

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

Friday, October 2, 2015; 11 AM CT

Draft Call Summary

### In attendance

Tim J. Hall, PhD (Co-Chair)

Brian Garra, MD (Co-Chair)

Andy Milkowski, MS (Co-Chair)

S. Kaiser Alam, PhD

Michael André, PhD

Jun Chen, PhD

Shigao Chen, PhD

Elaine Collins, RDMS

Mathieu Couade, PhD

Steven Fick, PhD

Albert Gee

Gilles Guenette, RDMS, RDCS, RVT

Alpana Harisinghani, MD

Mike MacDonald, PhD

Kathy Nightingale, PhD

Nancy Obuchowski, PhD

Mark Palmeri, MD, PhD

Nicolas Rognin, MSc, PhD

Stephen Rosenzweig, PhD

Remi Souchon, PhD

Theresa Tuthill, PhD

Matthew Urban, PhD

Michael Wang, PhD, MASC

Keith Wear, PhD

### RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Hall

### Review of August 7<sup>th</sup> US SWS BC call notes

- One minor edit needed prior to wiki posting

### Report from [International Tissue Elasticity Conference \(ITEC\)](#)

- Dr. Hall presented results from the Phase II Phantom Study
- The data were very encouraging and demonstrated how well the systems currently agree, particularly in terms of stiffness measurements and dispersion of media
- There were very few outliers, and those were within +/- 10%
- Dr. Palmeri will be presenting an additional new analysis of this phantom data at the IEEE conference in Taipei
  - He is looking at trends as a function of focal depth as well as overall performance of the technology
  - A draft poster and paper for the IEEE conference will be distributed for review and comment
  - Co-authors were asked to email Drs. Palmeri and Wear indicating their consent for publication by 10/6:  
[mark.palmeri@duke.edu](mailto:mark.palmeri@duke.edu) and [Keith.Wear@fda.hhs.gov](mailto:Keith.Wear@fda.hhs.gov)

### Phantom Studies

- New participants from Hitachi and INSERM (France) will be added to the phantom study.
- Dr. Hall to coordinate a timeline for these additional participants

### Simulation Data

- Vendors are using the simulation ground truth data to bring systems into line
  - Matches on the simulation data will pave the way for future clinical studies
  - There are some challenges with the motion artifacts *in vivo*
  - Mr. Milkowski to review / tweak simulation data to get agreement from vendors to proceed to the next phase  
- pursuit of a clinical study

### QIBA US SWS Poster and Working Meeting at RSNA 2015

- Drs. Samir and Dhyani are coordinating the SWS Biomarker Committee poster for the QIBA Kiosk.
- Dr. Palmeri will contribute data from the phantom study
- The QIBA Working Meeting will be held on Wednesday, December 2<sup>nd</sup>, (2:30 pm CT) with ample time for breakout sessions, starting at 3 pm CT
- Dr. Wear requested all co-authors to submit a "author confirmation" directly to him if they want to be included in name on the poster: [Keith.Wear@fda.hhs.gov](mailto:Keith.Wear@fda.hhs.gov)

### Profile

- The QIBA Process Committee is making updates to the sections on conformance (formerly compliance), which will be incorporated into a revised template for BC use

- Any updates to the Profile are on hold for now until the new template is available
  - Alternate sources of funding to pursue possible technical and clinical confirmation phases for the Profile were discussed; Drs. Garra and Samir have agreed to be representative clinical sites
  - ACRIN and EIBALL were discussed as potential partners
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#### **Upcoming QIBA Ultrasound Calls (Fridays, 11 am CT):**

##### **October:**

- Oct 16: Clinical Task Force
  - Oct 23: **No call – IEEE IUS 2015 and SRU Meetings**
  - Oct 30: **Optional Poster call, if needed** (deadline for PPT file to RSNA)
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##### **November:**

- Nov 6: US SWS BC
  - Nov 13: Systems/ Phantom Task Force
  - Nov 20: Clinical Task Force
- RSNA 2015: November 29th – December 4th
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##### **December:**

- Dec 11: US SWS BC