

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

Thursday, May 3, 2018 at 3 PM (CT)

Call Summary

Participants

Scott Reeder, MD, PhD (Co-chair)

Takeshi Yokoo, MD, PhD (Co-chair)

Mustafa Bashir, MD

Gavin Hamilton, PhD

Diego Hernando, PhD

Harry Hu, PhD

Edward Jackson, PhD

Nancy Obuchowski, PhD

Jonathan Riek, PhD

Suraj Serai, PhD

Andrew Trout, MD

RSNA

Joe Koudelik

Susan Stanfa

Review of Previous Call Summary

- The 04.05.2018 call summary was approved as presented

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

- Round-robin multi-vendor study to be conducted to determine bias (acquisition and reconstruction specifications for each scanner needed) with vendor-specific recon kernels
- Calimetrix has agreed to loan one commercial-grade PDFF phantom for this study packaged in a travel kit for shipping between imaging sites
- Because Dr. Reeder is a co-founder of Calimetrix, a possible conflict of interest exists; Drs. Reeder and Jackson (QIBA Chair) have been drafting an agreement between Calimetrix and QIBA
- The distributed QIBA/Calimetrix agreement was discussed, and feedback and questions were reviewed
 - Calimetrix will not pay for shipping, nor will it be liable for any damages or injuries that result from the use of the phantom, e.g., dropping, etc.
 - Concern regarding next steps, should the phantom be lost or damaged in transit
 - Insurance rider from the courier may be included, which will cover in-transit damage; the Calimetrix team can help with shipping arrangements
 - Drs. Jackson and Yokoo to discuss a solution, should damage be incurred at a site; Calimetrix would be unable provide a replacement due to the substantial cost of the phantom and the fact that the phantoms are not identical
 - Discussion regarding the impact on the study and the phantom as a reference standard, should a new phantom or rebuilt phantom be needed
 - Because each phantom is validated separately, there is ground truth
 - Drs. Jackson and Yokoo are working on a modified version of the agreement that should address the authorship issues that were raised
 - Suggestion to set a time frame on Calimetrix review of a manuscript prior to publication, e.g. 14 days
 - Concern voiced whether Calimetrix had a right to block a publication

- Calimetrix 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, therefore data-use agreements between QIBA and imaging sites are not needed
 - Site data could be uploaded to a private folder on the QIDW and only made public once approved/released by the PDFF BC leadership
 - Concern that if Calimetrix wanted to use the study data for marketing, a data use agreement would be needed

- “Calimetrix 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.”
 - Question regarding definitions of “raw data” and “processed imaging data” and whether these would be used for publication or the PDFF maps from the vendors’ implementation
 - In case other algorithms are used to extract PDFF maps, Dr. Peeters (Philips) requested to receive that data to know what analyses were based upon

- Drs. Reeder and Jackson to finalize the QIBA\Calimetrix agreement and circulate it

- Dr. Hu to lead the round-robin phantom study
 - Data from the nine participating sites to be sent to Dr. Hu for anonymization
 - Timeline to be developed
 - Protocol for scanning sequences is needed; Dr. Yokoo has site contact info and will start an email chain and Dr. Hu will draft a message
 - Sites will be informed that no funding will be granted except for the loaned phantom
 - Each site investigator is asked to cover his/her time, scan time and shipping cost of the phantom (\leq \$250, including insurance)
 - Standardization of protocol and imaging manuals are needed
 - Dr. Hu to create a calendar and develop a phantom transportation schedule that will allow each of the nine sites at least one week to complete scanning
 - It is anticipated that the data will be published and the site investigators will be invited to contribute as co-authors
 - Phase one analysis: participants uploading data to repository (QIDW)
 - Post-processing analysis: tbd who will do this. If each site does independently, will get variability from site-to-site.
 - If aiming for completion of an abstract by November, suggestions needed to perform standardized scans (one orientation), field of view, slice thickness, etc. (instructions from Calimetrix)
 - Suggestion to consult vendors on optimum protocol

- System sequence default parameters for each site is needed; survey to include vendor-specific sequences to document site/vendor-specific parameters used
 - Discussion on whether to use head or torso coil type; recommendation to use coil pertaining to Profile and Claim
 - Ideas will be drafted regarding number of scans and set of combinations
 - Dr. Obuchowski will be consulted on study plans
 - Drs. Hu and Yokoo to compile information, plans, imaging manual and connect with sites
 - Dr. Riek volunteered to create a repository for this study in which PDF study leaders will have global access and each site will have access to their own folder
 - Discussed option to reduce the number of sites to expedite an abstract
- Current list of nine participating sites:
 - University of Wisconsin (UW) (GE; Drs. Reeder/Hernando)
 - Duke University (Siemens; Dr. Bashir)
 - Nationwide Children's Hospital, Columbus Ohio (Siemens 3T x2, GE 3T x1; Dr. Hu)
 - University of Texas Southwestern (UTSW) (Philips; Dr. Yokoo)
 - University of California, San Diego (UCSD) (GE 3T, 1.5T; Middleton)
 - Children's Hospital of Philadelphia (CHOP) (Siemens 3T & 1.5 GE 3T; Serai)
 - Mayo Clinic (Siemens 1.5T, GE 1.5T & 3T; Shu)
 - University of Michigan (Philips 1.5T & 3T; Malyarenko/Chenevert)
 - Cincinnati Children's (Philips; Trout)
- Breakdown of sites by vendor/manufacture
 - GE (UW, Nationwide, UCSD, CHOP, Mayo): 1.5T(3), 3T(5)
 - Siemens (Duke, Nationwide, CHOP, Mayo): 1.5T(3), 3T(3)
 - Philips (UTSW, U Michigan, Cincinnati): 1.5T(3), 3T(3)
- Calimetrix will scan the phantom for pre- and post-round robin for quality control/stability; phantom will be returned to Calimetrix after all sites have scanned it

Next call: Thursday, June 7, 2018 at 3 PM CT

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