QIBA Lung Density Biomarker Committee (BC) Call

February 27, 2019 at 1:30 PM CT (special time)

Call Summary

In attendance

Sean Fain, PhD (Co-Chair)	Philipp Hoelzer, PhD	Amin Motahari, PhD	**RSNA**
Heather Chen-Mayer, PhD	Philip Judy, PhD	Nancy Obuchowski, PhD	Joe Koudelik
Charles Hatt, PhD			Julie Lisiecki

Moderator: Dr. Fain

Discussion regarding what is needed to finalize the Profile:

- Dr. Fain shared the change log and discussed the HU bias number of ± 6 as being difficult to meet since some scanners experience truncation artifacts
- Ways to manage truncation as a source of bias in the difference measures with respect to claims were discussed
- A footnote should be added to note exceptions in cases of low/minimal disease
    - Wording change of "stated 95% *coverage* no longer applies"
    - The group would be looking at replicate observations on the same patient for longitudinal claims
    - Drs. Obuchowski and Motahari to work offline on related calculations
- Section 4 was reviewed
    - The purpose of the software (algorithm) challenge within section 4 was twofold:
        - Establish the degree/ range of variability of data from different software packages
        - Establish if repeated application of a software contributes to variability over time, i.e., if output is reproducible, then a longitudinal claim could be pursued

Questions remaining

- How best to combine the repeatability coefficient with the reproducibility coefficient for two software programs
- Some suggestions included:
    - Use a reference CT dataset
    - Provide variability observed where the maximum error you would see is "x" value
    - Look at what the repeated use of the software is and how it contributes to variability in the claim
    - User calculates value on their own using the reference appendix instead of a specification within the Profile, applying them same software for timepoints 1 and 2
        - Scans would be available for reference on the QIDW for this purpose
- Section 4.2:
    - Instead of "mean," use the "median" to compute variance between user's own software versions
    - Remove outliers and look to fall within a certain percentage of the median
    - If a user is within 20% of the median, the data qualifies
        - This would provide only one comparison, instead of the seven comparisons provided with the vendor variability study
    - How to compute the reproducibility coefficient (RDC) is still unknown
        - Variation must be known to establish the longitudinal claim

Action items provided by Dr. Fain:

- Dr. Motahari will develop a report in the non-parametric test for defining the CI's specifically for the RA-950 claim and share with Dr. Obuchowski.
- Drs. Hatt and Kirby will move the assessment procedure for software vendor qualification into an Appendix. Only test/re-test RDC for the repeated measures using the same software tool will be included in the specification table. The software assessment for a given study will thus be required to be within the RDC for this test/re-test experiment (possibly we require our data set of 50 CT scans to provide a range of disease; but should discuss). The assessment procedure for vendor qualification, beyond demonstrating test/re-test repeatability will be deleted from Section 4 and moved to the appendix.
- In item 2 above, we specifically focus on test/retest of the same software vendor for reducing added variation to our claims.
- Drs. Obuchowski and Judy requested specific changes to the footnote for the first Claim regarding RA-950:
    - Replace -1000 HU with "-1024 HU"
    - Replace "interval" with "coverage"

Next steps:

- Feedback is encouraged regarding additional societies or vendor contacts for the upcoming Profile public comment review phase
- Ideas for proposed groundwork studies should be sent to the co-chairs prior to the next call
    - Projects that advance the Profile were suggested, especially in support of field-testing efforts

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