

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

18 April 2023 at 12 PM CT

Draft 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)*

Jared Christensen, MD, MBA

Caroline Chung, MD, FRCPC

Marios Gavrielides, PhD

Timothy J. Hall, PhD

Claudia Henschke, PhD, MD

Mathis Konrad, MSc

Nancy Obuchowski, PhD

Kevin O'Donnell, MASC

Juan Carlos Ramirez-Giraldo, PhD

Anthony Reeves, PhD

David Yankelevitz, MD

Lifeng Yu, PhD

Gudrun Zahlmann, PhD

### RSNA

Joe Koudelik

Julie Lisiecki

**Moderator:** Dr. Mulshine

### Discussion Topics:

- Introduction to new co-chairs
- Updates for lung cancer screening efforts, in U.S. and Europe
- Lung-RADS update
- Research (Dr. Jirapatnakul)

### Introduction of New Leaders

- Dr. Myers
  - Left FDA in 2021 after 35 years in research and regulatory tool development
  - Was Director of the Division of Imaging, Diagnostics, and Software Reliability in the Center for Devices and Radiological Health
  - Now independent consultant
- Dr. Jirapatnakul
  - Associate professor at Mt. Sinai working in lung cancer screening for 10+ years
  - Develops algorithms for lung cancer nodule detection / measurement
  - Research is in developing algorithms for volumetric measurement, and in diseases of the lung
- The BC would like to thank Drs. Armato and Gierada for their many years of service
  - They will continue to lend their support to BC efforts as their schedules allow and have decided to step down due to other responsibilities

### Lung cancer screening efforts

- Lung cancer screening was nationally implemented in the U.S. in 2013 and became eligible for reimbursement in 2015; made possible by the Affordable Care Act
- Dr. Christensen noted that the literature to date has been mixed on the evidence that the volumetric approach is more effective than the mean diameter approach; however, the next version of Lung-RADS is transitioning to a volumetric approach
- Dr. Mulshine noted that the Profile group has been aware of the absence of a consensus accepted volumetric tool
- There is not a volumetric option that is generally available to screening sites within a routine clinical workflow. This is an important challenge holding back scalability of screening implementation in various settings.
- The SLN Profile document has been developed with an understanding about the need for robustness in thoracic CT screening measurements as this data could soon influence and drive clinical decision making
- The SLN Profile group has worked within QIBA with Accumetra on two projects funded over the last several years by the Prevent Cancer Foundation to implement the SLN conformance process in Poland. This effort on implementation of the SLN conformance has extended to additional countries and involves a number of European Centers.
- Leadership is planning a small pilot study to test the Small Lung Nodule Profile with a subset of sites within the European Lung Cancer Screening efforts

- The European Respiratory Society ([ERS](#)), the European Society of Radiologists ([ESR](#)) and the European Imaging Biomarkers Alliance ([EIBALL](#)) are involved with the lung cancer screening effort for 27 countries in the EU
- Quantitative measurements are sometimes done in parallel but not typically in routine practice, though QIBA hopes to encourage increased use of quantitation
- Each country has its own protocols and procedures, making this more challenging
- Two countries have already published reports with using the SLN Profile approach in their national screening implementation, and a third manuscript on a European national implementation effort using the SLNP within the lung cancer screening process will be submitted soon.

#### Harmonization efforts

- The FDA has developed their MDDT qualification approach which may be helpful to use relative to developing tools for QI used for the lung cancer screening process.
- It was noted that harmonization and standardization for data elements and reporting structures for screening may enable more rapid progress with scalability of lung cancer screening at the interface of clinical data and imaging informatics.

#### Profile Validation Study

- Dr. Thomas Griglock is writing a paper based on an [independent validation assessment](#) of different measurement methods utilized by Oregon Health & Science University ([OHSU](#)), Mt. Sinai, and Accumetra
  - Literature to support the different approaches will be included in this paper
  - Conclusion was that actor results achieved using different methods were quite similar for Accumetra, OHSU, and Mt. Sinai
- SLN and Lung Density Profile members just published a paper about the co-detection of lung cancer and emphysema on thoracic CT scans acquired for lung cancer screening. The article in [AATS](#) demonstrates the need for high quality CT image acquisitions to enable additional QI evaluations for such images.

#### Dr. Jiraptnakul's Research

- Dr. Jiraptnakul's research has been sponsored by the Prevent Cancer Foundation ([PCF](#))
- The same scanner and protocol are used with a slight time difference between scans
- The open source lesion sizing toolkit was used in this study, along with other tools
- Some of the data has been donated to the FDA for open source research, under Dr. Petrick's oversight
- A manuscript is in the works
- This scan – rescan data could be very helpful to various QIBA Profiles and includes lesions ranging from 5 – 15 mm targeted for screening, informative re: the CT Volumetry Advanced Profile (targets lesions from 10 mm and up) and the SLN Profile (target lesions 6-10 mm)
- Need a mechanism to manage how this data can be shared with QIBA researchers consistent with IRB requirements from Mt Sinai.
- SLN leadership is willing to discuss with RSNA's Medical Imaging and Data Resource Center ([MIDRC](#)) how this can be accomplished.

#### **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
- 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.)
- These details were discussed on past 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
- Mr. Avila to create checklists and divide assignments among relevant BC members

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**Next call:** *Tuesday, May 16, 2023 @ 12 pm CT*

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