

# QIBA MRE Biomarker Committee (BC) Call

Thursday, January 23, 2020 at 2 p.m. CT

## Call Summary

### Participants

Richard Ehman, MD (Co-Chair)  
Edward Ashton, PhD  
Michael Boss, PhD  
Darryl Hwang, PhD  
Shintari Ichikawa, MD  
Claudia Kirsch, MD

Ninad Mantri, MS  
Paul McCracken, PhD  
Michael Middleton, MD  
Frank Miller, MD  
Nancy Obuchowski, PhD

Mark Palmeri, MD, PhD  
Kay Pepin, PhD  
Suraj Serai, PhD  
Mikio Suga, PhD  
Sudhakar Venkatesh, MD

### RSNA

Joe Koudelik  
Susan Stanfa

**Moderator:** Dr. Ehman

### Review of Previous Call Summary

- The April 1, 2019 call summary from the last MRE BC meeting was approved

### Discussion on Open Issue in the Profile re: Region of Interest (ROI) Minimum Size

- The latest [MRE Profile document](#) can be found on the QIBA Wiki
- MRE BC members met at the QIBA Working Meeting breakout sessions during the December 2019 RSNA Annual Meeting and discussed the minimum pixel requirement for ROIs; as quorum was not met, no decision was made
- In the absence of formal research data, the MRE BC had originally deemed 2,000 pixels (500 pixels x 4 slices) acceptable
  - There was speculation on whether a smaller number would work for clinical trials
  - A repeatability study to examine a large amount of back data to determine where the minimal pixel cut off was conducted, e.g. 500 vs. 700 vs. 2000 vs. 4000 pixels
- The presentation that Dr. Middleton gave during the annual meeting: “Evaluation of liver MRE analyzability criteria using a simulation method based on successively and concentrically decreasing the size of selected regions-of-interest: a proof-of-concept study” was distributed prior to the Jan. 23, 2020 MRE BC call
  - Based on a study he led in collaboration with Liver Imaging Group (UCSD Dept. of Radiology), Gilead Sciences Incorporated and Mayo Clinic (Rochester, MN)
  - The methods were summarized: cases containing large ROIs were examined and the pixel threshold was adjusted lower while maintaining image quality
- Discussion continued re: whether the proposed limit of 500 pixels per exam (rather than 500 pixels per slice) based on the simulation study should be adopted into the Profile
- An ROI area cutoff of four slices as low as 500 pixels was deemed acceptable for drug development clinical trials, and probably also for clinical care
- There were no objections to this Profile revision with the caveat that this smaller ROI size was specific to homogeneous disease conditions; clarifying text to be added

### Discussion on Open Issue re: Requirement for Weighted Average in Profile Checklist

- The usability checklist drafted by Dr. Pepin was distributed to Dr. Khan’s site and feedback on practicality/feasibility was provided
  - The only issue identified was the recommended calculation method for liver stiffness; most radiation oncologists calculate “mean,” not “weighted-mean”
  - Calculating a weighted-mean was more logical, but greater clinical pushback was expected
  - Dr. Middleton offered to compare and assess the difference between mean to weighted-mean and report back to the committee by the next t-con
  - The checklist will be distributed to additional sites for additional feedback

- Current Profile text in: “3.11: Image Interpretation:”
  - Parameter: liver stiffness
  - Actor: radiologist
  - Requirement: overall mean stiffness of liver is reported by calculating the mean stiffness value of each ROI and then reporting the mean value, weighted by ROI size
  - Discussion re: difficulty weighting by ROI size, which will be a matter of post-processing software which is not currently available for MRE
- Additional information, perhaps analysis, needed before a decision can be made

### Next Steps

- It was clarified that [Stage 3: Technically confirmed](#) requires only that several sites perform the Profile and find it to be practical and *expect* it to achieve the claimed performance
  - To do this, checklists need to be performed on at least two vendor platforms and at two or more sites and found to be clear and not burdensome/impractical
  - At this stage, there is not yet a need to confirm the Claim
  - Only two Profiles have reached Stage 3
- [Stage 4: Claim Confirmation](#) requires that some sites have performed the Profile and found it achieved the claimed performance
- No QIBA Profile has yet to achieve Stage 4
- Stage 4 is a major undertaking that would require funding
- Discussion re: Foundation for the National Institutes of Health’s (FNIH) Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) project and its potential usefulness for Stage 4
  - More information can be found on the [FNIH website](#)
  - Usable data may be published, saving the MRE from performing a costly project
  - It remains to be seen, however, whether the study will address all MRE Profile needs/gaps
  - An additional study confirming a longitudinal Profile Claim for repeatability may need to be performed

### User-friendly Guide

- It was noted that after being directed to the MRE Profile on the QIBA Wiki, some clinicians have stated that material within the Profiles was not relevant to clinical practice and the language was foreign, e.g., “actor”
- Suggestion to draft a user-friendly guide on performing MRE (a subset of the full Profile); volunteers include Drs. Pepin, Ehman and Miller
- Potential publication locations include: 1st: *Radiology*; 2nd: *Society of Abdominal Radiology*; 3rd: *RadioGraphics*

### Profile Appendices (see Word docs 2D and 3D MRE)

- Small changes in acquisition parameters are needed when implementing the Profile for pharma trials
- Appendices B&C were completed; maintenance update was released in June 2019
- Vendor-specific scanning protocols in Appendix D were also updated and a newer version will be made available

### Q&A / Comments / Suggestions from MRE members

- QC procedures provided for all vendor platforms
- Discussion re: description of phantom set-up / QC to be performed for each platform; it was noted that this procedure is for installation and not calibration