QIBA Lung Density Biomarker Committee (BC) Call

March 11, 2020 at 2 PM (CT) Call Summary

In attendance

Sean Fain, PhD (Co-Chair) Charles Hatt, PhD (Co-Chair) Miranda Kirby, PhD (Co-Chair) Ehsan Abadi, PhD David Lynch, MD Amin Motahari, PhD Nancy Obuchowski, PhD Juan Carlos Ramirez-Giraldo, PhD **RSNA** Joe Koudelik Julie Lisiecki

Moderator: Dr. Hatt

Lung Density Biomarker Qualification Update (Dr. Lynch):

- Dr. Lynch reached out to leaders of the American Lung Association study regarding a possible qualification for the Profile, and they have agreed to test it
- Dr. Lynch noted that the COPD Biomarker Qualification Committee submitted a letter of intent (LOI) to the FDA for Lung Density (BM), and the QIBA Profile was considered the backbone of this application

Profile Public Comment Resolution:

- The BC is working through resolution of public comments received from AAPM and Mr. O'Donnell
- A Google link for Public Comment Resolution has been created for ease of sharing updates with the group:

 https://drive.google.com/file/d/1uOzBaB 77vLSv8FKtQ59AxpfcAswtJ4t/view?usp=sharing
- Because Google documents eliminate line numbers, it is necessary to reference the original document that was sent out for Public Comment, which can be found on the QIBA Wiki Profiles Page:
 - o <u>http://qibawiki.rsna.org/index.php/Profiles</u>
- Dr. Fain has addressed the majority of the AAPM CT Subcommittee comments
 - Help is needed to address some of the remaining comments posed by AAPM that require medical physicist expertise
 - There is concern that one of the AAPM questions might not be possible to resolve without changing the phantom setup, which may prove too difficult
 - Consensus was that requiring a certified (AAPM) medical physicist may be overly ambitious and result in site pushback; suggestion made to eliminate the certification requirement for this actor
- Dr. Hatt will assign Public Comment resolution issues to BC members based on their expertise
 - Assignments will be included in the comment resolution spreadsheet under the "owner" column
- Once responses are complete, they will be posted on the **QIBA Wiki Profile Comment Resolution Page**

Next Steps:

- Once public comments are addressed, a vote will be held to publish the Profile as Consensus (Stage 2)
- Following Consensus, the BC will consider how to move the Profile to Technically Confirmed (Stage 3)

Profile Stages:

- To officially reach Consensus (Stage 2), the BC must complete its response to the Public Comments received and request a vote to publish at both the BC and CT CC levels
 - Checklists and Conformance Procedures must also be established

Action items:

- 1. BC members may be assigned follow up items (based on expertise) to resolve public comment questions and report back to the BC on a future call (Drs. Hatt and Fain to follow up offline)
- 2. Dr. Fain to follow up with Mr. O'Donnell (QIBA Process Cmte Chair) re: next steps for Profile advancement

Next meetings: 4/22, 5/27, 6/24, 7/22