

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

30 August 2021 at 10 AM CT

Call Summary

In attendance

Samuel Armato, III, PhD (Co-Chair)
David Gierada, MD (Co-Chair)
James Mulshine, MD (Co-Chair)
Rick Avila, MS
Kirsten L. Boedeker, PhD

Alexander Guimaraes, MD, PhD
Timothy J. Hall, PhD
Annelise Malkus, PhD
Nancy Obuchowski, PhD

Kevin O'Donnell, MASc
Anthony Reeves, PhD
Mario Silva, MD
Gudrun Zahlmann, PhD

RSNA

Fiona Miller
Joe Koudelik
Julie Lisiecki

Moderator: Dr. Mulshine

Updates (Dr. Mulshine)

- In preparation for the September 8th call with QIBA Leadership to discuss the AAPM independent validation approach for Accumetra conformance, Dr. Mulshine and SLN BC leaders requested more details via email to review prior to the discussion
- Discussing conformance in general terms of deliverables relative to the marketplace, timelines, and step-by-step processes would be beneficial to all biomarker committees
- Dr. Guimaraes explained that independent 3rd party vendor tool validation (not part of the Profile development process) needs to be made for all QIBA Profiles to provide a pathway for BCs to test new vendor tools/services used for conformance testing
- [Thomas Griglock, PhD, DABR](#) at OHSU has been working on the independent validation process for the small lung nodule Profile
- The discussion on 9/8 may also address some of the data from the independent validation testing from Dr. Griglock, if available

CTLX2 Phantom Update (Mr. Avila)

- The CTLX2 phantom has been distributed to 14 sites and 15 more are expected to ship to Poland soon
- Requirements for resolution and CT Hounsfield Unit (HU) bias are being met by different scanners and protocols; a decision needs to be made regarding where to set the cut point for image quality
- Claim modification may be needed based on the results from this data
- The water bags for the phantom have recently been upgraded with a thicker, higher-quality material; Dr. Silva will receive his new bags soon
- Dr. Silva hopes to have some initial screening data available by the next BC call

[U.S. Preventative Services Task Force Recommendation \(USPSTF\)](#)

- Leadership of the SLN and Lung Density BCs have had discussions with regarding Profile harmonization to look at the correlation between smokers and COPD
- In studies, 85% of smokers were unaware that they had COPD
- This is a complex issue that underscores the importance of early detection of COPD through lung cancer screening
- While the SLN BC has not been in a direct advisory capacity for Centers for Medicare & Medicaid Services (CMS) decisions, expert opinions have been requested and are advising CMS review
- Widening the eligibility for screening has been recommended from age 55+ to 50+ and from 30-pack years down to 20
- This will increase the eligible screening population from 8 to 14 million
- Concerns remain regarding how to manage at technical, clinical, and monitoring levels
- Quantitative imaging (QI) could be very helpful in the management of screening efforts
- More study is needed regarding what will be involved in the clinical implementation phase
- This is an important opportunity for QIBA to play a role in influencing the international community

- Moving the Lung Density Profile forward to present information to CMS is important especially as a diagnostic Profile could be very complementary to low-dose screening efforts
 - Further evaluation will be required to develop criteria based on screening and to provide more comprehensive diagnostic study guidelines
 - Modifications to the Profiles may be needed
 - Radiomics-related reanalysis will be occurring more broadly
 - Dr. Obuchowski noted that the multiparametric papers are nearly ready to be submitted for publication consideration

Publications shared (Dr. Mulshine)

- Lathan C. **Increased Access for Vulnerable Patient Populations to Promote Equity in Lung Cancer Screening—Clearing a Path.** *JAMA Network Open.* 2021;4(8): e2120699. [doi:10.1001/jamanetworkopen.2021.20699](https://doi.org/10.1001/jamanetworkopen.2021.20699)
- Prosper AE, et al. **Association of Inclusion of More Black Individuals in Lung Cancer Screening with Reduced Mortality.** *JAMA Network Open.* 2021;4(8): e2119629. [doi:10.1001/jamanetworkopen.2021.19629](https://doi.org/10.1001/jamanetworkopen.2021.19629)

Wiki Updates for Technical Confirmation (ongoing)

- Mr. Avila to update Profile [technical confirmation resolution sheet](#) with latest details
- BC leaders / Mr. Avila to provide RSNA staff with documents to post on the wiki (e.g., the technical confirmation / feasibility surveys, technical confirmation feedback resolution spreadsheet, etc.)
- These details were discussed on recent calls (summaries can be found on the [wiki](#))
- The “shalls” in the Profile needed to be translated to the checklist and vice versa for document alignment

Action items (ongoing)

- Mr. Avila to create checklists and divide assignments among relevant BC members

Next call: TBD per Dr. Gierada's clinical schedule
