QIBA Lung Density Biomarker Committee (BC) Call

December 20, 2017 at 2 PM CT Call Summary

In attendance RSNA

Sean Fain, PhD (Co-Chair) Stephen Humphries, PhD Nancy Obuchowski, PhD Julie Lisiecki David Lynch, MD (Co-Chair) Kevin O'Donnell, MASc Gonzalo Vegas-Sanchez-Ferrero, PhD, MSc

Bernice Hoppel, PhD

RSNA 2017 Breakout Session Update: (Dr. Fain's breakout session notes)

Dr. Fain reviewed updates from the QIBA f2f breakout meeting at RSNA 2017, focusing primarily on the Profile

Topics discussed included the following:

1. Profile, final questions to be resolved:

- a) Appendix sample protocols for first public release (Drs. Lynch and Fain)
 - Dr. Hoppel to aid with the vendor sections
- b) Management of target CT dose of 3 mGy
 - Discussion regarding whether it is appropriate to allow vendors to adjust CT dose according to patient size and shape using vendor-specific AEC models
 - Conclusion was that this is likely acceptable for longitudinal claims, but needs to be better resolved for cross-sectional claims in a subsequent draft of the Profile
- c) Incorporation of a simplified harmonization procedure (section 4.1.1)
 - This involves mapping the scale of the HU values, adjusting Perc 15 and the scale for determining the RA-950 cutoff
 - Discussion resolved that the harmonization needs more testing and validation and is better targeted for a cross-sectional claim in a future draft of the Profile

2. Progress and approach to vendor conformance statements (Drs. Hoppel, Hoelzer, and Crotty)

a) It was determined that it will be necessary to construct a conformance statement that is more aligned with quantitative density

3. Harmonization field test updates, "QIBA-SRM Calibration Procedure." (Drs. Humphries & Chen Mayer)

a) Presentation by Dr. Humphries showed good progress and practical implementation of quadratic calibration model seems very promising. More to come as analysis is ongoing.

4. Funding next phase updates

- a) Supplementary Proposal to COPD Gene to be submitted jointly to NHLBI and NIBIB (Drs. Fain & Sanchez-Ferraro)
 - Current structure of the aims is focused on QIBA-specific goals. Strategy would include a separate proposal, possibly an R21, to address more novel aspects such as lung inflation models.

Vendor Protocols:

- Drs. Hoppel and Crotty to work together to provide guidelines for what specific details should be included when reporting results
 - 1. Each new scanner changes the protocol ever so slightly, and it is important to specify scanner version, phantom type, software version, etc.
 - 2. A range of parameters that would meet the claim to simplify the process may be suggested
- Dr. Fain referred the group to line #824 of the QIBA Small Lung Nodule Profile, which details the equipment / vendor performance procedures, using a factorial design and a systematic approach to variation

Conformance Statement for the Profile:

- Important considerations will include:
 - 1. The dependence of the density measurement on the AEC model
 - 2. Patient size and shape
 - 3. Kernel use for reconstruction
- No conclusive statements can be made until a field test is conducted
- A good set of image quality metrics are needed
- It was suggested that the method be constrained but not the results, as technology and techniques will change
- Will need to provide language within the conformance statement that points to proper conformance protocols
- Vendor participation and input is key to this process
 - 1. Appendix D will be tied to the conformance statement
 - 2. Dr. Fain is working on Section 4
 - 3. Dr. Hoppel and Mr. O'Donnell to work on the conformance document

Funding next phase updates:

- Dr. Lynch to review the wording of the aims for the COPDGene supplemental funding proposal and provide feedback to Dr. Fain over the holidays
- Drs. Estepar, Ferrero, Fain, and Humphries to be included in this review
- Dr. Ferrero to provide an update to the group mentioned above in order to avoid any overlap with his research

Profile:

- Dr. Fain is incorporating final suggestions and making minor edits, particularly to sections 3.1.2 and 4
- Additional information will be included regarding repeatability and analysis software once more details are available from the comparative study
- Profile to be circulated among the BC once additional changes have been made
- Once internal BC review is complete, an <u>e-ballot</u> at the BC and CC levels will be needed to release the Profile for public comment, per the <u>Profile Process</u> outlined by the <u>Process Committee</u>
- Dr. Fain requested a volunteer to serve as co-editor of the Profile, as it is proving to be too time-consuming for one person; anyone interested is asked to email Dr. Fain: sfain@wisc.edu
- Mr. O'Donnell also recommended that BC members begin compiling a list of experts and outside organizations that would be interested in reviewing the Profile once it is released for public comment; email addresses will be need for RSNA staff to include in the distribution list