

## QIBA Lung Density Biomarker Committee (BC)

Wednesday, July 27, 2022, 2 PM CT

Call Summary

### In attendance

Charles Hatt, PhD (Co-Chair)

Miranda Kirby, PhD (Co-Chair)

Ehsan Abadi, PhD

Samuel Yoffe Ash, MD

Raúl San José Estépar, PhD

Philip F. Judy, PhD

Mathis Konrad, MSc

David A. Lynch, MB

Hatem Mehrez, PhD

John D. Newell, Jr., MD

Sam Peterson, MS

### RSNA

Julie Lisiecki

**Moderator:** Dr. Hatt

### The following topics were discussed:

- Requirements for [Clinically Feasible Stage](#) (formerly [Technical Confirmation \(Stage 3\)](#) for the Lung Density Profile
- Update re: the [Air-trapping Profile](#)
- Proposed reproducibility study
- FDA biomarker qualification for lung density as a biomarker for emphysema

### Discussion:

#### Lung Density Profile Checklist Update

- Dr. Humphries is working with his technologists to evaluate the feasibility of the Lung Density Profile checklist for technologists
- Dr. Hatt has received feedback from Dr. Lynch re: the Radiologist portion of the checklist and will solicit input from Drs. Kazerooni and Newell
- Feedback on the checklist is needed from image analysis core experts

#### Reproducibility Study

- The QIDW is no longer a viable image storage option for the study
- Dropbox or another image/data storage alternative that will allow public access is being considered
- Dr. Humphries suggested a “mini-DICOM” format, where some headers are excluded, reducing PHI risk
- The [Grand Challenge](#) site was also suggested as a possibility
- It is uncertain whether a new ancillary study is needed or if the previous one might be amended  
A consistent method to segment phantom images will be discussed

#### Proposed FDA Biomarker Qualification

- Dr. Lynch, in collaboration with the [COPD Foundation](#), the [Fleischner Society](#), and QIBA colleagues, is working on a position paper for FDA biomarker qualification of Lung Density as a biomarker for emphysema
- Question was raised if the BC should consider updating the existing Lung Density Profile to include new technical parameters, e.g., new scanners, Photon Counting CT Technology (PCCT), etc.
- Not enough is known about PCCT at this time; so, either new research would be needed, or a statement could be added to the “open issues” section of the Profile
- Dr. Lynch has also reached out to Dr. Cynthia McCollough re: PCCT
- Vendor expertise in evaluating Profile feasibility is also needed; Dr. Lynch to reach out to Dr. Ramirez-Giraldo and another Siemens colleague

### Action items:

- [Dr. Lynch](#) to follow up with QIBA Leadership re: proposed FDA Biomarker Qualification for Lung Density as a biomarker for emphysema
- [Dr. Hatt](#) to follow up with Dr. Humphries re: ancillary study / data questions

**Previous action items (please strike if complete):**

- [Drs. Kirby, Hatt](#), and [Vegas Sánchez-Ferrero](#) to provide detailed plan of what specific additional resources will be needed for the proposed ~50 COPDGene subject software comparison study
  - [Proposal needs approval by](#) QIBA CT CC and the QIBA Steering Committee
- [Dr. Hatt](#) to look into existing studies (e.g., spiromics, etc.) that might be compatible with the Lung Density Profile to aid with reaching Technical Confirmation and validating the algorithms used
  - Plan to replicate software comparison study with gas-trapping Profile
- [Dr. Hatt](#) to contact Drs. Zahlmann, Boss, and Mr. O'Donnell for advice regarding Technical Confirmation and Profile conformance re: the original emphysema Profile
- [Mr. Avila](#) to follow up with Dr. Noël offline to discuss reproducibility and replication of 3-D printed phantoms
- [Drs. Hatt, Mulshine](#), and [Mr. Avila](#) to discuss a proposed combined Claim Confirmed (Stage 4) study with lung density and small lung nodule

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- [Dr. Fain](#) to follow up with a colleague, Alejandro C., regarding COPDGene papers, including FRC, Phase II, etc.
  - [Dr. Hatt](#) to add some notes about the 3/23 discussion to the gas-trapping Google Profile document
  - [Dr. Hatt](#) to ask Dr. Newell re: spiromics data ancillary studies once paper has been published
  - [Dr. Hatt](#) to connect with Dr. Abadi re: virtual imaging
  - Volunteers may be needed to assist Dr. Vegas-Sánchez-Ferrero with segmentation work
  - [RSNA staff](#) suggest contacting [Dr. Hoppel](#) re: the multi-site Lung Density “road trip” experiment data
  - Standardized naming of actors across QIBA Profiles (medical physicist or image analysis core, TBD)
  - Exploration of cross-sectional claim instead of longitudinal for gas-trapping Profile

**Next meetings:** 8/24, 9/28, 10/26

**References:** [Profile Stages page](#) | [Technical Confirmation Process](#) | streamlined Profile [conformance checklist](#)

- [Notes](#) posted to the [Lung Density BC QIBA wiki page](#) can be referenced for detailed descriptions of biomarkers