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

Friday, July 10, 2015; 11 AM CT Amended Call Summary, 8/17/2015

In attendanceRSNABrian Garra, MD (Co-Chair)David Cosgrove, MDMark Palmeri, MD, PhDFiona MillerS. Kaisar Alam, PhDManish Dhyani, MDStephen Rosenzweig, PhDJoe Koudelik

Michael André, PhD Albert Gee, MD Marijean Trew
Jun Chen, PhD Mike MacDonald, PhD Theresa Tuthill, PhD
Shigao Chen, PhD Yasuo Miyajima, MS Keith Wear, PhD

Elaine Collins, RDMS Nancy Obuchowski, PhD

Moderator: Dr. Garra

Review of June 12th US SWS BC call notes

Approved as written

Phantom Studies

- Dr. Palmeri is in the process of analyzing phantom data collected from the M+Box and
 - o The first set of phantoms returned to Duke just recently have stable measurements
 - o Duke also remeasured Set 1, the set that had potential bubbles
 - o Phase II (set 2) phantoms are with Dr. Palmeri at Duke
 - Phase II (set 1) phantoms are with Dr. McAleavey at U Rochester
 - Zonare and Samsung also plan to test the Phase II phantoms (sets 1 and 2); Phantoms will then be returned to Duke for final testing
- The BC would like to utilize these measurements for the fall IEEE meeting poster
- Dr. Wear reminded the group that the AIUM abstract submission deadline is the end of September

Simulation Study (Dr. Palmeri)

- Datasets for download have been created for testing by manufacturers
- A few manufacturers have downloaded data but have not yet had time for processing / analysis
- Feedback will be helpful and it is hoped that this phase of the project will be completed by the end of the summer
- The next phase will include RF and IQ simulation for system model configuration
- Software source code and data analysis files have been uploaded to GitHub

Update on Clinical Project (Dr. Dhyani)

- 3 patients have been tested; 2 more expected later in July
- Letters have been sent out to another 50 of the 90 patients that had biopsies
- Target goal of 20 patients is within reach
- Challenges with the study include scheduling of exam rooms with simultaneous availability of 3 machines for testing

Brief Update of the <u>Ultrasonic Imaging and Tissue Characterization Symposium</u> (UITC) – (Dr. Wear)

- Dr. Hall outlined the Phase II Phantom Study at the meeting
- Drs. Nightingale and Palmeri gave a presentation outlining the variability in SWS and efforts of the QIBA SWS BC
 - It was suggested that a more in-depth presentation for the System Dependencies/ Phantom Task Force could be shared on their next call

Round-5 US SWS Funded Project Proposals

- Two proposed projects submitted were:
 - 1) Analysis of Sources of US SWS Measurement Inter-System Variability (PI: Mark Palmeri, MD, PhD)

Julie Lisiecki

- 2) Establishing the Effect of Protocol Deviations on Least Detectable Change on Serial Somoelastography (PI: Anthony Samir, MD)
- The US Coordinating Committee (CC) recommended funding scaled-back versions of both projects, with a 'preference' to the simulation project (Dr. Palmeri), due to its practical application and accessibility
- Dr. Palmeri has scaled back two objectives for linearity and source of statistical bias, for consideration by the Steering Committee

Proposed New Ultrasound Biomarkers

- Voting has come to a close for the new biomarker recommendations, and the two highest ranked were:
 - 1) Blood Volume Flow and
 - 2) Quantitative Contrast Enhanced Ultrasound (CEUS)
- Next steps include:
 - 1) Discussion between the QIBA US CC and the AIUM TSC regarding biomarker ranking and level of AIUM admin support moving forward
 - 2) Formal proposal for one new biomarker following QIBA guidelines

Action items:

Drs. Wear, Hall, and Garra to follow up with AIUM regarding the recommendations for a new biomarker

Upcoming Calls (Fridays, 11 am CT):

July:

• July 17: System Dependencies/ Phantom Task Force (Dr. Wear)

July 24: Clinical Applications Task Force (Dr. Samir)

July 31: No call

August:

• August 7: US SWS Biomarker Ctte (Dr. Hall, if available)

August 14: System Dependencies & Phantom Task Force - (Dr. Palmeri, if available)

August 21: Clinical Task Force - (Dr. Samir, if available)

August 28: No Call