QIBA Proton Density Fat Fraction Biomarker Committee (BC) Update Call

Thursday, January 4, 2018 at 3 PM (CT)

Call Summary

Participants			**RSNA**
Scott Reeder, MD, PhD (Co-chair)	Diego Hernando, PhD	Nancy Obuchowski, PhD	Joe Koudelik
Takeshi Yokoo, MD, PhD (Co-chair)	Harry Hu, PhD	Suraj Serai, PhD	Susan Weinmann
Mustafa Bashir, MD	Michael Middleton, MD	Yunhong Shu, PhD	
Gavin Hamilton, PhD			

Review of Previous Call Summary

- The 11.02.2017 call summary was approved as presented

2017 RSNA Annual Meeting Update

- Discussions at the QIBA face-to-face breakout session included:
    - Vendor-/model-specific protocols (1.5 and 3T) for multi-echo SGRE that are consistent with each other are needed
        - GE: IDEAL IQ by UW group (Dr. Sirlin)
        - Siemens: LiverLab by Duke group (Dr. Bashir)
        - Philips: mDixon Quant by UTSW group (Dr. Yokoo)

Profile Conformance Requirement: Who, What, How

- Who:
    - Dr. Obuchowski provided an overview of the conformance process and the target audience
    - Claims and their underlying assumptions to be determined
    - User should be able to follow the Profile and meet performance criteria set out by QIBA for clinical trial work, and eventually clinical care
    - Acquisition and reconstruction protocols to be addressed separately
    - Bias and reproducibility to be documented when protocols are developed

- What:
    - It was agreed that a repeatability study with human subjects will be conducted
    - Discussion on whether phantom can be used to determine linearity and bias; it was stated that the FDA accepted GE data based on phantoms
    - Current Profile Claim is supported by phantom study data
    - Phantoms may help identify imaging sites that implement the Profile correctly, i.e., conformant sites
    - Linearity and Bias testing shall be performed by either:
        - Repeatability testing shall be performed only in human subjects by:
        - Scan-rescan experiment by complete removal of the subject from the magnet prior to rescanning
    - QA/QC procedures for acquisition and reconstruction to be addressed separately

- How:
    - Standard Reference Object for Bias (i.e. Phantom)
        - General guideline for recipe (commercial phantom available)
        - Discussion on phantom concentrations; 0-50% PDFF range with suggested values of: 0, 5, 10, 20, 30, 40, plus 100 (optional for complex-data recon)
        - Fat-water phantoms with known PDFF values using phantom-specific recon protocol helpful but may not be sufficient (i.e. human studies needed)
        - Dr. Reeder to follow up with Dr. Yokoo re: next steps

    - Human Testing for Bias

PDFF Profile

- Dr. Reeder to discuss remaining Profile-writing assignments and PDFF BC will be provided an update

Next call: Thursday, February 1, 2018 at 3 PM CT
