

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

27 May 2021 at 2 PM CT

Call Summary

Additional notes provided by Dr. Mulshine

In attendance

Samuel Armato, III, PhD (Co-Chair)

David Gierada, MD (Co-Chair)

James Mulshine, MD (Co-Chair)

Rick Avila, MS

Kirsten L. Boedeker, PhD

Alexander Guimaraes, MD, PhD

Artit Jirapatnakul, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Anthony Reeves, PhD

Mario Silva, MD

David Yankelevitz, MD

Gudrun Zahlmann, PhD

RSNA

Fiona Miller

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Mulshine

Publication update (Dr. Yankelevitz)

- A new clinical imaging article was recently published regarding a review of 50,000 patients with COPD and emphysema
- More than twenty percent of patients were documented via CT scans as having emphysema, with no knowledge of having the illness
- In many cases, the emphysema was severe, which demonstrates the importance of screening to get at-risk patients the treatment they need in a timely manner

CTLX2 Phantom Update (Mr. Avila)

- Mr. Avila gave an overview of the new, low cost (~\$600) CTLX2 phantom design for measuring the fundamental properties of CT image acquisition systems.
 - This new design was in response to criticism of the initial CTLX1 phantom that it did not have sufficient mass to fully simulate the conditions encountered with thoracic CT imaging.
 - The first CTLX2 phantom has shipped, and five more are ready for shipping
- The inner foam core holds 3 cylindrical modules, and an access port to add a collection of nodules to test software performance
- 3D printed modules are positioned at isocenter, 75mm, and 150mm off isocenter to mimic a large patient
- The phantom accommodates four 1600 ml "hydration packs" to add water
- Hydration packs save on material/production and shipping costs, providing flexibility
- The 3 lb. EVA foam density has a CT attenuation of -955 HU
- The fixed mAs method was used in initial testing
- Dr. Silva plans to do some testing with automatic exposure control (AEC) with a mixture of water and contrast agent
- Any data obtained will be extremely useful and will be analyzed by the BC members along with statistical and metrological review provided by Dr. Obuchowski
- Mr. Avila noted that if the BC approves this phantom design, slight modifications will be needed to the SLN Profile to address the higher CT noise values observed due to the greater phantom mass, i.e., performance parameters will vary slightly for the CTLX1 and CTLX2 phantoms
- Drs. Yankelevitz, Mulshine, and Mr. Avila noted that the CTLX1 and CTLX2 phantoms were developed with the BC in conjunction with the Profile and the analysis software
 - Multiple vendors were consulted in the development of the CTLX2 phantom
- Dr. Mulshine reiterated that the Profile conformance process (phantom and software) is not exclusive to Accumetra; any approach that could match or exceed the performance as outlined in the Small Nodule Profile that achieves the requirements of the Claims is acceptable.
- At this time, we are not aware of an alternative product that can be used for this function. However, the Profile team is working on developing open reference tools for the relevant volume range for early lung cancer characterization, to enable transparent evaluation of imaging performance for devices, software, and related research.

Questions re: phantom

- Mr. Avila to reach out to vendor stakeholders and the AAPM for feedback; Mr. O'Donnell offered to facilitate discussion with AAPM
- Dr. Boedeker requested the water equivalent diameter (an AAPM metric) and revisited questions on behalf of MITA
- Mr. Avila noted that questions remain regarding a specific reference for the phantom calculation using the MTF method from MITA and their preferred method
 - Dr. Boedeker offered to follow up with SLN BC leadership directly

Advice regarding future software conformance testing (Dr. Zahlmann)

- Dr. Zahlmann explained that the QSIC is interested in a formal process that can be used to validate performance of software used to analyze the phantom
 - QIBA is considering another 3rd party service provider pilot with an MR-based group, and any practical advice would be appreciated regarding validation tool/process development
 - The goal is to validate a 3rd party's software output against QIBA ground truth to assess performance
- Dr. Mulshine noted that the software aids with the complexity of analysis in a clinical setting, and is an important component

Wiki Updates for Technical Confirmation (ongoing)

- Mr. Avila to update Profile [technical confirmation resolution sheet](#) with latest details
- BC leaders / Mr. Avila to provide RSNA staff with documents to post on the wiki (e.g., the technical confirmation / feasibility surveys, technical confirmation feedback resolution spreadsheet, etc.)
- These details were discussed on recent 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

Action items (ongoing)

- Mr. Avila to create checklists and divide assignments among relevant BC members
- Mr. O'Donnell / Dr. Boedeker to follow up offline regarding MITA / AAPM questions

Next call: TBD for June per Dr. Gierada's clinical schedule
