QIBA Proton Density Fat Fraction Biomarker Committee (BC) Update Call
Thursday, January 4, 2018 at 3 PM (CT)
Call Summary

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

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