QIBA Lung Density Biomarker Committee (BC) Call

March 27, 2019 at 2 PM CT Call Summary

In attendance RSNA

Sean Fain, PhD (Co-Chair)
David Lynch, MD (Co-Chair)
Charles Hatt, PhD

Philip Judy, PhD Miranda Kirby, PhD Amin Motahari, PhD Nancy Obuchowski, PhD Julie Lisiecki

Moderator: Dr. Fain

Discussion regarding what is needed to finalize the Profile:

- Dr. Fain has modified the Profile according to suggestions made on the last call
- The claim regarding the -950 Hounsfield Unit (HU) threshold was updated
- Data near the 1000 HU value may not have been normally distributed due to truncation from some CT scanners
- The 95% number referring to a confidence interval has been changed to more accurately reflect the 95% range within the measurement and how to compute the reproducibility coefficient
- Data regarding the software comparison image analysis have been incorporated into the Profile in Appendix F
 - Appendix F is related to Appendix E, which describes the software comparison study design in detail
 - Data in Appendix F will serve as guidance for vendors to self-assess their reproducibility coefficients
- The group may propose adding these data to the Quantitative Imaging Data Warehouse (QIDW)
 - o The data have been de-identified twice and are not linkable to the COPDGene database
 - It would be ideal to keep these data in the QIDW, as they could be a valuable reference data set for software developers, against which they could compare their results
- Dr. Obuchowski noted that no other QIBA BC has provided this type of tool yet, and thinks that it could be very helpful in promoting use of the Profile
- The anonymized dataset contains 50 subjects with 100 images
 - Drs. Hatt and Kirby have added additional anonymization to the already existing anonymization to make the data more secure
 - The data are considered a "consensus reference standard"
- The test utilized the same images and software, and there was no change in image acquisition
- Both inter- and intra-software variability were tested
- Software packages were deterministic, not variable in their outputs, thereby not contributing additional variation

Preparation for Profile Public Comment:

- Once additional changes are integrated, Drs. Fain and Lynch would like to send the Profile for review to the BC along with a ballot to vote for its release
- This is anticipated in approximately one week

Proposals for groundwork projects:

- The proposals should be designed to eliminate hurdles for completing the Profile or to advance the biomarker
 - 1. One suggested proposal was to consider looking at the impact of resolution on density measurements
 - This may include a possible sub-study on airway measurements, as some scanner changes which would impact the way these measurements are obtained are being considered
 - 2. Another suggested proposal might be to consider using the COPDGene phantom to automate analysis and provide an online tool or system for determining conformance to the Profile
 - Automated software tools that are user friendly and more widely available would be ideal
 - Dr. Motahari to draft a proposal for a software analysis tool for the phantom
 - He would like to be able to provide a tool with reporting for field testing candidates, similar to the system that is available for the QIBA Small Lung Nodule BC utilizing the QIBA Conformance Certification Service provided by Accumetra
 - RSNA Staff to provide Mr. Avila's contact info
 - 3. Dr. Lynch suggested a pilot study with COPDGene and spiromics data
 - This might include charts that demonstrate shifts over time in multi-center trials and could aid with streamlining applications for drug development

 Dr. Lynch intends to approach the COPD Biomarker Qualification Consortium (CBQC) for additional support and will be addressing the group at their annual meeting, the Friday before the main <u>American Thoracic Society (ATS) meeting</u>, May 17-22

Next steps:

- Ideas for proposed groundwork studies should be sent to the co-chairs prior to the April 15th deadline
 - Projects that advance the Profile were suggested, especially in support of field-testing efforts
- Additional society or vendor contacts for the upcoming Profile public comment review phase are being sought and can be sent to jlisiecki@rsna.org

Next meeting: Wednesday, April 24, 2019 at 2 pm CT