

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

Friday, August 7, 2015; 11 AM CT

Call Summary

Notes provided by Dr. Garra

In attendance

Tim J. Hall, PhD (Co-Chair)
Brian Garra, MD (Co-Chair)
S. Kaiser Alam, PhD
Paul Carson, PhD
Shigao Chen, PhD
Manish Dhyani, MD
Steven Fick, PhD
Albert Gee

Zaegyoo (Jay) Hah, PhD, MBA
Alpana Harisinghani, MD
Ravi Managuli, PhD, RDMS
Stephen McAleavey, PhD
Yasuo Miyajima, MS
Kathy Nightingale, PhD
Nancy Obuchowski, PhD

Mark Palmeri, MD, PhD
Eric Perlman, MD
Nicolas Rognin, MSc, PhD
Anne Shelchuk
Marijean Trew
Theresa Tuthill, PhD
Keith Wear, PhD

RSNA

Joe Koudelik
Julie Lisiecki

Moderator: Dr. Hall

SWS Biomarker Committee meeting 8-7-2015 notes---Brian S. Garra, MD

Call Summary review -July 10th:

- Zonare noted that they do not have any phantoms at this point as suggested in notes.
- Discussion regarding location of phantoms and where they should go next resulted in the following plan
- Currently phase II set one are at Rochester and phase II set 2 are at Duke

Plan:

- Zonare will ship phase I phantoms to Samsung
- Duke will ship phase II set 2 to Zonare and from there they will go to Samsung then back to Duke
- Rochester will ship phase II set 1 to Zonare and from there those will go to Samsung then back to Duke
- No grant funds are available any longer for shipping.
- Participants were reminded by Dr Hall that all shipping addresses are on a list in Box.com (Dr. Carson's site) and that the list should be updated with any changes and can be used to obtain shipping addresses.
- The target is to have all data uploaded to Box by 31 August

Round 4 final reports:

- **Due at the end of August**
- Comment by Manish Dhyani that 8 patients are complete at MGH with 6 scheduled for next week. He anticipates having all patient data by the end of August. Can probably complete an analysis for the report using the pathology report in the patient record but it will take longer to get the final pathology from a single pathologist. It was decided that the "final" report could have an analysis based on interim pathology results but a paper would have the final pathology read analysis.
- Mark Palmeri noted that a delay in uploading data to QIDW has occurred but is being addressed. The data upload should be complete and the final report will be on time.
- Mark also noted that at least the distribution of values in the data will be available for the IEEE meeting.
- The question of whether to deidentify the data for phase II was discussed extensively and after the discussion where some potential issues with non-deidentified results were mentioned the decision was to deidentify

the sites and the ultrasound systems. Mark will leave it to the statistician as to what designations will be used in the deidentification process.

- The question of phase II data availability to the committee members was raised and Tim Hall noted that the agreement was to release the data to the committee AFTER all data acquisition was complete.

Round 5 project review status:

Tim Hall summarized the status:

- Two proposals were submitted, a clinical proposal and an extension of the simulation proposal. Due to NIBIB prohibitions on clinical studies all clinical proposals were dropped from consideration.
- The simulated RF data proposal with analysis received a high score but the budget was thought to be quite large. A smaller, cheaper version of the proposal that drops two of the six objectives. Acoustic radiation force impulse propagation effects on SWS and non-linear SW propagation effects on SWS were dropped. This resulted in a decrease in budget from approx. \$145,000 to approx. \$95,000.
- The steering committee will vote on funding of proposals in about two weeks and further updates will be made available by the end of August.

New Biomarkers:

An ultrasound biomarker coordinating committee meeting on 8-27-15 is scheduled to discuss how to proceed with two selected new biomarkers, US Contrast Agents for evaluation of Inflammatory Bowel Disease and a new method of Volume blood flow estimation. The tentative plan is to ask for support from the Pharmaceutical industry to move forward with preliminary work on the US contrast biomarker. A request for support from AIUM for preliminary work on the volume blood flow biomarker in conjunction with QIBA will also be made.

QIBA SWS Profile:

Brian Garra noted that the QIBA process committee was revising parts of the profile template so that work on a new version of the profile will commence when the first round of revisions are substantially complete. Brian G will query the process committee on when would be an appropriate time to revise the existing version 1 profile using the revisions in the template. Manish Dhyani also noted the manufacturer specific information will be collected for appendices of the profile as soon as the committee feels that the analysis of phase II data is far enough along so that manufacturers have time to revise their procedures based on those results.

Committee adjourned at 1:06 PM EDT.

Upcoming Calls (Fridays, 11 am CT):

August:

Aug 14: System Dependencies & Phantom Task Force - (Dr. Palmeri)

Aug 21: Clinical Task Force - (Dr. Samir)

Aug 28: **No Call**

Proposed September:

Sept 4: US SWS Biomarker Ctte (Mr. Milkowski, if available)

Sept 11: **No Call (Bubble Conference)**

Sept 18: System Dependencies & Phantom Task Force (2 hours)- (Dr. Wear, if available)

Sept 25: Clinical Task Force - (Dr. Samir, if available)