies integrated
- To reach the claim confirmed stage, the following details will be needed:
 - o Number of cases and sites (Dr. Obuchowski offered to help identify these numbers)
 - o Multiple sites will be needed to prepare the sample size

- Phantom scanning to generate assessment metrics
- Qualification of scanners that are used for clinical trial work; not all site scanners need to be qualified (this should reduce the effort needed)

Next Steps:

- Reviewing binning of lesion sizes (e.g., small, med, large) as a change proposal for the Profile
- Obtain input from Dr. Obuchowski regarding the work of Dr. Samei's group to determine if a revised coefficient of variation is needed

Action items:

- RSNA Staff to set up a Task Force call in 2 3 weeks via doodle poll for Drs. Beaumont, Hoye, Jarecha, Samei, Siegelman, Obuchowski, and Mr. O'Donnell
- A call for the BC to be scheduled in 4 6 weeks per doodle poll (Dr. Hoye to provide a simulation study update)
- Invite Dr. Schwartz to a future CT Volumetry call to discuss his study

Next Call: To be determined via doodle poll. Doodle poll will be used to confirm participation.