

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

23 March 2021 at 1 PM CT

Call Summary

### In attendance

Samuel Armato, III, PhD (Co-Chair)

David Gierada, MD (Co-Chair)

James Mulshine, MD (Co-Chair)

Rick Avila, MS

Rudresh Jarecha, MBBS, DNB, DMRE

Ella Kazerooni, MD

Annelise Malkus, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Anthony Reeves, PhD

Mario Silva, MD

Bino Varghese, PhD

David Yankelevitz, MD

Gudrun Zahlmann, PhD

### RSNA

Joe Koudelik

Julie Lisiecki







**Moderator:** Dr. Mulshine

### Publication Updates (Mr. Avila)

- The guidance document on thoracic CT imaging for COVID-19, which was written in collaboration with the Lung Density BC and contains lung cancer and COPD Gene protocols, has been published by *Clinical Imaging*
  - Avila RS, Fain SB, Hatt C, Armato SG, Mulshine JL, Gierada D, Silva M, Lynch DA, Hoffman EA, Ranallo FN, Mayo JR, Yankelevitz DF, Estepar RSJ, Subramaniam R, Henschke CI, Guimaraes A, Sullivan DC,  
**QIBA guidance: Computed tomography imaging for COVID-19 quantitative imaging applications**, *Clinical Imaging*, Volume 77, 2021, Pages 151-157, ISSN 0899-7071, <https://doi.org/10.1016/j.clinimag.2021.02.017>.
  - <https://www.sciencedirect.com/science/article/pii/S0899707121000735>
  - The article has been featured on [QIBA LinkedIn](#) and [Twitter](#), and is available via [QIBA Endnote](#)
- Another article by Dr. Yankelevitz on lung cancer screening efforts has also been published in *Clinical Imaging*
  - Kunwei L, Liu X, Yip R, Yankelevitz DF, et al. **Early prediction of severity in coronavirus disease (COVID-19) using quantitative CT imaging**. *Clinical Imaging*, In Press, Pre-Proof, Published online: February 10, 2021. <https://doi.org/10.1016/j.clinimag.2021.02.003>

### Proposal for the Small Nodule Conformance Certification Process Update (Rick Avila)

- A formal presentation will be given to the QIBA Sustainability Implementation Committee (QSIC) on 3/24
- Some clarification of the definition for Technical Confirmation is needed
  - Mr. Avila stated that Technical Image Quality Confirmation does not necessarily mean that an actor is completely conformant to the Profile, but rather has achieved a high level of image quality
  - Mr. O'Donnell stressed that conformance to the Profile means meeting all requirements
    - Mr. O'Donnell to provide some edits for the definitions
- Ribbons were discussed as an optional "component" layer for certification for
  - 1) image quality and
  - 2) software quality
- Wording for each mark may change slightly from a Technically Confirmed Profile to a fully conformant Profile
- There are differences in wording for independent testing (3<sup>rd</sup> party) vs. self-testing (self-attestation)
- Certification has been primarily focused on imaging sites though vendor certification is also planned
- A relationship between QIBA Profile Stages and conformance was discussed
  - Most Profile actors cannot be fully conformant at Stage 3 (Technically Confirmed)
  - Mr. O'Donnell thought that weaving QIBA Profile Stages (what QIBA does with Profiles) into conformance (what end-users do with Profiles) is very confusing
  - Conformance = meeting requirements fully
- Dr. Zahlmann added that we must differentiate between the QIBA Process and what the site would do

		Method		
		Self Testing	Independent Testing	
Meaning	3 Full Profile Conformant	 CT Small Lung Nodule Profile Self-Attestation Conformant	 CT Small Lung Nodule Profile Conformant	Certification Mark : Claim Conformant
	2 Technical Conformance	 CT Small Lung Nodule Technically Self-Attestation Conformant	 CT Small Lung Nodule Technically Conformant	Certification Mark : Technically Conformant
	1 Component Conformant (Optional)	 Clinical Site Name QIBA CT Small Lung Nodule CT Image Quality Self Conformant	 Clinical Site Name QIBA CT Small Lung Nodule CT Image Quality Conformant	Certification Ribbon

**Statistical consideration with conformance testing (Dr. Obuchowski)**

- Dr. Obuchowski mentioned that there are variations in methods to achieve Stage 3 and Stage 4 amongst the Profiles due to differing requirements
- Dr. Obuchowski emphasized that we need the appropriate rigor to be certain that the claims are being met
  - Conformance is only satisfied when sites are meeting the claim(s)
- Dr. Mulshine suggested that we do not yet know what the marketplace will think about the QIBA “marks” and QIBA teams need to come to an agreement about the definitions to convince colleagues in the industry that conformance is a way to reduce variance
- Dr. Zahlmann said that it is important to keep the conformance documentation simple and easily understood
- Mr. Avila urged the group to work toward a decision
- Dr. Armato summarized that a solution is needed that is logical, timely, and will allow QIBA to move forward
- Dr. Mulshine promised more time for Dr. Obuchowski to discuss the statistical aspects on the next call

**Wiki Updates for Technical Confirmation**

- 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)**

- On the next BC call, Dr. Obuchowski to discuss the statistical background for the conformance marks
- On the next BC call, Dr. Jirapatnakul to provide an update on his experiments
- Mr. Avila to create checklists and divide assignments among relevant BC members
- Mr. Avila to ship one CTLX1S phantom to Dr. Silva for testing

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

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