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

Thursday, February 4, 2021 at 3 p.m. (CT) Call Summary

Participants RSNA

Takeshi Yokoo, MD, PhD (Co-chair)Dariya Malyarenko, PhDJ.M. (Hans) Peeters, PhDJoe KoudelikJean Brittain, PhDMichael Middleton, MD, PhDJonathan Riek, PhDSusan StanfaGavin Hamilton, PhDNancy Obuchowski, PhDSuraj Serai, PhD

Discussion on In-House Solutions (non-product), e.g., LipoQuant (LQ)

- It was noted that though it is used by a variety of entities, LQ is not a commercially available software
- If 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
- Discussion re: whether to provide Profile users a choice, e.g., complex sequences and magnitude, vs. magnitude only
 - While complex is better, there are obstacles to using it such as availability, cost, and/or incompatibility with scanners containing old magnets
 - If complex sequences become more accessible over time, the Profile can be updated to make it a requirement
 - Consensus was to allow drug studies to use the sequences of their choice
 - There are plenty of other reliable, FDA-accepted techniques that have been used for decades and they will be included in the Profile
- It was noted that temperature correction is needed for phantom studies (not needed for human studies)
- The value in the longitudinal Profile claim: +5% change = true change, however, this may not be true for LQ; Dr. Obuchowski to be consulted on how to address this issue
- A reference standard for bias is needed for the cross-sectional claim; phantom data are used for bias and reproducibility; clinical data are used for repeatability
- Dr. Obuchowski recommended that the wSD and Bias assumptions underlying the Claims be documented
- Suggestion to include MR Spectroscopy as an adjunct to verify the phantom's PDFF values for a cross-sectional Claim
- Consensus was reached re: the inclusion of magnitude data to the greatest feasible extent
- Due to limited data for complex sequences, PDFF BC support for a magnitude Claim was greater than the support for complex
- Dr. Yokoo to follow up with Drs. Reeder and Hernando with an update on this discussion and revised cross-sectional and longitudinal claim values

Next QIBA PDFF BC call: Thursday, March 4, 2021 at 3 p.m. (CT)

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