

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

15 August 2023 at 12 PM CT

Call Summary

Additional notes provided by Dr. Mulshine

In attendance

Artit Jirapatnakul, PhD (Co-Chair)

Kyle J. Myers, PhD (Co-Chair)

James Mulshine, MD (Co-Chair)

Rick Avila, MS

Kirsten L. Boedeker, PhD

Caroline Chung, MD, FRCPC

David Gierada, MD

Timothy J. Hall, PhD

Claudia Henschke, PhD, MD

Ella Kazerooni, MD

Mathis Konrad, MSc

Kevin O'Donnell, MASc

J.C. Ramirez-Giraldo, PhD

Anthony Reeves, PhD

David Yankelevitz, MD

Lifeng Yu, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Mulshine

Discussion Topics:

- QIBA Transition
- New field work publications —*Mr. Avila*
- Status of implementation of SLN Profile within national lung cancer screening programs—*Dr. Yankelevitz*
- Review process for draft alternative version of the Profile—*Dr. Myers*
- Publication efforts for the Lesions Library Study – *Dr. Jirapatnakul*
- Comments on Profile, Version 2 – *Mr. O'Donnell*

QIBA Transition

- New RSNA committee, the Quantitative Imaging Committee (QUIC) will assume oversight of RSNA's quantitative imaging initiatives
- QIBA BCs and standing committees will be dissolved in ~4 months
- In-process work to be completed **by December 22nd**
- In-process Profiles to be advanced to nearest stage or summary / white paper of the Profile to be published
- The QUIC will review future Profiles for inclusion in the QIBA Profile library, (processes TBD)
- QUIC may initially focus on 1-3 QIBs
- Feasible BC deliverables need to be determined for 4-month window
- [QIBA Wiki](#) will continue to be accessible post-transition
- BC members are welcome to submit comments or questions to the [Future Direction of QIBA Activities Form](#)
- There will be a QIBA Symposium at RSNA 2023 on Wednesday, 11/29, starting at 2 pm CT

Field Work Update (Mr. Avila)

- Mr. Avila provided the history and rationale for splitting the SLN Profile from the CT Volumetry Profile
- He noted that a paper this study utilizing the Point Spread Function (PSF) method had been published recently:
 - Avila, et al, **Calibration phantom-based prediction of CT lung nodule volume measurement performance.** [Quant Imaging Med Surg](#) 2023
 - Another paper will soon be published in the [Journal of Thoracic Oncology](#) (JTO) and will focus on projects for the [Early Lung Imaging Confederation](#) (ELIC) including image quality from a collection of 100 cases of lung cancer CTs with images from two time points from 7 international sites using the Amazon cloud to enable federated image analysis of the assembled cases based on using Amazon regional nodes in a GDPR-compliant fashion.
 - JTO is a major thoracic journal with impact factor around 25.
- Version 1 of the Profile is currently being used in national lung cancer screening programs throughout Canada, Europe, and Australia
- As plans to reconcile the two Profiles are being considered, Mr. Avila requested the authors of the Version 2 Profile review the data

National Lung Cancer Screening Programs Updates (Dr. Yankelevitz)

- After a formal analysis of image quality approaches, 70 sites in Canada have adopted the SLN Profile, V1 and utilize the cloud-based calibration tool for scanners
- Sites in Poland have also adopted the Profile, V1 and the cloud-based tool (including in a pilot grant supported by the Prevent Cancer Foundation with RSNA/QIBA and Accumetra).
- [Dr. Matthijs Oudkerk](#), co-PI of the NELSON trial, also intends to use the small lung nodule Profile, V1, and the cloud-based calibration tool in this trial
- All sites intend to adopt the small lung nodule Profile, V1 to perform high quality lung cancer screening
- Israel and Egypt are considering adopting the Profile, V1 as well
- A new initiative sponsored by Bristol-Myers-Squibb will utilize the Profile, V1 in five African countries soon
- Australian colleagues have also expressed interest
- Colleagues that are using the Small Lung Nodule Profile, V1, consider it to be the global standard for how image quality should be measured based on an ease-of-use process

Lesions Library Resource (Dr. Jirapatnakul)

- Analyzing biopsy scans that utilized the same scanner and protocol
- Some of the data have been donated to the FDA for open-source research
- Mt. Sinai has signed data use agreements to enable sharing with the FDA; IRB approvals are pending
- An article on this research has been submitted to a cardiothoracic journal, for consideration

Task Force on Small Lung Nodule Profile Harmonization (Dr. Myers)

- Dr. Myers has agreed to set up a Task Force to consider issues with the two Profiles relative to the defined context of use and ability to meet the current claims
- Evaluation criteria will be developed, and the strengths of each Profile will be considered, particularly for the feasibility and robustness of measurements
- Timeline for this review is mid-October for a recommendation to be discussed by the SLN BC

Questions regarding Profile Version 2 (Mr. O'Donnell)

- Dr. Yankelevitz inquired about authorship and rationale for the Small Lung Nodule Profile, V2
- Mr. O'Donnell indicated that
 - Version 2 of the Profile was written collaboratively with AAPM and vendor input and was based on the CT Vol Profile, but focused on Modulation Transfer Function (MTF) and tailored for small lung nodules between 6 and 10 mm in size
- Mr. Avila asked for literature citations for international standards on the calculation of MTF
- Dr. Yankelevitz urged all BC members to move past the debate regarding PSF vs. MTF methods and to refocus efforts collectively on applying learning to define a functional Profile, which would highlight the strengths of both approaches
 - This is necessary for continuing high-quality lung cancer screening for the best patient care

Wiki Updates for the Clinically Feasible Stage (formerly Technical Confirmation) (ongoing)

- Mr. Avila to update Profile [technical confirmation resolution sheet](#) with latest details pending resolution of validation studies, as previously approved
- BC leaders / Mr. Avila to provide RSNA staff with documents to post on the wiki (e.g., the clinically feasible confirmation / feasibility surveys, clinically feasible confirmation feedback resolution spreadsheet, etc.)
- The “shalls” in the [Profile](#) needed to be translated to the checklist and vice versa for document alignment subject to the judgement of the BC committee
 - Mr. Avila to draft checklists based on prior call discussions to ensure compliance, and divide assignments among relevant BC members
 - Should any area of complexity emerge, topics will be brought back to the Profile chairs and/or the BC
 - Track change versions of Profile updating will be shared with the Committee prior to finalizing.

Next call: *Tuesday, September 19, 2023 @ 12 pm CT*
