

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

19 September 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

Timothy J. Hall, PhD

Mathis Konrad, MSc

Nancy Obuchowski, PhD

Kevin O'Donnell, MASC

J.C. Ramirez-Giraldo, PhD

Anthony Reeves, PhD

David Yankelevitz, MD

Gudrun Zahlmann, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Mulshine

Discussion Topics:

- Screening Update from IASLC World Lung Conference - *J Mulshine*
- Update on Clinical Outcomes with Delays in Screening Work-ups - *D Yankelevitz*
- Status of Profile Update Task Force initial call - *K Myers*
- Update on CTLX2 evaluation - *R Avila*

Highlights from the IASLC World Lung Conference (Drs. Mulshine and Yankelevitz)

- Screening updates:
 - 4.6 million submissions have been added to the ACR Registry for Thoracic Oncology
 - Screening has achieved greater public and medical acceptance / participation
 - The Centers for Medicare and Medicaid Services (CMS) have [uncoupled requirements for screening](#) and registry submission so that screening numbers will be harder to track going forward.
- Screening is effective in finding cancer with a delicate balance between overdiagnosis and losing opportunity for cure
 - No tools to definitively predict nodule growth rate
 - Need for precise nodule volume between baseline and follow up scans, e.g., 3, 6, 12 months
 - Challenges in getting patients to return for their second scan
- Nodule management should be different for baseline screening and annual follow-up based on recent publication from Yankelevitz and colleagues in the *Journal of Thoracic Oncology (JTO)*.
 - Minimal screening nodule size recommendation is now 4 mm on annual follow-up
 - With appropriate early screening and small nodule size, there is an 83% survival rate
 - Optimal interval time for a follow-up diagnostic scan depends on nodule measurement accuracy – the greater the measurement accuracy, the shorter the follow-up time to confidently measure growth
- The most reliable biomarker predictor of survival outcome is nodule growth rate

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

- Dr. Myers and the Task Force are looking at areas of commonality between Version 1 and a new proposal of the small lung nodule Profiles, including but not limited to:
 - Role of vendors vs. sites physicists and other actors
 - Noise characterizations
 - Major claims (precision, CV)
 - Precision is a function of size
 - Resolution and noise are likely to be the assessments that need to be made and constrained
 - Agreement that resolution decreases from isocenter
 - Recon kernel and slice thickness need to be assessed and controlled
 - Edge enhancement should be monitored
 - Straightforward approaches to make it easier for users
 - Measures of resolution to account for spatial dependence
 - Characterization at periphery – how far and how?
 - Required / acceptable phantoms
 - Utility of anthropomorphic phantom images and RIDER data for software characterization
 - Digital, anthropomorphic, and clinical data

- Other opportunities for software characterization
- Auxiliary metrics in V2 that were included in V1 that are seen as necessary
- Sections that delineate roles for vendors and roles of sites

[Update on CTLX2 evaluation \(Mr. Avila\)](#)

- The Prevent Cancer Foundation (PCF) has funded RSNA/QIBA and Accumetra for the development, distribution, and certification of sites using the CTLX1 and CTLX2 phantoms. The CTLX1 \$50K grant was completed years ago. A second \$50K PCF grant to provide Poland with CTLX2 phantoms and QIBA certifications was started just before the pandemic.
- The CTLX2 grant to support the Poland CT lung cancer screening initiative has not been completed yet due to delays with the pandemic, global supply shortages, and delays in rolling out screening in Poland.
- One deliverable for the CTLX2 grant was to add part-solid lung nodule support to the CT Small Lung Nodule Profile and a proposal to do so will be made to the SLN BC in the coming weeks.
- Updates regarding CTLX2 data will be shared soon, and the CT SLN Profile BC will need to consider adding the CTLX2 phantom to the SLN Profile.

[Action items](#)

- Drs. Zahlmann and Mulshine to reach out to clinical contacts for lung cancer screening
- Mr. Avila to provide data regarding partial-solid nodules to support Profile updates
- BC members are welcome to submit comments or questions to the [Future Direction of QIBA Activities Form](#)
- If BC members are interested in joining future Task Force calls, please contact [RSNA Staff](#)

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

- 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
 - 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, October 17, 2023 @ 12 pm CT*
