### QIBA Lung Density Biomarker Committee (BC) Call

April 25, 2018 at 2 PM CT Draft Call Summary

In attendanceRSNASean Fain, PhD (Co-Chair)Stephen Humphries, PhDNancy Obuchowski, PhDJoe KoudelikCharles Hatt, PhDMiranda Kirby, PhDGonzalo Vegas-Sanchez-Ferrero, PhD, MScJulie LisieckiBernice Hoppel, PhDJohn Newell, Jr., MD

## **Profile Updates:**

- Dr. Fain has made updates to the Profile based on internal BC comments received
- An issue regarding allowing automatic exposure control (AEC) dose modulation within a certain percentage is close to being resolved
  - Because use of AEC may be a source of additional variability for comparisons across different scanner makes and models, Dr. Lynch would like to reevaluate whether or not the Profile dismisses the effects of variability as "sufficiently small" and perhaps revisit AEC for future cross-sectional claims.
  - Resolution is to have AEC be an open issue. It is acceptable in the current longitudinal claim for dose reduction, assuming it is used for both time points; however, AEC is an open issue for development of a future cross-sectional claim.
- Radiologist has been changed to Technologist within actor tables
- For the assessment of variability introduced by the analysis software, the committee is uncertain as to how to state the upper bound of the 95% confidence intervals for the bias of RA-950 and Perc 15 since ground truth is not known
  - Want to make sure that tools are conformant with stated parameters
  - o A repeatability coefficient needs to be defined
  - Once a performance cut point is determined to separate high from low(er) performing sites, some additional vendor image analysis by the high performing sites will be needed to determine test/re-test analysis repeatability.
  - Vendors will be asked to measure lung volume, RA-950 and Perc 15 for the reference images again so we can evaluate bias and repeatability for the same software tool and compare this to the between software analysis already performed.
- An Excel spreadsheet will be made available with anonymized data for conformance testing for Profile users. This could include an automated calculation to determine conformance.

#### **CBQC Meeting at ATS 2018 Conference:**

- Dr. Lynch will present at the COPD Biomarker Qualification Consortium (CBQC) to raise awareness of the Profile on Friday, May 18<sup>th</sup> in the evening; Please let Dr. Lynch know if you can attend: <a href="mailto:LynchD@NJHealth.org"><u>LynchD@NJHealth.org</u></a>
- There will also be an informal meeting of QIBA Lung Density BC members at the ATS 2017 Conference; Dr. Fain will follow up with details for those attending

## **Software Challenge Analysis Results**: (Drs. Kirby and Hatt)

- There were nine vendors who participated:
  - o Two used research software tools; One used an open-source tool; Six used commercial tools
  - Of these, seven were fully-automated and two were semi-automated
- Bias is unknown, as there is no "truth" measurement; however, variability may be obtained for inter-vendor comparison
- Additional updates to the Profile will need to be made based on results of the software comparison study once intra-vendor bias and repeatability is known.

# Next steps:

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

**Next meeting:** Wednesday, June 27, 2018 at 2 pm CT (Calls will now be scheduled monthly, for the 4<sup>th</sup> Wednesday)