

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

20 June 2023 at 12 PM CT

Call Summary

In attendance

Artit Jirapatnakul, PhD (Co-Chair)

Kyle J. Myers, PhD (Co-Chair)

James Mulshine, MD (Co-Chair)

Rick Avila, MS

Caroline Chung, MD, FRCPC

Debra S. Dyer, MD, FACR

David Gierada, MD

Mathis Konrad, MSc

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

J.C. Ramirez-Giraldo, PhD

Anthony Reeves, PhD

Gudrun Zahlmann, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Mulshine

Discussion Topics:

- Review of Minutes from May 16, 2023 SLN call
- Discuss review of COI process for SLN calls
- Review MRI FDA qualification process presentation from QIBA Annual Meeting
- Lesions Library Resource and Toolkit

Updates

- The call summary from May 16, 2023, was approved as presented

QIBA Conflict of Interest (COI) Policy

- Clear distinction to be made between business/company presentations and biomarker committee scientific work to ensure transparency
- Any potential conflicts should be declared at the beginning of each BC call

FDA Qualification Model, MRE (Dr. Mulshine)

- 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](#)
- SLN BC may have an opportunity for FDA qualification with new technology
- Dr. Mulshine to invite Dr. Ehman to an upcoming BC call to describe the qualification process and share insight re: how to best collect supporting data required by FDA
- Three types of FDA qualification include: 1) drug development; 2) medical devices; 3) biomarker
 - Advancement for biomarker qualification is difficult because clinical use must be demonstrated
- Letter of Intent for the MRE use case was submitted to FDA in 2020; link to the [FDA's acceptance](#)
- FDA funding received by Dr. Ehman to complete supporting data collection

Lesion Sizing Toolkit (Mr. Avila)

- The original tool for studying lesion sizing algorithms was funded by the Air Force and has been publicly available for 10+ years
- The open-source Lesion Sizing Toolkit has been updated (Apache 2 license)
- More publicly available datasets have been provided to Dr. Petrick at the FDA
- The QIDW cannot accept patient data; alternatives are being explored

Lesions Library Resource (Dr. Jirapatnakul)

- The library of biopsy tissue consists of a set of zero change nodules
- The same scanner and protocol were used with a slight time difference between multiple 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

- Data use agreements have been signed by Mt. Sinai to enable data sharing with the FDA and that approach may serve as a model for QIBA researchers in addressing the activities permitted by the Mt Sinai IRB.

Action item (new)

- Dr. Mulshine to invite Dr. Ehman to an upcoming BC call
- RSNA staff to distribute draft Profile document, version 2, for review and consideration by the Committee members

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
 - Mr. Avila to draft checklists based on 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, August 15, 2023 @ 12 pm CT {no call in July}*
