

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

20 November 2018 at 1 PM CT

Call Summary

In attendance:

Samuel G. Armato, III, PhD (Co-Chair)

James L. Mulshine, MD (Co-Chair)

Rick Avila, MS

Philipp Hoelzer, PhD

Nancy Obuchowski, PhD

Mario Silva, MD

Raja Subramaniam, PhD

RSNA:

Joe Koudelik

Julie Lisiecki

Moderator: Mr. Avila

Profile Updates (Mr. Avila)

- Recent edits to the next version of the Profile include the following:
 - The requirement that clinical sites need to verify the performance of their nodule volume software on a small number of datasets (e.g. 5 cases with 2 timepoints each) has been added
 - This has been added to ensure that quality control is in place and that sites will not be able to state that they are conformant based on their use of FDA approved software and CT scanners
 - Section 3.9.2 – Nodule Margin Conspicuity
 - Mr. Avila may provide teaching files for difficult nodules, e.g., above or below the threshold size limit, or attached to peripheral structures
 - These teaching files may be added as an appendix to the Profile or provided online
 - Section 3.10.2 – Image Analysis Tool
 - Scanner and software vendors will be expected to achieve QIBA certification for their products
 - Presently, no requirement is in place for software vendors, but a requirement and metric are needed to assess coefficient of variation and bias
 - Additional details will be added to the conformance section, and use of a small dataset will be required to verify performance
 - Once the Profile is claim confirmed, actors will not be required to complete so many steps; however, until that happens, sufficient evidence must be acquired
 - At least 3 sites need to verify that they can follow the Profile,
 - Software companies need to assess 20 cases with 2 time points
 - Drs. Armato and Silva volunteered to be test sites for the Profile conformance check
 - Dr. Yankelevitz has already contributed data from Mt. Sinai demonstrating use of the Profile with 20 cases provided, with 5 repeat scans for each (greater lesions/cases deemed more statistically powerful than more repeat scans/time points)

Brief Phantoms Update (Mr. Avila)

- 65 phantoms have been distributed worldwide
- 4 different scanner manufacturers are represented
- 23 scanner models are represented
- 16 unique CT scanners are included

Next Steps:

- Dr. Mulshine to confer with Dr. Gierada
- Sites to be contacted regarding details for the field tests to achieve the [Technically Confirmed Stage](#)
 - Some suggested contacts were:
 - Dr. Heidi Schmidt, U-Toronto
 - Dr. Eliot Siegel, U-Maryland
 - Mr. Avila and Dr. Mulshine to follow up

Next call: *tentatively scheduled* for December 13th at 1 pm CT