QIBA CT Small Lung Nodule (SLN) Biomarker Ctte (BC) Call
06 September 2018 at 1 PM CT
Call Summary

In attendance:			**RSNA:**
Samuel G. Armato, III, PhD (Co-Chair)	Philipp Hoelzer, PhD	Mario Silva, MD	Joe Koudelik
David S. Gierada, MD (Co-Chair)	Nancy Obuchowski, PhD	David Yankelevitz, MD	Julie Lisiecki
James L. Mulshine, MD (Co-Chair)	Kevin O'Donnell, MASc		

Moderator: Dr. Mulshine

ELIC Pilot Project (Dr. Mulshine)

- Mr. Avila will present a live demonstration of computational experiments at 10 international sites at the *19th World Conference on Lung Cancer* (**WCLC**) in Toronto on September 22nd
- A subset of the IASLC, *the Early Lung Imaging Confederation*, (**ELIC**), is supporting a pilot project for an open-source quantitative lung volume experiment project aimed at validating drug and tool evaluation in a non-competitive space
- The ELIC cloud-based secure tool is comprised of a centralized analysis hub-and data-shared (multi-site) spoke architecture and a de-identified image archive.
    - This framework will help remove IRB barriers to site participation, providing access to high quality data while meeting the clinical data regulatory requirements for the European Union (EU)
- There are 10 global spokes on the Amazon Cloud, each providing 100 de-identified CT lung images (total of 1,000)
- Two separate open-source algorithms/tools will be used to assess the following:
    - lung lesion volume (a lesion sizing tool)
    - nodule segmentation
- This will demonstrate that prospective CT image quality can be monitored and optimized in the hub and spoke environment with the RSNA / QIBA Small Lung Nodule Profile
- This proof-of-concept study is to demonstrate that analysis tools can work in different cloud-based environments
- The desired goal would be achieving identical results across all 10 sites
- All code is being distributed as free open-source software, and sites are welcome to contribute to software development

Software Conformance Testing

- Dr. Gierada will analyze data received utilizing spreadsheets to tabulate results and software conformance
- To date, he has used software from Mt. Sinai and the VA, testing the software conformance phantom with 80 nodules
- No straightforward answers exist to determine measures of variance; clear instructions are needed for case analysis
- Software tools are in place to measure lesion volume
- Once complete, repeat scans will be released and made publicly available
- These scans will contain three different size categories of nodules, scanned at 5 different time points
- While these resources will be made available, it has not yet been determined how to best package them for use
- Dr. Yankelevitz has conducted some varied scans with five repeats to obtain additional data based on standard lung cancer screening protocols
- Drs. Schwartz, Kelloff, and Sullivan have noted that the FDA is moving away from using RECIST criteria to utilizing more recognized volumetric criteria for imaging
- The FDA has been very supportive of the ELIC Pilot Project, and they are becoming more granular in what data to submit
- The Small Lung Nodule BC members are working to provide specific data to address any FDA concerns
- Quantitative endpoints are more accurate than RECIST criteria; however, specific context of use cases are needed
- It would be helpful to acquire the FDA status on volumetric processes for qualification
- Mr. O'Donnell indicated that it may be necessary to distinguish between clinical and technical performance claims
- It is possible that a publication may be developed based on these efforts to deliver reliable performance

Phantom Logistics

- Dr. Yankelevitz shipped the phantom he recently tested to Dr. Supanich at Rush University
- Dr. Supanich will ship the phantom to Dr. Armato at the University of Chicago
- Dr. Armato will ship the phantom to Dr. Gierada at Mallinckrodt Institute of Radiology, Washington University

Sharing the News

- Mr. O'Donnell indicated that he would pass along information to the CT section at MITA (*the Medical Imaging & Technology Alliance*) to share information about the pilot project with potentially interested manufacturing vendors
    - It was suggested that providing a test dataset for the Small Lung Nodule Profile might be helpful to add to *the Quantitative Imaging Data Warehouse* (QIDW)
    - Dr. Mulshine to follow up with Dr. Erickson, (Chair of the QIBA QIDW Oversight Committee), and Dr. Frank (former Chair of the Molecular Imaging Section of MITA)
- Dr. Yankelevitz indicated that he would publicize efforts on Mt. Sinai's website
- Algorithm challenges were suggested as another collaborative vehicle for future consideration

Next Steps

- Dr. Mulshine to follow up with Mr. Avila to coordinate a live demonstration of the cloud-based resource for BC members
- Additional promotional efforts to be identified regarding the study

Next call: October 18th at 1 pm CT

- Calls will be scheduled bimonthly in the near future and will eventually be scheduled monthly