QIBA Ultrasound Shear Wave Speed (SWS) Biomarker Committee (BC) Call

Friday, April 6, 2018; 11 AM CT

Call Summary

In attendance

Tim Hall, PhD (Co-Chair) S. Kaisar Alam, PhD Michael André, PhD Paul Carson, PhD Jun Chen, PhD Shuyan Du, PhD Al Gee Rik Hansen, PhD Mike MacDonald, PhD Stephen McAleavey, PhD Nancy Obuchowski, PhD Arinc Ozturk, MD Mark Palmeri, MD, PhD Anthony Samir, MD, MPH Keith Wear, PhD Jim Zagzebski, PhD **RSNA** Joe Koudelik Julie Lisiecki

Moderator: Dr. Hall

Manuscript update:

- A paper is being written for possible submission to *Radiology* that summarizes conclusions from the ultrasound shear wave speed (US SWS) phantom phase I & II experiments, which will inform the Profile regarding acoustic attenuation in the liver and what is deemed an acceptable relatively narrow range
- Questions remain as to whether or not the paper should include a comparison of US SWS measurements to magnetic resonance elastography (MRE) and Fibroscan
- A focused message is needed, supported by a maximum of six figures; the current study results will need to be pared down considerably
- 60 Hertz for SWS has been suggested as a guidance measurement for comparison with MRE
- Feedback regarding using this low frequency may be needed from manufacturers
- The issue of concern is that MRE frequencies may work in phantoms but are not high enough for the liver measurements in a clinical setting
- MRE and Fibroscan wavelength estimates are lower than SWS or the equivalent and users should be advised in making clinical decisions, as the measurements depend on the material being scanned
- While it may seem ideal to provide phase velocity data from manufacturers, this is not possible in practice due to data quality control issues
- All software modifications for scanners follow strict manufacturer protocols with which they must comply
- System and site variability are important factors for consideration
- Additional citations are needed for the final draft of this manuscript, as well as some additional discussion on the phantoms and their relationship to in vivo data
- Any additional citations are requested prior to the next call, May 4th
- Dr. Hall offered assistance to Dr. Palmeri for manuscript editing and mentioned that he would follow up with the *Radiology* Editor, Dr. Bluemke

Profile update:

- Statistical analysis has been completed using anonymized data
- A special call may be needed to discuss Profile updates once Dr. Garra has had time to make updates
- Dr. Palmeri welcomes Profile formatting assistance from committee members
- Comments welcome to Dr. Garra: <u>Brian.Garra@fda.hhs.gov</u>; <u>Brian.Garra@va.gov</u>; <u>bgarra@gmail.com</u>
 - (Please use all three emails)

Profile Approval Process Next Steps:

- See voting and balloting process links http://gibawiki.rsna.org/index.php/Process
- Voting to release the Profile for public comment will be done electronically

Next QIBA WebEx calls are as follows:

- Apr 13: CEUS BC
- May 04: SWS BC
- May 11: CEUS BC