QIBA Lung Density Biomarker Committee (BC) Call

January 23, 2019 at 2 PM CT Call Summary Notes provided by Dr. Lynch

In attendanceRSNADavid Lynch, MD (Co-Chair)Raúl Yebana HuertasMiranda Kirby, PhDJoe KoudelikHeather Chen-Mayer, PhDStephen Humphries, PhDAmin Motahari, PhDJulie Lisiecki

Discussion regarding what is needed to finalize the Profile:

Philip Judy, PhD

- With regard to the HU Bias issue, Dr. Motahari raised the issue of truncation as a source of bias in the difference measures mentioned in the claim, i.e., if a patient has 0% LAA-950, the standard deviation of this measurement cannot be normally distributed.
- Dr. Obuchowski suggested that we insert a footnote to that effect under the claim essentially stating that the confidence intervals may not apply when the measurement is close to 0. She indicated that she would write this.
- Dr. Judy remains concerned about the issue of bias related to truncation in measurement of the phantom, as indicated in his email of 1/20.
 - \circ He is concerned that it is therefore imprecise to imply that a specification of 1000 HU \pm 6 HU for inside air is always feasible in noisy data or patient data.

Nancy Obuchowski, PhD

- However, I think we agreed that we could address this by a footnote indicating that these specifications apply to phantom data and are not applicable to patient data particularly when noisy.
- With regard to the software comparison, Dr. Kirby presented updated specifications.
 - See email to Drs. Hatt and Kirby
- We found a couple of minor issues:

Bernice Hoppel, PhD

- o In section 4.1.1.3 a, the value 1000 HU ± 6 is missing the leading minus sign
- o In section 4, bullet 3, it would probably be clearer to delete the words "lung equivalent foam regions of the" since we are scanning the entire phantom.
- Given these residual (though minor) issues, we elected not to have a committee vote today (to release for public comment). I think we should try to finalize the document by email and solicit any final input by email, followed by an email vote.
- We didn't have time to address the "next steps" items

Next steps:

- Discuss the cross-sectional claim
- Review iterative reconstruction and advanced dose reduction protocols
- Definition of the repeatability coefficient from the software analysis results
- Feedback is encouraged regarding additional societies or contacts for the upcoming public comment review phase

Next meeting: Wednesday, February 27, 2019 at 2 pm CT