QIBA Lung Density Biomarker Committee (BC)

September 28, 2016 at 2 PM CT Draft Call Summary

In attendance RSNA

Sean Fain, PhD (Co-Chair) Charles Hatt, PhD Miranda Kirby, PhD Julie Lisiecki

Matthew Fuld, PhD (Co-Chair)Stephen Humphries, PhDNancy Obuchowski, PhDHeather Chen-Mayer, PhDPhilip Judy, PhDDaniel Sullivan, MD

Profile Editing Review (Dr. Fain)

- Topics discussed included the following:
 - Organization of the Profile and open issues
 - Lung inflation volume within a 10% difference
 - Subject handling
 - o Tailoring of the Profile with accessible language so that it is applicable to many audiences
 - Clinical Context
 - Assessment of statistical significance of change
 - o Addition of a diagram or figure to better illustrate certain concepts at-a-glance
 - o Confidence intervals and the measured change within the range defined for the claims
 - Real change would show that perceived change is not just measurement variability

Calibrated Foams

- Careful statement of variations assuming that a true measure of density is known
- Each calibrated foam has its own value and certificate
- Each foam has its own "truth"
- Expected Hounsfield Unit (HU) measurement depends on specific density for a phantom
- Qualification of the scanner requires calibration of the HU values with foam standards to improve precision and reduce bias
 - Dr. Chen-Mayer to review descriptive statements related to the calibrated foams

Standard deviation (SD) of the noise

- Determine whether region of interest (ROI) matters and affects the measurement
- Mean would change but not the SD
- SD as a measure of the noise in the water vial and air insert

Analysis Tool(s)

- U-lowa software was utilized by the vendors via specific permission rights for analysis
- A long-term solution for the public would be use of the QIDW and suggested analysis tools, such as MIRC's Clinical Trials Processor (CTP) or other similar tools
 - It will also be necessary to provide parameters and specs for the ROI in order to determine a standard procedure
 - Many sites do not have an assigned medical physicist on site
 - Suggestions on how to measure and specific instructions for the actor who will perform the measurements will be needed
 - Plan to use a standard measure of MTF in order to move forward

Claim Wording (section 3.4.2)

- Dr. Obuchowski reviewed the claim wording and suggested addition of sample calculations with realistic values
- 2 3 examples that demonstrate the magnitude of the change would be helpful
 - Reminder that Δ x = measured change
 - The measured change from the claim to replace the wording in blue highlight in section 3.4.2 under the discussion details

RSNA 2016 Lung Density BC Poster - Due October 31st

• The next call, October 12th, will focus on getting the poster completed with BC input

Next call: Wednesday, October 12, 2016 at 2 pm CT

Schedule of calls until RSNA 2016 print-ready poster is due:

October 12 October 31st (Monday): Due date for QIBA print –ready poster PPT template

October 26

RNSA 2016 Reminders:

QIBA Kiosk Poster Meet-the-Expert Session for RSNA 2016:

- 1. Please visit the RSNA 2016 MTE Sessions Google sign-up sheet
- 2. Select your Biomarker Committee from the tabs along the bottom of the sheet
- **3.** Type in your name next to the presentation time slot that works for you (It would be helpful for each 30 minute time slot to be filled by at least one committee member)
- **4.** Simply close out of the document there is NO save button changes will automatically save for you

QIBA Working Meeting at RSNA 2016 {Wednesday, Nov 30th, 2:30 – 5 pm}:

Please let us know whether you plan to attend the **QIBA Biomarker Committees- Working Meeting** by responding to the Google Form.

A response by Wednesday, October 19th would be appreciated.