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

24 October 2023 at 10 AM CT Call Summary

In attendance RSNA

Artit Jirapatnakul, PhD (Co-Chair)

Kyle J. Myers, PhD (Co-Chair)

James Mulshine, MD (Co-Chair)

Chuck Hatt, PhD (guest speaker)

Timothy J. Hall, PhD Ella Kazerooni, MD Mathis Konrad, MSc Nancy Obuchowski, PhD Kevin O'Donnell, MASc David Yankelevitz, MD Lifeng Yu, PhD

Gudrun Zahlmann, PhD

Joe Koudelik Julie Lisiecki

Moderator: Dr. Mulshine

Discussion Topics:

- Brief overview of Imbio's new 510K approved thoracic CT tool—Dr. Hatt
- Summary of the status of the Draft Profile Review Task Force—Dr. Myers
- Review Next steps for SLN Profile—Dr. Mulshine

Overview of Imbio's FDA approved Thoracic CT Tool

- Imbio has received FDA 510(k) clearance for a new cardiothoracic imaging algorithm, CAC analysis
- The tool provides quantitative findings
- The software agrees well with what human readers were reporting
- Next step will be to look at repeatability and reproducibility in longitudinal studies

Other topics

- There is limited access to quality datasets that are linked to outcomes
- To get to ground truth, data are needed
- Lack of clinical demand/justification for billing remains a challenge for many similar QI tools
- Clinicians need to understand the value of QI before willing to pay and devote extra time to implement; this remains a greater challenge than the science/technology development
- A CPT code has been approved for post-processing AI thoracic CTs

Small Lung Nodule Profile Harmonization Task Force (Dr. Myers)

- Dr. Myers and the Task Force have evaluated areas of commonality between Version 1 and a new proposal of the small lung nodule Profiles during a recent 4-hour call
- Dr. Myers will be working on incorporating updates
- Once complete, she will share the updated document with the Task Force and then the full BC for review
- Discussions included characterization of lesions and reinforcement that small nodules are important for early cancer detection
- Disconnect between the medical physics field and clinicians needs to be addressed by demonstrating how measurement performance can affect clinical decision making
- Plan is to complete Profile updates by December 22, 2023
- The SLN group will continue to meet after December with possible admin support from the American Lung Association

Quantitative Imaging Workshop (Nov. 2-3, 2023)

- The Prevent Cancer Foundation (PCF) and American Lung Association (ALA) will be co-hosting a virtual Quantitative Imaging Workshop
- Many topics affecting radiologists will be addressed; all are welcome to attend

Action items

- Drs. Zahlmann and Mulshine to reach out to clinical contacts for lung cancer screening
- Mr. Avila to provide data regarding partial-solid nodules to support Profile updates

Wiki Updates for the Clinically Feasible Stage (formerly Technical Confirmation) (ongoing)

- The "shalls" in the <u>Profile</u> needed to be translated to the checklist and vice versa for document alignment subject to the judgement of the BC committee
 - o Mr. Avila to draft checklists based on prior call discussions to ensure compliance
 - o Should any area of complexity emerge, topics will be brought back to the Profile chairs and/or the BC
 - o Track change versions of Profile updating will be shared with the Committee prior to finalizing.

Next call: Tuesday, November 21, 2023 @ 12 pm CT
