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

19 March 2020 at 1 PM CT

Call Summary

In attendance			**RSNA**
Samuel Armato, III, PhD (Co-Chair)	Artit Jirapatnakul, PhD	Kevin O'Donnell, MASc	Fiona Miller
James Mulshine, MD (Co-Chair)	Nancy Obuchowski, PhD	Dan Sullivan, MD	Joe Koudelik
Tim Hall, PhD			Julie Lisiecki

Moderator: Dr. Mulshine

Technical Confirmation Vote Update

- The CC vote-to-publish the Profile for the Technically Confirmed stage was successful.
  - The ballot closed on Thursday, March 19th with a majority (9 votes) in favor to release the Profile (N=16), with 1 abstention and 2 opposed.
- Steps will be taken to reach consensus on outstanding issues as follows:
  - The QIBA SLN Leadership will meet to resolve the discrepancy in Profile requirements vs. checklist statements
  - Various stakeholders will gather to review the three most pressing issues in an effort to reach consensus; this may potentially be a – two to three-hour WebEx
- Special care should be taken to update the Profiles and respective comment resolution sheets and checklists
- Profile writing guidelines, are available on the wiki
- Mr. Avila is in the process of updating the SLN Profile comment resolution sheet with latest details, in the format requested by the Process Committee

Discussion Overview

- Mr. O'Donnell to reach out to Dr. Samei and other physicists and vendors with a difference in philosophy regarding the use of Point-Spread-Function (PSF) vs. Modulation Transfer Function (MTF) values; specific issues need to be articulated more clearly
- Dr. Mulshine noted that a 15-page response was drafted regarding the Profile requirements; however, Mr. O'Donnell, Chair of the QIBA Process Committee, would like to see the questions addressed one-by-one with a question and answer format, which can be posted to the wiki under the Profile Comment Resolutions Page
- Leadership stressed that all communication needs to be specific and concise to prevent future misunderstandings
- Dr. Armato noted that much of the comment resolution work was originally done in small groups; and for the sake of inclusivity and transparency, a larger group meeting may be needed to resolve any remaining issues
- It was noted that the CT Lung Density Profile utilizes PSF in a similar manner; there were no technical issues raised, further confusing this physics issue
- A function that would allow for translation of PSF values to MTF values would be desirable
- Dr. Sullivan reiterated the importance of peer-reviewed publications that support the SLN methodologies
  - While Mr. Avila is working on some publications, it would be very helpful if team members could contribute to moving those manuscripts to publication more quickly

PSF vs. MTF

- The controversy between use of PSF vs. MTF is not well understood
- Dr. Hall provided an overview of the difference in philosophies
  - PSF is more widely used in clinical diagnostic settings, particularly applicable to the Lung Nodule Screening Profile, whereas MTF is more widely used by the medical physics community
  - These two methods represent different ways of thinking about the same problem
  - One method is not more correct than another; there are interdisciplinary differences in how parameters are characterized with these two methods
  - In moving toward more quantitative language, connections must be made
- In general terms, PSF is a measure of resolution, whereas MTF looks at how well the imaging system reproduces the contrast of scanned bar targets

    - Medical physicists believe that more data can be obtained using MTF
    - Pushback may be due to the perception that MTF is recognized as the current standard metric
- The SLN Profile is written around providing a summary measurement for a particular task; this may not match the typical way physicists think about these issues
    - Lung cancer screening is done in an ambulatory setting, where it is vital to have a simplified approach
- While physicists are not thinking of the problem in the same way, both groups want to see the same performance demonstrated by both methods
- SLN conformance must simple for customers and the process must minimize the need for novel phantoms and metrics to better engage the medical physics community
    - If novel metrics must be used, an explanation is needed
- It was suggested that independent validation of phantom measurements should be considered
    - It would be very helpful to have a paper on the analysis of performance data obtained from instruments all over the world, which could also provide MTF calculations
- Accumetra has a web-based calculator available which allows clinicians and engineers to enter CT lung nodule volume measurements observed at two time points and provides guidance and statistics on the measurement error associated with volume change measurements: https://accumetra.com/qiba-nodule-profile-calculator/

Medical Imaging and Technology Alliance (MITA)-related

- Mr. O'Donnell suggested extracting the three most pressing issues to address from the MITA discussion table; solving all issues was not necessary
- Dr. Mulshine noted that there are MITA members who currently advocate use of the SLN Profile
- Vendor input will be helpful to determine how their processes and measurements are affected

Software Conformance

- The issues with software conformance are evolving for the field as the group learns more from collected data
- The BC is working toward validation and wants to address software conformance in a more robust way while developing metrics that support quantitative imaging
- Mr. O'Donnell expressed appreciation for the pioneering use of automation in the conformance process

Profile Suggestions from Mr. O'Donnell

- Add clear text explaining what constitutes a pass for 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
- Resorting the Profile requirements table by actor will be helpful for updating the conformance checklist

Next steps

- Dr. Mulshine to follow up with Mr. Avila to provide a summary of the discussion and to identify next steps
- Mr. O'Donnell to ask Dr. Samei and others to identify the top three issues from the Profile public comment resolution or the MITA document to discuss
- Mr. O'Donnell to follow up with the SLN BC Co-Chairs regarding outlining 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
- A QIBA SLN Leadership call to be scheduled with Mr. O'Donnell to address technical confirmation documentation and review section 3.2 of the Profile
- 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

Action items (ongoing)

- Mr. Avila is in the process of drafting two peer-reviewed manuscripts for publication in 2020, 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
- Mr. Avila to confer with Drs. Jirapatnakul and Silva regarding drafting an abstract for RSNA 2020
- Dr. Mulshine to update the Dashboard with SLN BC details prior to the Q2 CT CC call
    - Details will include Profile changes, field test completion, and results of the votes to move the Profile to the Technically Confirmed Stage

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Next call: **04/16/2020** CT Small Lung Nodule BC call, 1 pm CT

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