QIBA CT Volumetry Biomarker Ctte (BC) Call

12 February 2018 at 11 AM CT Draft Call Summary

In attendance:			RSNA:
Gregory Goldmacher, MD, PhD, MBA (Co-Chair)	David Gustafson, PhD	Kevin O'Donnell, MASc	Joe Koudelik
Rick Avila, MS	James Mulshine, MD	Ying Tang, PhD	Julie Lisiecki
Hubert Beaumont, PhD	Nancy Obuchowski, PhD		

Moderator: Dr. Goldmacher

Announcement:

- Dr. Goldmacher announced that he will be stepping down as co-chair of the QIBA CT Volumetry BC due to increasing responsibilities at work
- Dr. Goldmacher's leadership and focus on working the next steps to get the Profile released for the next stage have been greatly appreciated. The news that he will continue to be involved in the committee is welcome.
- Dr. Jarecha has accepted the position of BC co-chair, and will co-lead with Drs. Siegelman and Samei
- Dr. Jarecha also serves as a QIBA CT Coordinating Committee Co-Chair

Vol CT Advanced Disease Profile Technical Confirmation Feedback Efforts:

- Dr. Goldmacher reviewed remaining outstanding to-do items
- Dr. McNitt-Gray had evaluated the lesions in the test set against the Profile criteria and 11 of the 31 cases failed
 - o Possible reason: Lesions were not conformant with the Profile, i.e. segmented lesions were incorrectly selected; identification of correct lesions is critical for anyone evaluating the test set

Follow-up actions:

- Mr. O'Donnell has revised the spreadsheets and test procedure text
 - o All 31 cases were left in the dataset for reference; however, ones that did not meet the criteria will be removed from calculations
 - Six large and fourteen small lesions remain part of the testing
- Table values for pass/fail rationale were recalculated based on correct dataset cases by Drs. Obuchowski and Petrick
 - The revised table has been sent to Mr. O'Donnell and Dr. Petrick for review
 - Mr. O'Donnell to update the Profile
 - Dr. Samei to review the expanded dataset
- The desire to have additional types of lesions in the dataset in the future to make the Profile testing match the declared Profile scope, e.g. beyond lung lesions, was reiterated.
- Dr. Petrick to send the DRO (Assessment Procedure 4.3) to the QIDW and send Mr. O'Donnell the text for the Profile
 - o Dr. Petrick will update the description of the data to be used for linearity measurements (section 4.5, line 934)
 - A follow-up discussion will be needed before making the updates
- Mr. Tervé has been working with Dr. Obuchowski to clean up the spreadsheet for Assessment (section 4.5)
 - o Mr. Tervé will add confidence intervals and then verify calculations with Dr. Obuchowski
- The committee agreed with Mr. Buckler's proposal that the "disqualified" cases be left in the Assessment 4.4 dataset and spreadsheet as being instructive for testers, but be removed from the performance calculations.
- Once the spreadsheets have been updated, they will be added to the download bundle on the QIDW
 - o Mr. O'Donnell will update the 4.4 spreadsheet
 - o Dr. Petrick will update the QIDW with the results and the 4.3 and 4.5 spreadsheets
 - Goal would be a single "truth file" dataset that is usable on multiple platforms

Next steps:

- The next step for the Profile would be a motion that the profile is ready to circulate in an email ballot asking the Biomarker Committee to approve it as meeting the criteria for Technically Confirmed.
- The committee may want to start thinking about the logistics of moving toward the claim confirmed stage
- Would need clinical trial data from patients with actual lesions documented, not only virtual
- Scan and re-scan data needed

- Consideration for how to measure repeatability within subjects in the field would need to be worked out; Dr.
 Obuchowski offered statistical guidance
- This will be added to the agenda for discussion at the next BC meeting

Next Call: TBD by the co-chairs