

QIBA Lung Density Biomarker Committee (BC) Call

July 24, 2019 at 2 PM CT

Call Summary

In attendance

Sean Fain, PhD (Co-Chair)

David Lynch, MD (Co-Chair)

Charles Hatt, PhD (Co-Chair)

Byoung Wook Choi, MD

Stephen Humphries, PhD

Philip Judy, PhD

Nancy Obuchowski, PhD

Amin Motahari, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Fain

Leadership Transitions:

- Dr. Fain will work with Dr. Hatt to ease the transition during the Profile public comment period (3Q2019) and will remain on as a co-chair until the end of the calendar year
- Dr. Fuld has officially stepped down from his role as co-chair and has been succeeded by Dr. Hatt

Preparation for Profile Public Comment:

- The BC vote-to-release for public comment was successful. The ballot closed at EOB on Friday, July 15 with a majority (7 votes) in favor to release the Profile (N=8), with 0 “no” votes or abstentions.
- Presently, the CT CC vote-to-release is active until EOB on Friday, August 16.
- Once voting procedures are complete, there will be a 60-day Public Comment period

Profile work:

- Dr. Fain will focus on meta-analysis and work on the claim in order to publish on the group’s work
- He also intends to transition Profile writing to other BC members using a team approach
 - Sections will be divided up for responses once public comments are received

Profile edits needed:

- Appendices are not showing up in the Profile Table of Contents; Dr. Fain to fix this prior to public comment
- Action items were reviewed for various actors as Dr. Fain has begun work on extrapolating a checklist
 - While the checklists may not be ready in time for public comment, they will be added to the Appendices once they are complete

Lung Density and Small Lung Nodule BC Collaboration Update:

- Drs. Hatt and Mulshine had an offline discussion regarding a combined screening protocol
- It was determined that a combined CT Profile for multiple biomarkers may deviate too much from a single biomarker imaging protocol, possibly causing errors, and would likely prove to be too complex, causing expansion of scope for multiple biomarker committees
 - an ad hoc call may be scheduled to discuss the average CT doses for lung density and lung cancer screening
- For lung density, the AAPM recommends the upper end of a reduced dose at 3 milligray (mGy)
- In addition, the best repeatability cohort for lung density may be spiromics, which may encourage further investigation
- Dr. Hatt will follow up with Dr. Gierada regarding obtaining some low-dose lung cancer screening data to do some repeatability testing and obtain performance data for low-dose scans

Re-engagement of vendors needed:

- Dr. Lynch noted that the group needs to prioritize re-engagement of manufacturers in the discussions
- Perhaps a new Siemens representative can be engaged, as Dr. Hoelzer seems to have limited volunteer time due to new work responsibilities
- Greater software representation needed; a new representative from VIDA would be very helpful
 - Dr. Lynch to ask Jered Sieren about identifying someone
- Other software mentioned to consider included YACTA, Verona, 3D-Slicer, and Coreline

- It is hoped that vendor input can help the BC to address iterative reconstruction (IR) questions despite the changing landscape
- Exploring filter and back-projection was discussed
- If standardization of IR is not possible, try to find a stable IR value for the Profile
- Dr. Fain thinks that variation may be related to segmentation and how it changes the line of regression

Other data:

- National Lung Screening Trial (NLST) data was deemed too dated for the committee's needs
- NELSON study data might be helpful, if it might be available for sharing
- Dr. Lynch to draft an email summarizing the current status of the Lung Density BC with plans for the future, to go to colleagues with a request for clinical data
- Dr. Lynch mentioned that the American Lung Association (ALA) will be releasing some helpful data in the next year and that it would be good to collaborate

Protease Inhibitor 10 (Pi10):

- Dr. Kirby did follow up on Pi10 and has provided supporting literature for review
- This may be a more robust measurement to consider
- A software comparison using Pi10 might be considered to offer guidance for reproducibility measures, as commercial vs. non-commercial methods are quite different

Dr. Judy's suggestions for future consideration:

- Dr. Judy mentioned that the original biomarker committee was formed to study COPD and Asthma while lung morphology was put on hold
- Now may be the time to revive morphology as there is expertise and interest within the Lung Density BC
- A reproducibility study, with vendor support, was suggested, along with additional study of airways using the COPDGene data for airway morphology; work might then transition to an airway biomarker
- Current Profiles are somewhat conservative; the BC would need to specify bias and repeatability for another Profile

Next steps:

- More discussion is needed regarding how to leverage COPDGene data for the Profile's Checklist as well as how to work in parallel to complete feasibility testing and achieve Stage 3: Technical Confirmation
- Perhaps Dr. Humphries would be able to help with a comparison between conventional and low-dose studies to test the Profile and obtain additional repeatability data for low-dose scans

Action items (provided by Dr. Fain):

1. Fix Profile appendix links to sections (Dr. Fain)
2. Build checklists (Dr. Fain)
3. Invite vendors to our meetings to discuss a software comparison project for Pi10 (Dr. Kirby?)
4. Reach out to leaders of the American Lung Association study that is in planning regarding a possible qualification for the profile (Dr. Lynch)
5. Consider a recent CT lung screening data set for testing repeatability and bias of coronary calcium score, lung parenchymal density, and Volumetry to establish a baseline for multi-parametric performance for low dose chest CT (Dr. Hatt).

Next meeting: Wednesday, August 21, 2019 at 2 pm CT