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

Thursday, April 1, 2021 at 3 p.m. (CT)

Call Summary

Participants			**RSNA**
Scott Reeder, MD, PhD (Co-chair)	Gavin Hamilton, PhD	J.M. (Hans) Peeters, PhD	Susan Stanfa
Takeshi Yokoo, MD, PhD (Co-chair)	Diego Hernando, PhD	Suraj Serai, PhD	
Mustafa Bashir, MD	Michael Middleton, MD, PhD	Claude Sirlin, MD	
Jean Brittain, PhD	Nancy Obuchowski, PhD		

RSNA Staff attempt to capture all committee members participating on Zoom calls. However, **if attendees join only by phone, or do not use a recognizable name, identification is not possible.** Participants are welcome to contact RSNA staff at QIBA@RSNA.org if their attendance is not reflected on the call summaries.

Lab-based vs. Commercial PDFF Techniques

- There was a discussion on Self-attestation (Registered) or QIBA Tested (Certified) opportunities and the benefits of conformance-testing (i.e., complying with technical specifications as specified by a BC)
    - The Profile Conformance page on the QIBA Wiki was referenced
    - Differences and level of rigor regarding conformance via Self-attestation vs. QIBA or designee tested were discussed
    - Until the value of QIBA certification is broadly recognized, there is no real disadvantage to non-conformant vendors at this time

- If a decision is reached to recommend lab-based techniques, specifications would need to be very carefully defined
- Discussion on ensuring conformance across different platforms and whether a Profile should address only one platform at a time
    - Other QIBA groups have used a phantom to determine differences across vendors and platforms
    - A list of parameters and settings for sequences would be provided in the Profile
    - It was noted that there is better version-control in industry than in labs

- If LipoQuant (LQ) were to be included in the Profile, users developing new PDFF quantification techniques would be able to rely on a phantom to improve the accuracy of their method vs. being required to conduct a major validation study
- LQ software has been used in many clinical trials and there was a discussion re: FDA requirements
    - According to one PDFF BC member's experience, documentation of change, date, and person responsible had been requested, but lifecycle was not required
    - Many molecular assays are developed in labs and while they are not products, they are subject to the Clinical Laboratory Improvement Amendment (CLIA) which applies to pathology, not imaging
    - Lab procedures are not products, so there was uncertainly re: whether they would be subject to FDA regulation
    - There was concern that if imaging standards are not set by QIBA members, others will do so

- Dr. Obuchowski stated that there has been discussion in QIBA about "conformance" being specific to the stage of the Profile
    - If the Profile has reached Technically Confirmed (stage 3) and not yet Claim Confirmed (stage 4), then an actor/site can be conformant to the Profile without any testing of bias, linearity, and precision
        - In this case, the Claims would be labeled as provisional, or untested

- Suggestion that the PDFF BC set standards for magnitude imaging and provide guidance on testing for bias and repeatability; if a site meets those requirements, then it has conformed to the Profile
    - Boundaries to be defined re: when recalibration would be recommended, e.g., software version changes or substantial change in reconstruction

- Acquisition parameters to be specified
- Dr. Reeder to lead a small working group to draft proposed guidelines; Dr. Middleton volunteered to help with the QC aspect

Next QIBA PDFF BC call: TBD