

QIBA MRE Biomarker Committee (BC) Call

Monday, January 30, 2017 at 3 PM CT

Call Summary

Participants

Patricia Cole, PhD, MD (Co-Chair)

Edward Ashton, PhD

Thomas Chenevert, PhD

Edward Jackson, PhD

Claudia Kirsch, MD

Michael Middleton, MD

Frank Miller, MD

Nancy Obuchowski, PhD

Kay Pepin, PhD

Suraj Serai, PhD

Elif Sikoglu, PhD

Claude Sirlin, MD

RSNA

Joe Koudelik

Susan Weinmann

Moderator: Dr. Cole

Profile Review

- Writing group has been working extensively with Dr. Pepin to organize all of the comments received
- It was noted that breath-holding needs to be consistent among subjects in the Profile
- Discussion on 3.10. Image Analysis section: “To avoid areas of incoherent waves, avoid regions immediately under the paddle and stay ~1 cm inside the liver boundary and contain a minimum of 500 pixels per slide.”
 - Industry studies typically use a 700 pixel minimum resolution based on technical recommendations
 - The decision was to leave at a 500 pixel cut-off based on current literature findings and research further in the future
 - To include sentence in the Profile to explain why “500” was chosen
- Based on a re-analysis of data for this manuscript the claim for the profile was updated; the threshold for percentage stiffness change that represents a biological change was adjusted
 - The Claim read: “The clinical performance target is to achieve a 95% confidence interval for a true change in stiffness has occurred when there is a measured change in hepatic stiffness of 22% or larger.”
 - Revised to a “repeatability coefficient of $\leq 19\%$ is conformant with this Profile.”
 - Clarify that the repeatability coefficients data table applies to new vendor products, not established MRE systems
 - Discussion on whether to lower percentage further
 - Issue to be taken back to MRE Profile-Writing TF
- Discussion on converting Word Profile doc to a Google doc to allow more efficient collaboration
- Deadline of EOB on February 6 for MRE BC members to submit comments
- RSNA staff to forward any committee internal review comments to MRE TF
- The next steps in the MRE Profile review process are as described on the QIBA Wiki at:
http://qibawiki.rsna.org/index.php/Review_Process
 - Dissemination to full MRE BC members (and ad hoc t-con needed) to vote by e-ballot to approve release for public comment after review period of 2 – 4 weeks (next step)
 - MR Coordinating Committee voting members to complete a ballot to approve the Profile for public comment
 - Details on the voting process can be found on the QIBA wiki at:
http://qibawiki.rsna.org/index.php/Voting_Process