

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

Friday, May 5, 2017; 11 AM CT

Call Summary

### In attendance

Tim J. Hall, PhD (Co-Chair)

Brian Garra, MD (Co-Chair)

Andy Milkowski, MS (Co-Chair)

S. Kaisar Alam, PhD

Michael André, PhD

Paul Carson, PhD

Anil Chauhan, MD

Jun Chen, PhD

Todd Erpelding, PhD, MSE

Kathy Nightingale, PhD

Nancy Obuchowski, PhD

Mark Palmeri, MD, PhD

Nicolas Rognin, MSc, PhD

Stephen Rosenzweig, PhD

Anthony Samir, MD

Matthew Urban, PhD

Michael Wang, PhD, MASc

Keith Wear, PhD

### RSNA

Joe Koudelik

Julie Lisiecki

**Moderator:** Dr. Garra

**Review prior call summary:** April 7<sup>th</sup> summary approved as submitted

### Profile Updates/Open Issues

- Dr. Garra to follow up with Dr. Obuchowski regarding the claims section
  - Different statistical assumptions underlie the claim and must be clarified
  - Test / re-test data to be provided for conformance testing, or Profile users may be required to provide their own datasets
  - For those who did not meet test / re-test criteria, individual actors must be evaluated to determine which is out of range and what is causing excessive noise in the overall measurements
  - Once this evaluation has been completed, a few likely candidates will be chosen for confirmation and additional site conformance discussions
- Appendix D requires some minor editing
  - A uniform format is desired for the manufacturer checklists; manufacturers will need to approve first
  - Current checklists are organized by “actors”; however, Dr. Garra suggests temporal ordering for better organization of the workflow in a clinical environment
  - Checklists are an important tool that must be completed prior to proceeding with a technical confirmation study
- Dr. Palmeri re-ran statistical data which will need to be reincorporated into the Profile after Dr. Obuchowski has had time to review
  - Dr. Palmeri to share anonymized data of the manufacturer results only with Dr. Obuchowski for re-analysis; reaching out to manufacturers may be needed
  - She may be able to perform some re-analysis, but may need to speak with manufacturers
- Dr. Garra to follow up with Dr. Cosgrove offline for some additional details
- Institutional Review Board (IRB) recommendations are complete for Mass General and the Washington DC VA
- (Round-6 funded project update – Dr. Samir)
  - Some acceptance testing to follow
  - The Profile is designed to provide Profile confirmation, though the process must be completed in an accurate and cost-effective manner
  - It is preferred that machines be checked for accuracy with a phantom prior to leaving the factory; however, a dependable phantom is not yet available for this purpose
  - The requirement that “Manufacturers will verify performance” has not been challenged
    - This may prove difficult once implementation is tested
    - Drs. Garra and Dhyani to follow up with manufacturers and obtain latest details on equipment
- Workaround for the phantom issue may be a calibration against the standards for Verasonics equipment
  - Verasonics machines will be used for calibrations and measurements on phantoms
  - Verasonics representatives have expressed an interest in discussing their hardware

- Drs. Garra and Hall to try to get a Verasonics representative on the next BC call
- Number of sites necessary for long-term conformance studies has not yet been determined
- Dr. Lynch has indicated that CIRS or a phantom manufacturer could provide QIBA-verified phantoms with calibration values
  - This might prove to be a solution for conformance issues
- Mayo and Duke labs to work on getting systems matched up in preparation for the technical confirmation study

**Existing Phantoms**

- Location of all existing Round 1 and 2 phantoms needs to be determined as well as number and suitability of phantoms for additional testing
  - Simplicity and stability are the most desirable characteristics for any phantoms in development
- Dr. Lynch is working on new phantom prototypes
  - One will be visco-elastic to match the others
  - Another may be an elastic phantom with a casing that has sound-absorbing properties
  - Dr. Nightingale is working on a robust way to report on the visco-elastic phantoms
  - Elastic phantoms may prove easier for manufacturers to use in calibrations
- Dr. Samir to follow up with Dr. Hall regarding the number code on the phantoms he has at MGH

**Profile Release Plan**

- Some roadblocks remain that may require additional discussion
- Volunteers will be needed for internal BC review prior to release for public comment
- Any further comments regarding the Profile should be sent to Mr. Milkowski, and Drs. Dhyani and Garra: [andy.milkowski@siemens.com](mailto:andy.milkowski@siemens.com); [Dhyani.Manish@mgh.harvard.edu](mailto:Dhyani.Manish@mgh.harvard.edu); [bgarra@gmail.com](mailto:bgarra@gmail.com)

**AIUM Update (deferred to next BC call)**

- Dr. Nightingale was requested to present her AIUM talk on SWS propagation in phantoms on the next BC call
- This information would be valuable for vendors and buyers to communicate what they each need regarding boundaries on how measurements can be reproduced using viscoelastic phantoms.

**Action items:**

- For the next call, Dr. Garra would like to see if Dr. Nightingale might present her AIUM talk on shear wave propagation in phantoms
- Establish whether doing a test-retest with MRE would be reproducible and move forward
- Co-chairs to talk with Verasonics reps and invite to future SWS call for group discussion

**Dashboard Updates:** Please send Dr. Carson any relevant updates: [pcarson@umich.edu](mailto:pcarson@umich.edu). Thank you.

**Next QIBA WebEx calls are as follows:**

6/2	US Coordinating Ctte
6/9	CEUS BC
6/16	SWS TF (TBD)
6/23	CEUS TF (TBD)