

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

21 March 2019 at 1 PM CT

Call Summary

In attendance:

James L. Mulshine, MD (Co-Chair)
Rick Avila, MS

Artit Jirapatnakul, PhD
Nancy Obuchowski, PhD

Kevin O'Donnell, MASc
Mario Silva, MD

RSNA:

Joe Koudelik
Julie Lisiecki

Moderator: Dr. Mulshine

Prevent Cancer Foundation International Grant 1 Results Update (Mr. Avila):

- RSNA / Accumetra were awarded \$50K starting in August 2017
- A no-cost 6-month extension was granted so that the project could be completed by February 2019
- Major goals were to:
 - Set up an additional cloud-based CT image quality phantom analysis service in Frankfurt, Germany
 - This was completed in January 2018
 - Manufacture and distribute ≥ 40 phantoms to international sites with 80% of scanners passing
 - 42 phantoms were distributed globally by December 2018
 - The final 20 phantoms proved challenging to distribute, i.e., difficult to engage sites to accept and use the phantoms
 - Estimate improvement in small lung nodule volume measurement performance and publish two papers (one clinical, one technical)
 - 34 CT scanners were tested
 - Of these, 10 (27%) passed on the first attempt
 - 21 (63%) passed on the last/final attempt (after help provided by Accumetra)
- Data analysis is ongoing
- Two manuscripts are being developed that will report on the CT image quality data collected in this international study. Draft manuscripts to be ready for BC review by end of April
 - One manuscript will describe the technical methods used in the study, an assessment of the international variation observed for a wide range of current models of CT scanners, and an estimate of the impact the new CT image quality standards will have on small lung nodule measurement performance.
 - A Second clinical manuscript will assess the adherence of global low dose CT lung cancer screening image acquisition protocols to published lung cancer screening recommendations from clinical societies and institutions.
 - Both manuscripts will be submitted to major journals.

Challenges in Managing this Study:

- Some sites had language barriers and required the aid of translators
- While careful records were kept regarding when phantoms were shipped and when sites received them, sometimes there was considerable lag time before a site would begin and/or complete testing
- Satellite sites might not have completed testing until much later than their primary site
- Data was obtained from 34 CT scanners, with 63% passing
 - Fewer than 27% passed in clinical practice settings
- Unfortunately, a major scanner manufacturer changed all of their reconstruction kernels, resulting in additional challenges in providing instructions to testers

- There is ongoing work in this area to adjust protocols, as very little information is available on this recon kernel change
- 88 phantoms have been distributed around the world (including the US), and will soon surpass 100
- Data collected included DICOM data, measurement data, pass/fail data, etc.
- Participants in the study will receive a spreadsheet with their results, allowing them to compare against the best performers
 - Before results can be distributed, anonymization of results, site locations, and study descriptions is needed

Ellipsoid Phantom

- Mr. Avila has developed an ellipsoid phantom which allows the user to add mass via water tubes
- This phantom will be larger in size but will have adjustable features, making it more versatile
- The ellipsoid phantom will also be sent to sixteen imaging sites in Poland for the rollout of national lung cancer screening efforts

Medical Imaging & Technology Alliance (MITA):

- Mr. O'Donnell suggested that Mr. Avila present his findings to the CT Study Section of MITA
- Collaborating with MITA might be helpful to minimize some of the hurdles with manufacturer changes
- Transparency with metrics and methods was recommended to avoid possible vendor pushback
- Mr. O'Donnell to set up an appointment for Mr. Avila with the group in the near future

Other topics:

- A requirement added to the CT Vol Advanced Disease Profile regarding single collimation width was included in the SLN Profile, though it has since been determined that this is not necessary, as one can obtain data by reviewing the DICOM headers
- Therefore, this test has not been performed and perhaps can be eliminated
- Mr. Avila will include some text indicating that this is not a hard requirement in passing the conformance test, but a recommendation
- Additional discussion regarding this topic will occur on the next BC call

Next calls and deadlines:

- Deadline for ½ page groundwork proposals that will be included in the QIBA letter to pharma are due to Dr. Zahlmann and CT CC leadership on Monday, April 15th
- CT Small Lung Nodule BC: *tentatively scheduled* for April 18th at 1 pm CT
- Also – for CT Coordinating Committee members, the next call is Monday, April 29th at 2 pm CT