

## QIBA Lung Density Biomarker Committee (BC) Call

September 26, 2018 at 2 PM CT

### Call Summary

#### In attendance

Sean Fain, PhD (Co-Chair)

David A. Lynch, MD (Co-Chair)

Charles Hatt, PhD

Philipp Hoelzer, PhD

Bernice Hoppel, PhD

Stephen Humphries, PhD

Miranda Kirby, PhD

Nancy Obuchowski, PhD

#### RSNA

Joe Koudelik

Julie Lisiecki

#### RSNA 2018 Poster:

- It was decided that the BC will produce a poster for the QIBA Kiosk including updates as follows:
  - Algorithm reproducibility study including final results and reproducibility coefficients
  - Author list updates to include Dr. Kirby
  - Possible update regarding the FDA biomarker qualification effort in collaboration with the CBQC
- Dr. Kirby volunteered to help with editing the content for the poster, which will be circulated to the BC for review prior to the October 31<sup>st</sup> print-ready deadline

#### Comparative Study Update:

- RSNA Staff provided Dr. Kirby with data received from the Round 2 study
- Only two participants have not yet provided results; one indicated that results will be submitted after October 3<sup>rd</sup>
- Dr. Kirby noted that vendors have made some QA tweaks to their data and expects that the reproducibility coefficients will be much better in this second round
- She anticipates having final results ready for inclusion in the poster by October 31<sup>st</sup>

#### Profile update:

- Once data from the reproducibility study are analyzed, Dr. Fain to update the Profile with a more robust and uniform measurement and prepare the Profile to be released for public comment
- Feedback is encouraged regarding additional societies or contacts for the upcoming public comment review phase

#### CBQC Update (Dr. Lynch):

- The COPD Biomarker Qualification Consortium (CBQC) is pursuing biomarker qualification with the FDA for emphysema using the QIBA Profile, focusing on lung attenuation area (LAA) and Perc 15
- Dr. Lynch provided a letter of intent (LOI) for the CBQC meeting which was held during the [European Respiratory Society \(ERS\) meeting](#), and will distribute details to BC members for reference
- Due to FDA requirements that the letter of intent define a biomarker based on a single use, a separate/parallel letter of intent is required to address the second use: one for monitoring, and one for diagnosis
- Dr. Lynch also requested volunteers to join upcoming monthly calls with the CBQC to work on preparation for biomarker qualification
- Drs. Fain and Hatt volunteered to provide technical support
- Dr. Lynch will ask [Debbie Merrill](#) at the CBQC to add them to the monthly calls

#### Next steps:

- Definition of the repeatability coefficient from the software analysis results
- Integration of challenge results into the Profile
- Updating the RSNA 2018 poster for the QIBA Kiosk prior to the October 31<sup>st</sup> print-ready deadline

**Next meeting:** [Wednesday, October 24, 2018 at 2 pm CT](#) (Calls will now be scheduled monthly, for the 4<sup>th</sup> Wednesday)

#### QIBA Working Meeting and Meet-the-Experts Sessions at RSNA 2018:

- All are encouraged to RSVP for the [QIBA Working Meeting](#) on Wednesday, November 28<sup>th</sup>.
- All are invited to volunteer for [Meet-the-Expert](#) session times