

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

16 December 2020 at 10 AM CT

Call Summary

Additional notes provided by Dr. Mulshine

In attendance

Samuel Armato, PhD (Co-Chair)

David Gierada, MD (Co-Chair)

James Mulshine, MD (Co-Chair)

Rick Avila, MS

Artit Jirapatnakul, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Mario Silva, MD

David Yankelevitz, MD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Mulshine

Scheduling for the next call

- It was decided that the next call will be held on Thursday, January 21, 2021 at 3 pm CT

BC updates (Dr. Mulshine / Mr. Avila)

- The Profile has been updated to address Technical Confirmation feedback over the last several months
 - Mr. Avila is consolidating checklist requirements and updating the Profile
- The BC has been in communication with the Sustainability Implementation Group (SIG) about evolving the conformance service
 - Mr. Avila's proposed star system for conformance levels would assign a star for sections of the Profile on the QIBA mark (see [11/18/2020 call summary](#) for additional details)
 - The SIG approved this idea on 12/9, and Mr. Avila is moving forward with adapting the Profile
- The BC is organizing efforts in conjunction with Drs. Obuchowski, Yankelevitz, and others on demonstrating software conformances
 - Technical Conformance/feasibility surveys and data are available from four sites that participated and Dr. Mulshine asked where these documents should be posted
 - Mr. O'Donnell suggested the BC wiki committee page, as there is only room available on the [comment resolution](#) feedback page for a link to the Excel summary sheet
 - Dr. Mulshine thanked Drs. Silva and Gierada for their help with completing these feasibility surveys
- Collaboration with the Lung Density BC on writing a guidance document on thoracic CT imaging for COVID-19 has occurred and that paper is under review with the *Journal of Clinical Imaging Science*
 - Dr. Yankelevitz is on the editorial board for this journal and noted that if accepted, an editorial was to accompany the guidance document
 - Dr. Yankelevitz asked for recommendations for a senior, well known expert to pen the editorial
 - Dr. George Washko was nominated as a possible editorial author by Dr. Mulshine, due to his experience with the imaging component of the COPDGene project
 - Mr. Avila mentioned that the COVID-19 guidance document has a helpful table with reconstruction images, which will be useful in possible Profile harmonization efforts
- The BC worked with the *Prevent Cancer Foundation* on the [Quantitative Imaging Workshop](#), including a dedicated session on Quantitative Imaging Metrology and associated issues with the evolution of thoracic imaging for lung cancer screening

Software conformance / Reference validated Images Collection Data (Dr. Yankelevitz)

- Dr. Yankelevitz is working on an Institutional Review Board (IRB) approval for Mt. Sinai data release to support the SLN software conformance testing
- He inquired of the group:
 - Do we want to share this data publicly?
 - Should we sequester a portion of the data for the FDA?
 - Would we allow sharing of the data with BC members for testing and research?
 - What components of the software should be tested for the end user?
- Any decision regarding this data will need to be defined explicitly to ensure appropriate permission approved from an IRB standpoint

- An open dataset available for software conformance on a nodule setting would be helpful and could be a resource for validation and for the FDA
- The use-case for the IRB must be chosen carefully; from an efficiency perspective, it would be preferable to have one broad, overarching IRB document to address multiple goals as possible.
- The discussions of this profile group have been focused on clinical zero-change image data, which are available to address the precision of lung nodules for software and scanner conformance especially in regard to claim confirmation of the second claim involving the accuracy and robustness of volume change analysis over time. (JLM)
 - The working assumption is that the reference images used in conformance testing must also conform to the SLN Profile acquisition quality requirements
- The goal is to have zero-change clinical data sets with different size intervals (at least two) and some ellipsoids of different sizes
 - These two points were addressed as the goal of the software conformance testing process within the profile was clarified (JLM)
 - Mr. Avila reminded the group of the open-source lesion sizing toolkit, which is an available reference resource with peer review validation.
- Dr. Gierada suggested inserting synthetic nodules into scans with consideration of software conformance
 - This may be challenging, as reconstruction algorithms are constantly changing
- Dr. Yankelevitz mentioned that tumor doubling times are emerging as a high impact predictor of cancer growth and will be applied clinically in the not-too-distant future with a view toward selecting candidates for neoadjuvant therapy
- The BC to also explore radiomic features, which may need further discussion regarding optimal conformance review.

Action items (ongoing)

- Mr. Avila to create checklists and divide assignments among relevant BC members
- Dr. Obuchowski and Mr. Avila to follow up offline re: software questions
- Mr. Avila is drafting two peer-reviewed manuscripts for 2020 publication, which will support 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
- Mr. Avila to ship one CTLX1S phantom to Dr. Silva for testing
- Mr. O'Donnell inquired about whether or not a response is ready for MITA

Next call: 1/21/2021 (Thursday) CT Small Lung Nodule BC call, 3 pm CT
