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

16 May 2023 at 12 PM CT Call Summary

Additional notes provided by Dr. Mulshine

In attendance RSNA

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 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:
 - o 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 Updates (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
- The Profile provides guidance to sites regarding high performance volume change measurements for the CT scanner and measures fundamental properties of the acquisition system
- 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 providing global access for a screening conformance service at low cost with real-time feedback to evaluate for claim conformance in evaluating lung nodules from 6-10 mm is a challenge for which to date there are limited options.
 - The Accumetra model currently supports approximately 80 paying sites globally (it is endorsed as the default for conformance system for Canadian Lung Cancer Screening implementation with parallel national implementation efforts underway in Poland and other countries.
- Adjustments are being made to the Checklist to match descriptive Profile text, to be completed in one to two
 months
 - The open-source Lesion Sizing Toolkit has been updated to make it more compatible with additional software, and more publicly available datasets have been added
- Dr. Zahlmann is eager to have the Checklist updated to move forward with using the SLN Profile in European lung cancer screening efforts

Lesions Library Resource (Dr. Jirapatnakul)

- The library consists of a set of zero change nodules of specified volumes across the range of nodule sizes relevant to the Profile.
- 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 a pending publication along with other tools
- Some of the data have been donated to the FDA for open-source research, and a manuscript is being written
 to describe the provenance of the image collection as well as defining nodule measurement with existing
 tools.
 - A Data use agreement was prepared to enable data sharing with the FDA and QIBA researchers
- Dr. Jirapatnakul would like to make the data publicly available for QIBA use, but a suitable repository/platform
 has not yet been determined
- The QIDW cannot support any clinical data or data that require curation, so other options will be explored
- 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 <u>technical confirmation resolution sheet</u> 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

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