

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

Breakout Session

20 August 2020 from 1– 3 PM CT

Call Summary

In attendance

Samuel Armato, III, PhD (Co-Chair)

David Gierada, MD (Co-Chair)

James Mulshine, MD (Co-Chair)

Rick Avila, MS

Artit Jirapatnakul, PhD

Annelise Malkus, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Mario Silva, MD

Daniel Sullivan, MD

David Yankelevitz, MD

RSNA

Fiona Miller

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Mulshine

Technical Confirmation Update

- Mr. Avila shared updates to the technical confirmation spreadsheet, which, once finalized, will be posted to the QIBA wiki along with the respective [comment resolution sheet](#)
- Data are available with results from the technical confirmation testing, which will be posted along with the original survey and instructions, so that future users of the Profile can access these resources
 - This survey and data will be used by any sites wishing to test software performance
 - This relates to step 3.2 of the checklist
 - For anyone who wants to obtain the conformance certification mark for software, proper measurements must be taken for the participant to meet requirements
 - Dr. Gierada suggested a finite number of nodules to measure – enough to demonstrate conformance but not too many to be burdensome
- A list of conformant software packages will be provided

Automated Conformance Process

- Mr. O'Donnell reminded the BC leaders that the requirements in section 3.2 of the Profile should be reflected in the checklist
- Some updates are needed, e.g., there is no longer a requirement that software be FDA-approved
- Although the Profile does not require use of the automated conformance service; information is provided for those users who would like to use it
- Mr. O'Donnell mentioned that there were a few places where the checklist and Profile do not match, and he suggested a line-by-line check for accuracy
 - He volunteered to do a first pass to make the documents symmetrical and suggested that re-sorting the Profile requirements table by actor would be helpful when updating the conformance checklist

Outstanding MITA Concerns Discussed

- It was noted that the 15-page BC response to questions regarding the use of point spread function (PSF) instead of modulation transfer function (MTF) had been provided to medical physicists and MITA but no response was received
- Mr. Avila reiterated that the MITA edits made to the RSNA document following the October 2019 meeting should not be considered “consensus” since SLN leadership were not consulted or involved
 - Mr. Avila is working on a separate response and will provide details to QIBA soon
- Resolution remains elusive for questions from the medical physicists and MITA, causing movement forward for the BC to be challenging
 - Unfortunately, there is no requirement for dissenters to respond, placing the onus on the BC, which seems unfair and inhibiting to open dialogue
 - Mr. O'Donnell volunteered to review the 15-page response and highlight concrete answers to the various physicists' issues in hopes of building a bridge
- Dr. Yankelevitz stressed that the QIBA Process does not address how to handle this type of dissent and noted that it is not productive to maintaining momentum
- Dr. Mulshine noted that the issue with PSF is a larger QIBA-wide issue, not just an SLN BC issue, as the Lung Density BC also uses this metric in their Profile

- Mr. O'Donnell requested that any further responses be as specific as possible to address concerns
- Mr. Avila has data that have not yet been analyzed, which he wants to review and publish as soon as possible
- All were asked to consider any possible grant proposal ideas that may aid with future research

Software-related Innovations

- If there is a change in hardware or software, re-test or re-certification would be needed
- It is preferred that open-source software algorithms be used vs. commercial "black-box" packages
- AI-based reconstruction was suggested
- Vendors and QIBA are working in tandem to ID which kernels meet a specific measurement task for software
- Relevant metrics are needed for each measurement task
- Dr. Gierada suggested that if it is possible, it would be ideal to choose one kernel in a suite of kernels that would be designed specifically to optimize image accuracy

CTLX2 Phantom

- This new phantom with a water jacket will allow for more study opportunities and data
- Four compartments can be filled with water or other fluids to add 30-40 lbs. of mass to the phantom
- Dr. Silva will be receiving one of these new phantoms soon
- Dr. Obuchowski will be consulted regarding recommendations for the coefficient of variation

Summary / next steps

- Survey data that have been received from Drs. Silva and Gierada will be posted, along with the questionnaire
- Some references will be amended by Mr. Avila
- Mr. Avila will analyze and share new data to be made available for group review soon
- Mr. O'Donnell will review documents to see if any questions remain that have not been addressed; he will also compile any core details that can be shared with medical physicists and MITA regarding answers to their questions
 - Any response to MITA will be addressed through RSNA
- Mr. Avila is working with vendors on many open questions and should have additional details for QIBA soon

Virtual Workshop

- Dr. Mulshine indicated that the [Quantitative Imaging Workshop](#) (QIW XVII), sponsored by the *Prevent Cancer Foundation* that will be presented via ZOOM, October 28-30, 2020
- The workshop will present findings using low-dose CT scans, focusing on parenchymal imaging of the lung and current best practices related to clinical management applications with a focus on QI relative to early lung screening interventions
- Other organizations that are involved include the *American Lung Association* (ALA) and the *Initiative for Early Lung Cancer Research on Treatment* (IELCART)

Action items (ongoing)

- Mr. Avila is drafting two peer-reviewed manuscripts for 2020 publication, which will demonstrate the SLN conformance process and provide details regarding the data used to make decisions
- Mr. Avila to update Profile [technical confirmation resolution sheet](#) with latest details

Next call: 09/17/2020 CT Small Lung Nodule BC call, 1 pm CT
