

## QIBA Lung Density Biomarker Committee (BC) Call

June 28, 2017 at 2 PM CT

Call Summary

### In attendance

Sean Fain, PhD (Co-Chair)

David Lynch, MD (Co-Chair)

Andrew Buckler, MS

Heather Chen-Mayer, PhD

Gonzalo Vegas Sanchez-Ferrero, PhD, MSc

Charles Hatt, PhD

Stephen Humphries, PhD

Philip Judy, PhD

Miranda Kirby, PhD

### RSNA

Joe Koudelik

Susan Weinmann

Information from Dr. Fain's agenda incorporated into notes

### Proposed changes to Profile draft

- Updates made based on QIBA f2f meeting in May:
  - To include estimate of MTF from edge response function as preferred method (inclusion of reference from ISO standard provided by Dr. Estepar)
  - Spiromics CT protocols published in the Blue Journal do not meet dose specifications - alternative preferred protocols for Section 4 that will meet Profile Claims are needed
  - **The following are to be revisited as Open Issues:**
    - Calibration procedure in Section 4 to be revisited
    - Resolution of lobar segmentation and density analysis
      - Resolutions are not necessary to conduct density measure, but are useful
      - Setting a gold standard will be difficult; manual segmentation suggested as option
    - Airway measurements
  - QIBA-SRM phantom deemed the preferred method, but COPD Gene phantom to be specified as minimum standard and reference in sections 4.1 and 4.2
  - Imaging sites may suggest using alternate phantoms, e.g., ACR Phantom
  - Better calibration procedures needed to reduce system variation
  - Comments from Dr. Lynch to be resolved
  - Issue regarding 10% difference in lung inflation issue has been closed
  - Checklist of remaining issues to be distributed to the committee
    - Results of software comparison
    - References to be finalized

### Final Issues for Software Comparison

- Discussion on whether to allow multiple submissions per vendor
- Need to provide details regarding access to the "Test Scan Available" on the QIDW in appendix

### New Action Items for Follow-Up from Face 2 Face:

- Empirical specifications from MTF measured using PSF derived from radial ERF using Round 1 data to be obtained
  - Drs. Chen-Mayer & Fuld assigned with help from Drs. Estepar & Vegas Sanchez-Ferrero
  - Note that MTF is assumed to have isotropic in-plane spatial resolution
- Supplementary proposal with COPD Gene (Depending on Renewal Outcome)

- COPD Biomarker Qualification Consortium (CBQC) plans to submit a letter of intent to the FDA regarding CT as a biomarker of emphysema in clinical trials
  - No imaging standards developed yet
  - Submitting the Lung Density Profile to CBQC was suggested as initial collaboration and important supplement to the future “briefing document”
  - Dr. Lynch to spearhead this possible collaboration effort
  
- A non-inferiority design for low vs. conventional dose CT was discussed
  - Noise decorrelation techniques to be tested (aims summarized by Drs. Estepar and Vegas Sanchez-Ferrero)
  - Iterative reconstruction methodologies and consistency across vendors
  
- Field testing of QIBA lung density protocols should be supported
- Benefits of volume adjustment methods against PFT outcomes and progression should be tested
- Next steps:
  - Assign lead point person or team to follow-through with the proposal

**Next call:** Updates on the proposed comparative study will be discussed

**Next call:** [Wednesday, July 19, 2017 at 2 pm CT](#)