

QIBA CT Small Lung Nodule (SLN) Biomarker Ctte (BC) Call

15 August 2019 at 11 AM CT

Call Summary

In attendance:

Samuel Armato, III, PhD (Co-Chair)

David Gierada, MD (Co-chair)

James Mulshine, MD (Co-Chair)

Rick Avila, MS

Nancy Obuchowski, PhD

RSNA:

Joe Koudelik

Julie Lisecki

Moderator: Dr. Mulshine

Approval of 07.18.2019 call summary

- The summary was approved as written

Claim confirmation (Stage 4) study

- The Claim confirmation study needs sample size calculations
 - Dr. Obuchowski offered statistical assistance
- Plans will be discussed offline in greater detail to determine a path forward
- The Claim may need to be altered due to additional requirements

CTLX2 (water jacket) phantom update

- The CTLX2 phantom received development funding support from the Prevent Cancer Foundation
- This second - generation phantom includes additional materials, such as water jackets to simulate realistic body mass
- This phantom has been designed to allay concerns regarding insufficient mass for human comparison with the CTLX1 phantom
 - The nodules are spaced at 0, 75, and 150 mm out from isocenter
 - Because the simulated nodules are approximately 2 inches in diameter, differing from those in CTLX1, some modifications to the analysis software will be needed
 - These phantoms are designed to be similar to human lung size
- Sixteen of the phantoms will be sent to Poland for their national lung screening effort, and 3-4 more will be reserved for testing in the U.S.
 - In the next few weeks, the first phantom should be complete, and an image test will be performed
- Methods to verify the system performance are being developed

Phantom scanning and work toward technical conformance

- Phantom will be scanned with and without the water jacket to test the protocol and the scanner with high vs. low mass settings
 - Results from this testing will be added to the Profile for conformance certification
 - Radiation dose vs. image quality will be interesting to explore
- Modulation Transfer Function (MTF) curves will be generated for both phantoms, though there are some concerns about the sources and quality of the cases, but BC leaders believe that Dr. Yankelevitz has sufficient material to overcome any concerns
- High-level instructions will be provided to testers
- Dr. Armato, Mr. Avila, and others to devise a software study design to address criticisms that have been leveled at the Profile
 - Dr. Obuchowski to help with sample size calculations
 - This will aid with assembling a dataset for software conformance, with help from Dr. Yankelevitz

- Dr. Gierada emphasized that maintaining an organized plan for BC team members will be important as they work toward conformance and feasibility testing
- The next official step with regard to feasibility testing will be to get sites to complete a questionnaire
 - Mr. Avila has two VA sites that are willing to complete the survey: Phoenix and Atlanta
 - He will follow up with his contacts via email
 - Once this feasibility testing is complete, the Profile can move to Stage 3: Technically Confirmed

MITA

- Medical Imaging and Technology Alliance (MITA) submitted a letter to Dr. Jackson inquiring about metrics used in the SLN Profile
 - Drs. Jackson and Guimaraes are working with MITA offline to arrange a future face to face meeting later this fall; attendees to be identified

Next calls:

- For CT Coordinating Committee members, the next call is Monday, August 19th at 11 am CT
- CT Small Lung Nodule BC: *tentatively scheduled* for September 19th at 1 pm CT