**QIBA Proton Density Fat Fraction Biomarker Committee (BC) Update Call**
Thursday, September 7, 2017 at 3 PM (CT)
Call Summary

**Participants**

*Scott Reeder, MD, PhD (Co-chair)*
*Takeshi Yokoo, MD, PhD (Co-chair)*
Mustafa Bashir, MD
Thomas Chenevert, PhD
Patricia Cole, PhD, MD
Gavin Hamilton, PhD
Diego Hernando, PhD
Harry Hu, PhD
Edward Jackson, PhD
Michael Middleton, MD
Jonathan Riek, PhD
Nancy Obuchowski, PhD
Claude Sirlin, MD

**RSNA**
Fiona Miller
Julie Lisiecki
Susan Weinmann

**Review of Previous Call Summary**

- The 08.03.2017 call summary was approved as presented

**Profile Update**

- PDFF BC Profile section assignments can be found in the QIBA PDFF Task Force Dropbox folder: Dropbox/QIBA PDFF Task Force/Template/PDFF QIBA_Profile_2017.05.16.docx
    - For access, please contact: Takeshi.Yokoo@utsouthwestern.edu

- See guidelines on QIBA Wiki, "How to Write a Profile": http://qibawiki.rsna.org/index.php/How_to_Write_a_Profile
- "Profile Claim Guidance" can be found on the QIBA Wiki at: http://qibawiki.rsna.org/index.php/Claim_Guidance
- Significant progress has been made on the Profile
- Discussion of open issues:
    - There was discussion regarding whether phantoms or human patients should be involved in conformance testing or who will be required to perform conformance testing (i.e. vendors developing new PDFF product, or each site trying to use PDFF)
    - There was an inquiry as to whether these tests address linearity, bias, or precision, and whether conformance pertains to that of manufacturers or sites
    - Discussion on apparent diffusion coefficient (ADC), whether there is standardization across vendors, how to measure it, and whether the conformance is required for sites
    - PDFF products by GE, Siemens, and Philips are FDA-approved techniques, but only validated on phantom studies (implication: only phantom studies needed?)
    - It was disputed, however, that the FDA was not validating a biomarker, but rather a machine and/or technique, and therefore approached used by FDA may not be sufficient for biomarker conformance testing

- PDFF BC Members have published the following papers:
    - Multisite, multivendor validation of the accuracy and reproducibility of proton-density fat-fraction quantification at 1.5T and 3T using a fat-water phantom: https://www.ncbi.nlm.nih.gov/pubmed/27080068
    - Reproducibility of MRI-determined proton density fat fraction across two different MR scanner platforms: https://www.ncbi.nlm.nih.gov/pubmed/21769986

- Recommend the Reeder / Hernando phantom (or equivalent) as the "gold standard" in conformance testing on multiple scanners?
- Dr. Obuchowski reminded PDFF BC members that since conformance is related to a claim, statistical assumptions made building a claim must match the repeatability stated in the claim
- Text related to the discussion was taken from the current Profile Claim Guidance document available on the QIBA Wiki at: http://qibawiki.rsna.org/index.php/Claim_Guidance:
    - Repeatability represents the measurement precision under a set of repeatability conditions of measurement
    - Determining bias will likely require carrying out QIBA groundwork studies, or referring to external studies if available (cross-sectional claim)
    - In order to obtain a reliable estimate of the QIB's bias and assess its linearity property, a phantom study with at least 65 observations is needed
    - For longitudinal claims, the assumption of linearity must be assessed, along with estimates of the slope of a regression line of the measured vs. true biomarker values

- Dr. Obuchowski to assist the group with Claim development
- Human data is not needed for claim #1; accuracy can be demonstrated using a phantom
- A simple protocol for quality assessment will be created
- It was noted that if the PDFF BC wants the Profile user to conform to a claim, it needs to address the statistical assumption underlying the claim
- The Profile may contain a claim involving bias, and one concerning within-subject variability
- Each QIBA group to make their own decisions on whether a phantom study is sufficient
- Dr. Hu indicated that the new manufacturer / sequence needs to be tested using the phantom created by Drs. Reeder & Hernando at different field strengths, sites, days of scan and platforms
    - It would be very difficult and time-consuming for the vendor to carry out a clinical study.

- Suggestion made to conduct human studies to test accuracy
- Dr. Yokoo proposed that the group draft the remainder of Profile for the time being under the assumption that conformance testing is for scanner vendors and to revisit the Claims at a later date

- **If you plan to attend the 2017 RSNA Annual Meeting, the QIBA Working Meeting will be held on Wednesday, November 29, 2017, 2:30 – 6 PM. RSVP at: http://tinyurl.com/2017-QIBA-Working-Meeting!**

**Next call: Thursday, October 5, 2017 at 3 PM CT**

---

RSNA Staff attempt to identify and capture all committee members participating on WebEx calls. However, **if multiple callers join simultaneously or call in without logging on to the WebEx, identification is not possible.** Call participants are welcome to contact RSNA staff at QIBA@RSNA.org if their attendance is not reflected on the call summaries.

***SAVE-THE-DATE:***


**QIBA Working Meeting at RSNA 2017** | Wednesday, November 29, 2:30-6 pm – Lakeside Center

**RSVP at: http://tinyurl.com/2017-QIBA-Working-Meeting!**