

QIBA Lung Density Biomarker Committee (BC) Call

July 25, 2018 at 2 PM CT

Call Summary

In attendance

Sean Fain, PhD (Co-Chair)

David Lynch, MD (Co-Chair)

Bernice Hoppel, PhD

Stephen Humphries, PhD

Philip Judy, PhD

Miranda Kirby, PhD

Nancy Obuchowski, PhD

Raul San José Estepar, PhD

Jered Sieren, BSRT (R) MR CT

RSNA

Joe Koudelik

Julie Lisiecki

Comparative Study Update:

- Study designers will soon be requesting that all vendors reanalyze the data and include the QA step to evaluate the reproducibility coefficient
- The goal of this additional analysis is to see whether variability could be improved with a careful assessment of lung segmentation without calibration
- Study designers (*Drs. Hatt, Kirby, Estepar, and Mr. Sieren*) will look at the figures and segmentation to improve variability and to include a more robust and uniform measurement for the Profile
- Repeatability coefficients need to tie the results to the claim for the Profile, though this is challenging as ground truth is not known
- Dr. Lynch voiced concern about how these numbers differ significantly
- A 30-day window will be requested to recomplete this testing by vendors, after which the analysis will be incorporated into the Profile

Profile review:

- Dr. Fain intends to initiate internal review of the Profile with BC members soon
- Mid-September is the goal for Profile release for public comment
- Feedback from experts on the committee is needed for specific Profile sections
- Feedback encouraged regarding additional societies or contacts for the public comment review phase

CBQC Update:

- It was decided that the COPD Biomarker Qualification Consortium (CBQC) will pursue biomarker qualification with the FDA for emphysema using the QIBA Profile, focusing on lung attenuation area (LAA) and Perc 15
- Dr. Lynch to work on a letter of intent (LOI) in advance of the CBQC meeting to be held during the European Respiratory Society (ERS) meeting in September
- Dr. Lynch needs a mature Profile document **by mid-August** to include with this LOI

Next steps:

- Definition of the number that needs to be met (cut point) and request of re-analysis by the concordant vendors
- Definition of the repeatability coefficient from the software analysis results
- Integration of challenge results into the Profile

Next meeting: [Wednesday, August 22, 2018 at 2 pm CT](#) (*Calls will now be scheduled monthly, for the 4th Wednesday*)