

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

21 January 2021 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

Annelise Malkus, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASC

Juan Carlos Ramirez-Giraldo, PhD

Mario Silva, MD

David Yankelevitz, MD

RSNA

Julie Lisiecki

Moderator: Dr. Mulshine

Guidance document update (Mr. Avila)

- The guidance document on thoracic CT imaging for COVID-19, which was written in collaboration with the Lung Density BC, has been accepted by the *Journal of Clinical Imaging Science*
 - Publication of this guidance document is a significant achievement for QIBA

Discussion of Proposed New Conformance Mark Graphics (Mr. Avila)

- Mr. Avila shared a proposed alternative Profile conformance mark with three distinctive icons in place of the original star system, as requested by QIBA Sustainability Implementation Committee (QSIC)



- The Conformance wiki page would require a key to define the icons and provide detail about what it means to get a passing mark for each individual icon

Feasibility check for software conformance (Mr. Avila)

- Mr. Avila went on to describe how each clinical site will be asked to measure 5 ellipsoids to test their software
- He wanted to ascertain what is reasonable to ask of a clinical site before giving out a conformance mark
- Testing in the quantitation process seems logical, as many software programs have not yet been tested
- If the quantitative software used for nodule measurement has been FDA-approved, a quick check of actual software measurement of phantom ellipsoids in the relevant volume range may be all that is needed
- Dr. Silva will be the next recipient of the CTLX-S phantom to perform the software analysis
- Dr. Gierada had previously tested the phantom with two different types of software and discovered issues with bias and precision
 - Some adjustments for bias may be needed to meet the claims
- Mr. Avila to follow up with Dr. Obuchowski for a more in-depth claims discussion offline
- The BC would eventually like to post an approved list of software for Profile users to reference
 - Additional discussion will be needed on a future call

QIBA Campaign 2021 (Dr. Mulshine)

- The QIBA Campaign 2021 was distributed via e-mail to all active QIBA members on 1/8/2021, and will also be featured in the February 2021 *QIBA Newsletter*
- QIBA Leadership has identified a list of recommended goals for all BCs for 2021, based on previous achievements, and would like all BCs to work on meeting these goals:
 - a. Obtain clinical-user input re: the potential clinical role (i.e., clinical relevance) of the imaging biomarker, and the appropriateness of the Profile Claim. The “clinical-user perspective” may reflect:
 - i. Clinical trial needs
 - ii. Clinical practice needs
 - iii. Payer perspective
 - b. For Profiles that are:

- i. In development, or Stage 1 or Stage 2, advance the Profile at least one Stage within the year.
 - ii. At Stage 3 (Technically Confirmed), write a concept proposal for clinical data collection that would help move the Profile to Stage 4 (Claim Confirmed).
 - c. Draft at least one manuscript for a peer-reviewed publication.
 - d. Write a concept proposal for a groundwork or clinical research project that could form the basis for an application to an external funding entity.
 - e. Consider/discuss submitting a proposal to make a QIBA presentation at a professional meeting. Educationally oriented presentations to non-radiology organizations are particularly encouraged.
 - f. Discuss committee leadership succession planning and recruiting new committee members, where relevant.
- Dr. Mulshine suggested that the COVID-19 Guidance document meets the publication goal, and another manuscript on the evaluation of ellipsoid phantom for software conformance may be a second possibility
 - All are encouraged to consider presentations at professional meetings, additional publications, and plans to advance the Profile
 - Drs. Armato and Gierada thought that a more focused discussion should take place on the next BC call, where the BC members discuss and rank strategies for moving the Profile to stage 4 (Claim Confirmed)
 - Clinical confirmation would require qualification of a method or tool relevant to the small lung nodule Profile
 - Dr. Mulshine suggested that there could be sponsors interested in funding some of this QIBA work related to establishing performance of tools, e.g., the open-source reference measurement tool
 - A common denominator, reference tool may be of utility to allow comparisons of new conformance tools as well as for other applications. It would be of value to ensure the availability to the community of such validation tools.
 - An open dataset available for software conformance on a well characterized collection of nodules imaged in the screening setting would be helpful and could be a resource for validation and for the FDA
 - Drs. Gierada and Armato agreed that there are many potential paths forward to be discussed on the next call

Action items (ongoing)

- Dr. Obuchowski and Mr. Avila to follow up offline re: software questions
- Mr. Avila to create checklists and divide assignments among relevant BC members
- BC leaders / Mr. Avila to provide RSNA staff with documents to post on the wiki (e.g., the technical conformance / feasibility surveys, technical confirmation spreadsheet, etc.)
- Mr. Avila is drafting two peer-reviewed manuscripts for 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: *Thursday, February 25th at 10 am CT*
