

QIBA Proton Density Fat Fraction Biomarker Committee (PDFF BC) Update Call
Thursday, April 5, 2018 at 3 PM (CT)
Call Summary

Participants

<i>Takeshi Yokoo, MD, PhD (Co-chair)</i>	Harry Hu, PhD	Nancy Obuchowski, PhD	RSNA Joe Koudelik
Diego Hernando, PhD	Michael Middleton, MD	Suraj Serai, PhD	Susan Stanfa

Review of Previous Call Summary

- The 03.01.2018 call summary was approved as presented

Repeatability

- In vivo conformance tests for conformance bias and repeatability need to demonstrate that the standard deviation is constant across the full range of clinically-relevant PDFF values
- Dr. Yokoo to work with Dr. Obuchowski on study design and clinical sample size determination

Linearity & Bias

- Fat-water phantoms with known PDFF values using phantom-specific recon protocol should be used for bias assessment
- Linearity assessment will require human subject testing

Standard Reference Object for Bias (i.e. Phantom)

- Round-robin multivendor study to be conducted to determine bias (acquisition and reconstruction for each scanner needed) with vendor-specific recons
- Calimetrix has agreed to loan one commercial-grade PDFF phantom for this study
- Because Dr. Reeder is a co-founder of Calimetrix, a possible conflict of interest exists; Drs. Reeder and Jackson (QIBA Chair) discussed drafting an agreement between Calimetrix and QIBA
 - Dr. Yokoo briefly reviewed a few of the stipulations in the agreement
 - Calimetrix will loan a commercial grade phantom, packaged in a travel kit (to allow for shipping of phantom among sites)
 - At the end of the study, the phantom will be returned to Calimetrix
 - Calimetrix:
 - Will not pay for shipping, nor will it be liable for any damages or injuries that result from the use of the phantom
 - Will be provided electronic copies of all raw and processed imaging data, sufficient to reconstruct PDFF maps, from all sites participating in the study, within a reasonable time period needed to transfer data, and prior to any publications that result from this study. Calimetrix has the right to use these data for its own purposes.

- Understands that any data and data analysis used for publications that result from this study will not be under the control of Calimetrix. (All acquisition and data analysis procedures will be under QIBA control.)
 - Calimetrix will have the opportunity to provide technical assistance should technical difficulties be encountered. For example, should water-fat swaps be encountered, Calimetrix will be given the opportunity to work with sites to correct any technical failures.
 - Calimetrix will have the opportunity to review the manuscript prior to publication
 - Members of Calimetrix who are part of the study team and on the QIBA PDFF Task Force will participate in the preparation of the manuscript
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 - Will not be a participating site
 - The University of Wisconsin will participate unless the PDFF BC objects
- It was agreed that all elements of the proposal are fairly reasonable and a formal agreement will be drafted
- Dr. Yokoo to circulate this document for PDFF BC review and feedback; if no objections, the proposal will be presented to QIBA leadership
- Phantom projected to be shipped this Summer
- Current list of participating sites (both 1.5T and 3T platforms preferred)
 - University of Wisconsin (GE; Drs. Reeder/Hernando)
 - Duke University (Siemens; Dr. Bashir)
 - Nationwide Children’s Hospital, Columbus Ohio (Siemens 3T x2, GE 3T x1; Dr. Hu)
 - UT Southwestern (Philips; Dr. Yokoo)
 - Dr. Middleton volunteered University of California, San Diego as a participating site
 - Cincinnati Children’s (Philips; Andrew Trout) – Dr. Serai to invite Dr. Trout for participation
 - Vanderbilt (Philips) participated in previous round robin study and may be available to participate (Dr. Brian Welch)
- The preference is to have a minimum of two sites per vendor and for the same vendor to come from more than one institution. Both 1.5T and 3T scanners from each vendor need to be collectively represented.
- Discussion on whether to invite vendors to participate in this study; BC consensus to have them involved as consultants to avoid potential data access and control issues

Next call: Thursday, May 3, 2018 at 3 PM CT

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