

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

13 July 2020 at 10 AM CT

Call Summary

In attendance

Samuel Armato, III, PhD (Co-Chair)

David Gierada, MD (Co-Chair)

Tim Hall, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASC

Daniel Sullivan, MD

RSNA

Julie Lisiecki

Moderator: Dr. Armato

Technical Confirmation Update

- QIBA SLN Leadership met in April to discuss details needed to document technical confirmation
- Detailed responses are needed for the ballot comments per the [Process Committee recommendations](#)
- Site feedback was mentioned though details were not documented
 - It would be helpful to know which sites participated in the technical confirmation testing and to provide their feedback
 - This detail could be posted on the BC wiki committee page until a technical confirmation template is added for the comment resolution page
 - An updated Profile and resolution document are now requested with any ballots for advancement to new Profile stages in either a Word document or spreadsheet format
- Some of the “shalls” in the text for the Profile do not match up with Accumetra’s tool
 - Some portions of the Profile may not have been tested, as it is uncertain if the full range was tested
 - Updates may be needed
- QIBA SLN leadership plan to check consistency of the checklist and update the documents accordingly for posting to the QIBA wiki
- It was recommended that the checklist be sorted by actor
 - It is important that the checklist and Profile table with normative text be aligned
- Adding best practices is unnecessary if not related to Profile claims, as the Profile should remain focused on what affects performance
 - For example, there were some recommendations included regarding radiation dose which may be too restrictive and are not essential to the claims
- Special care should be taken in updating the Profiles and respective [comment resolution sheets](#) and checklists
- [Profile writing guidelines](#) are available on the wiki
- SLN leadership will check with Mr. Avila regarding status of updating the SLN Profile comment resolution sheet with latest details, in the format requested by the [Process Committee](#)

Medical Imaging and Technology Alliance (MITA) Update

- A summary with a reference table with comments and a “consensus” column was provided after the October 2019 f2f meeting at RSNA
- MITA reps provided some feedback in this document
- Mr. O'Donnell suggested that SLN leadership review the document again and try to move some of the comments into the consensus column
- Mr. O'Donnell provided some sample comments in an email on 6/22/2020 which summarized Point-Spread-Function (PSF) vs. Modulation Transfer Function (MTF) differences in methodology
 - Extensive details regarding this discussion were summarized in the [3/19/2020 call notes](#)
- There are approximately 20 comments from MITA; it would be helpful to provide responses to these soon
- Dr. Sullivan noted that SLN leadership must also incorporate Mr. Avila’s comments
- Once this document has been updated, follow up with MITA representatives via a letter or teleconference will be organized

Publications

- Dr. Gierada noted that publications are in progress and he is hopeful that these can be expedited
 - It would be very helpful if team members could work with Mr. Avila and contribute to moving those manuscripts to publication more quickly

Phantom Discussion

- Dr. Gierada suggested that it might be helpful to scan the latest ellipsoid phantom to determine which techniques conform to the Profile and to provide comparisons and observations
- If there are nonconformant techniques which provide results outside of the claim, it would be helpful to know
- It would also be helpful to determine how realistic the phantom is to demonstrate consistency across time points with different parameters
- This might be a good project to submit for publication

Dr. Samei's Research

- On a recent CT Volumetry BC call, Drs. Samei and Hoye presented research on simulated datasets, which may be helpful to the SLN BC regarding performance validation of small lesion sizes (<10mm)
- Patient scan data with digitally simulated lesions were used to simulate scan techniques and reconstruction parameters to explore the limits of measurability
- Dr. Sullivan suggested that it would be helpful for Dr. Samei to present his findings to the SLN BC on a future call; he will follow up with Dr. Samei to discuss this

Profile Suggestions from Mr. O'Donnell

- Add clear text explaining what constitutes scientific validation
- If a requirement does not contribute to the Profile claims, it should be deleted
- Original requirements could be simplified
- The checklist requirements re: scanners being FDA-approved can be deleted as long as the equipment is deemed safe
- Better alignment needed between the checklist and Profile, e.g., Field of View (FOV) spanning the anatomy is not in the checklist but is in the Profile
- Re-sorting the Profile requirements table by actor will be helpful when updating the conformance checklist
- Questions could be addressed one-by-one with a question and answer format, which can be posted to the wiki under the [Profile Comment Resolutions Page](#)

Next steps

- SLN BC Co-Chairs to summarize feedback received during Profile feasibility testing (i.e., for the technical confirmation process) to post to the QIBA wiki to demonstrate how questions were resolved
- The Profile requirements table to be regrouped by actor for ease of use, and mismatch between Profile and checklist to be addressed
 - The Profile has 50 – 52 actor requirements, whereas the checklist has 15
- SLN BC Co-Chairs to review MITA table and finalize comments for response to MITA

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 the Profile comment resolution sheet with latest details, in the format requested by the Process Committee
- Mr. Avila to incorporate change log items into resolution spreadsheet

Next call: 08/20/2020 CT Small Lung Nodule BC call, 1 – 3 pm CT [{breakout session}](#)
