

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

18 November 2020 at 3 PM CT

Call Summary

Additional notes provided by Dr. Mulshine

In attendance

Samuel Armato, PhD (Co-Chair)

David Gierada, MD (Co-Chair)

James Mulshine, MD (Co-Chair)

Rick Avila, MS

Timothy J. Hall, PhD

Artit Jirapatnakul, PhD

Philip F. Judy, PhD

Annelise Malkus, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Mario Silva, MD

David Yankelevitz, MD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Mulshine

QIW XVII Virtual Workshop Overview (Dr. Mulshine)

- Dr. Mulshine gave a synopsis of some of the highlights from The [Quantitative Imaging Workshop](#) (QIW XVII), sponsored by the *Prevent Cancer Foundation*
 - *If interested, a link to the recorded sessions can be requested through [Dr. Mulshine](#)*
- Topics included metrology, QI, integration of combined modality approaches, management of early detected lung cancers, and formalizing quantitative assessment of COPD for prolonged tobacco use
- Dr. Mulshine hopes that this workshop will aid the SLN BC in determining future directions for the SLN Profile, including ideas for management of pre-symptomatic disease, as well as overlapping issues related to COVID-19 studies
- Drs. Hatt, Fain, and Washko are interested in drafting a guidance for lung cancer screening, which may be a collaborative effort amongst respective CT BCs
 - They are interested in forming a consortium with lung cancer screening and lung density / COPD Gene studies due to the symbiotic relationship between Profiles
- Dr. Sullivan was honored with the James L. Mulshine, M.D., National Leadership Award for his efforts in the National Lung Screening Trial (NLST), a research study sponsored by the National Cancer Institute (NCI) and for his work in founding and chairing QIBA.
- Dr. Andrew von Eschenbach, former Director of the NCI in a pre-recorded video segment reviewed Dr. Sullivan's contributions to imaging research. His comments included highlighting Dr. Sullivan's role in launching the National Lung Screening Trial, which is the largest ever, single organ cancer screening trial as well as his efforts in advancing quantitative imaging through QIBA.
- Dr. Yankelevitz mentioned that tumor doubling time was determined as the only really usable measurement for validation of clinical aggressiveness of Stage IA lung cancer.
- Dr. Oudkerk, who as a co-PI of the recently reported NELSON study, is now involved in a Dutch/ Chinese collaborative study of low-dose thoracic CT and emphasized the need for standardization and quality-control measures for quantitative imaging; also concurred that measurement variance issues were essential to address with software tools.

MITA Update

- Mr. O'Donnell inquired about whether or not a response is ready for MITA
- Mr. Avila noted that he is discussing how to proceed with QIBA Leadership and intends to follow up with Dr. Sullivan for next steps
- He hopes to have an update for the BC on the next call

Phantom Updates (Mr. Avila)

- Additional institutions have requested the CLX2 phantom
- Dr. Silva will be receiving a phantom soon
- Mr. Avila is working to reconcile requirements for the checklist and the Profile to finalize conformance certification procedures
- Development of a CT table phantom was mentioned as a long-term goal for the SLN Profile

QIBA Conformance Levels (Mr. Avila)

- Dr. Zahlmann had discussed awarding certification marks for the imaging part of the Profile
- Mr. Avila proposed using a system of 3 small gold stars to modify the existing certification mark
- Each star would represent a section that was passed as follows:
 - Scanner + protocol
 - Scanner + protocol + software
 - Scanner + protocol + software + all other checklist parameters
- Mr. O'Donnell agreed with the need for the approach and noted that some Marks may need 4 stars depending on checklist complexity
- Dr. Gierada noted that even passing one section with one star would be helpful, and practical guidelines would be useful
- Mr. O'Donnell said that for clinical trials, the scanner + protocol would be very valuable
 - Other elements, such as breath hold, positioning, etc., would be important to track for technologists
- The order of the stars in the mark would be similar across Profiles
- A key on the wiki explaining what each tier means would be helpful

Data (Dr. Yankelevitz)

- BC members discussed statistical considerations for SLN Profile Conformance
- From previous discussions, ideally data should be available from different scanners. Currently, at Mt. Sinai, there are five cooperating sites with different scanner types as well as data from I-ELCAP sites potentially available.
- In discussion with Nancy Obuchowski, for rigorous software conformance purposes, fifteen nodules are required; but 20 – 25 nodules in each size would be preferable.
- Dr. Yankelevitz's goal is to get 20-25 cases of small nodules <10 mm in diameter and 20-25 cases with nodules > 12mm in diameter as the basic collection per Dr. Obuchowski's design, and variance will be examined
- These datasets will be made available to BC members and a portion for testing will be sequestered

Action items (ongoing)

- Mr. Avila to create checklists and divide assignments among relevant BC members
- Dr. Obuchowski and Mr. Avila to follow up offline re: software questions
- Mr. Avila is drafting two peer-reviewed manuscripts for 2020 publication, which will support the SLN conformance process and provide details regarding the data used to make decisions
- Mr. Avila to update Profile [technical confirmation resolution sheet](#) with latest details
- Mr. Avila to ship one CTLX1S phantom to Dr. Silva for testing

Next call: 12/16/2020 (Wednesday) CT Small Lung Nodule BC call, 10 am CT
