

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

Friday, November 2, 2018; 11 AM CT

Call Summary

In attendance

Brian Garra, MD (Co-Chair)

Paul Carson, PhD

Jun Chen, PhD

Todd Erpelding, PhD

Albert Gee

Edward Jackson, PhD

Stephen McAleavey, PhD

Nancy Obuchowski, PhD

Arinc Ozturk, MD

Anthony Samir, MD, MPH

Leah Schafer, MD

Theresa Tuthill, PhD

Keith Wear, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Garra

Approval of 09.07.2018 call summary

- The summary was approved as written

Manuscript update:

- Dr. Palmeri has submitted a comprehensive paper for publication consideration to *Radiology* as of September 7th
 - The paper summarizes conclusions from the ultrasound shear wave speed (US SWS) phantom phase I & II experiments, which informs the Profile regarding acoustic attenuation in the liver
 - He is awaiting feedback from the editors

Data Needed:

- Data are needed from clinical sites currently doing research in the area of shear wave speed (SWS) for training of technologists on new devices, as deemed important by the FDA
 - Patients having both FibroScan and SWS data needed for platform output comparison
 - Dr. Schafer volunteered to help gather data
 - It may also be useful to partner with hepatologists

Profile update:

- Dr. Garra is incorporating latest edits to the Profile and will soon redistribute for additional BC review
- Low priority comments have been addressed, and plans are to address remaining comments in parallel with public comment feedback at a later time
- Adjustments have been made to the References
 - There is a list in the back of the document; however, there are also applicable footnotes on every page for ease of reading
- All edits that have been addressed are referenced in the margin sidebars
- Open questions remain including the following:
 - Numerical values
 - Use of Verasonics for verification
 - Measurement changes related to Verasonics and MRE
 - Comparison with Fibroscan data – these numbers must be reconciled for the next version of the Profile
 - These open issues will need to be addressed on the next call or at the f2f meeting
- Industry-specific contacts for public comment should be provided to RSNA staff with emails: jlisiecki@rsna.org
- Comments are welcome to Drs. Garra and Hall: Brian.Garra@fda.hhs.gov; bgarra@gmail.com; tjhall@wisc.edu

Phantom:

- Financial and technical support is needed for the first several phantoms
- It is uncertain how conformance testing will be prescribed in the Profile
 - Phantoms may be used for conformance testing, and a list of viable ones will be needed

- Updates to the conformance text also need to be made
 - Much of the current conformance section was written prior to the new Profile template distribution and before guidance was available
 - As guidance is now more detailed and regulatory, additional text will be incorporated after suggestions are received from public comment
 - To expedite distribution of the Profile for public comment, only revisions that were sent as of January 2018 will be incorporated
- Concurrence for true values among sites is needed
 - Dr. Garra will be partnering with Dr. Eliot Siegel to obtain additional data from Baltimore area VA sites
- Dr. Chen indicated that he can provide MRE support regarding phantom testing
- Verasonics will be used for the gold standard but it must be in concurrence with MRE procedures

Next Steps:

- Concepts that may require further discussion include the following:
 - US imaging vs. Fibrosan data extrapolation and estimation of dispersion
 - Consideration of using the QIBA protocol that was recently published to run Verasonics software
 - Consider performing calibrations using an open-source tool for manufacturers
 - Manufacturer utilization of scanner calibration phantoms
 - Many calibration phantoms are available today (e.g., CIRS, uniform elastic phantoms, for use with the QIBA acquisition protocol)
 - Manufacturers utilization of standardized reporting with calibrated phantoms
 - Frequency range issue remains unsolved; only recommendations can be made
 - Profile tolerances are set for the elastic phantom, not the viscoelastic phantom
- Dr. Carson to draft a letter to the editor to accompany Dr. Palmeri’s manuscript with suggestions of studies to aid extrapolation from shear wave frequencies used in the US SWS imaging systems to those used in Fibrosan and MRE.

Profile Approval Process Next Steps:

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

QIBA US Schedule:

11/09	CEUS BC
12/07	US Coordinating Ctte
12/14	CEUS BC - TBD