

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

16 May 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)

Ehsan Abadi, PhD

Rick Avila, MS

Kirsten L. Boedeker, PhD

Debra S. Dyer, MD, FACR

David Gierada, MD

Timothy J. Hall, PhD

Mathis Konrad, MSc

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Anthony Reeves, PhD

Gudrun Zahlmann, PhD

RSNA

Julie Lisiecki

Moderator: Dr. Mulshine

Discussion Topics:

- QIBA Annual Meeting update
- Profile updates
- Lesions Library Resource

[QIBA Annual Meeting Update, May 9 - 10, 2023 \(Dr. Mulshine\)](#)

- Concerns re: long length of time needed for movement from one Profile stage to another
- Discussion regarding what may be optimal in Profile development
- The MRE BC worked with the FDA to achieve biomarker qualification; this path may serve as a template for BCs to strengthen claims
- Dr. Mulshine suggested BC members review Dr. Ehman's slides:
 - [MR Elastography: Biomarker and Profile Development and Implementation](#)
- Dr. Mulshine also suggested that BC members review Dr. Chung's presentation:
 - [Quantitative Imaging and AI](#)

[Profile Update for Wiki document as discussed from prior calls \(Mr. Avila\)](#)

- Current Profile measures 6 x 3.6 x 3.6 mm lesions; the BC hopes to reduce this number to 5 mm for improved screening outcomes in the future.
 - (Henschke CI, et al. Definition of a positive test result in computed tomography screening for lung cancer: a cohort study. *Ann Intern Med* 2013;158:246-52. PMID: 23420233)
- The Profile provides guidance to sites regarding high performance volume change measurements for the CT scanner and measures fundamental properties of the acquisition system to comply with requirements of Profile Claim.
- Accumetra provides sites with an automated report and quantitative data on scanner performance based on the [2018 Lung Cancer Screening Profile](#)
 - This model simulates what a scanner can do and has been in operation since 2017
 - Other phantoms or models are welcome to be tested with the Profile, though no other options are known to exist, but design parameters based on screening requirements are described in the Profile so that other approaches to claim compliance can be developed
 - The Accumetra model supports approximately 80 paying sites globally (most active users include Poland, Canada, and Australia) and outcomes with compliance reported at IASLC World Conference in Vienna in 2022
- Adjustments are being made to the Checklist to match descriptive Profile text, to be completed in one to two months
 - In order to support open research in this area, the open-source Lesion Sizing Toolkit has been updated to make it more compatible with additional software, and more publicly available datasets have been provided to the FDA and hopefully will at some point be available through QIBA as a Profile resource.
- Dr. Zahlmann is eager to have the Checklist updated to move forward with using the SLN Profile in European lung cancer screening efforts. (Two publications – from UK and Italy discuss use of the SLN Profile in their

screening related image quality efforts with an in-depth discussion of this process in Poland. Screening pilot activities to be submitted for publication soon).

Lesions Library Resource (Dr. Jirapatnakul)

- The library consists of a set of zero change nodules
- Scans are acquired during a fine needle biopsy procedure
- Multiple scans are available to aid with measuring variability
- 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 have been donated to the FDA for open-source research, and a manuscript is being written. Data use agreements are being prepared to enable data sharing with the FDA and QIBA researchers
- Dr. Jirapatnakul would like to make the data publicly available, but a suitable repository/platform has not yet been determined
- The QIDW cannot support any clinical data or data that require curation but will explore for options to make such references routinely available to the research community subject to regulatory and data integrity factors.
- Mr. O'Donnell noted that a write-up of the acquisition procedures would be helpful

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.
 - These are issues that have been discussed, and where relevant, approved by Profile committed vote as reflected in QIBA call minutes.
- 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
 - For the subject matter discussed on this call, Mr. Avila to draft checklists based on our prior call discussions to ensure compliance and divide assignments among relevant BC members if relevant, such as with accessing the Wash U software conformance data as previously discussed on SLN calls, and subject to review and approval of Profile leadership and full committee if relevant.
 - Should any area of complexity emerge in reviewing these matters, such topics will be brought back to the Profile chairs and brought back for discussion with the committee membership as appropriate.
 - Track change versions of Profile updating with be shared with the Committee prior to finalizing.

Next call: *Tuesday, June 20, 2023 @ 12 pm CT*
