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

Friday, January 22, 2016; 11 AM CT

Additional Notes provided by Dr. Garra

In attendance			**RSNA**
Tim J. Hall, PhD (Co-Chair)	Gilles Guenette, RDMS, RDCS, RVT	Anthony Samir, MD	Joe Koudelik
Brian Garra, MD (Co-Chair)	Riwa Kishimoto, MD	Marijean Trew	Julie Lisiecki
Michael André, PhD	Ravi Managuli, PhD, RDMS	Theresa Tuthill, PhD	
Paul Carson, PhD	Yasuo Miyajima, MS	Matthew Urban, PhD	
Shigao Chen, PhD	Kathy Nightingale, PhD	Keith Wear, PhD	
Mathieu Couade, PhD	Mark Palmeri, MD, PhD	Hua Xie, PhD	
Giovanna Ferraioli, MD	Stephen Rosenzweig, PhD	James Zagzebski, PhD	
Albert Gee			

Moderator: Dr. Garra

Review of December 11th US SWS BC call notes

- Notes were approved as written

Discussion

- A primary concern of the group is how to use the simulation / phantom data effectively to inform the Profile, etc.
- Some helpful guidelines would include:
  - An estimation of the time and effort needed for narrowing down the necessary metrics
  - Instructions on how to process and report the data
  - Remaining manufacturer and regulatory issues that need to be addressed
- A poll for manufacturers is under consideration to best determine appropriate action going forward
  - Dr. Palmeri volunteered to draft a spreadsheet for group reference and ease of idea organization
- Simulation data is housed on the QIDW

Profile for US SWS

- The Profile Writing Group is working with Dr. Obuchowski's guidance on a new claims section
- Dr. Hall plans to confer with other QIBA BC leaders regarding the Technical Evaluation Phase for the Profile
- A European / Japanese clinical trial collaboration is also under consideration for technical validation of the Profile
  - Some additional questions must be answered before considering this step
  - An internal test of the Profile prior to a collaborative clinical study would be preferred as a first step
- Draft Profile slated to be ready by the April QIBA annual meeting

Project Planning

- BC members are encouraged to think of new groundwork projects for Spring 2016 QIBA project proposals (Round 6)
  - Dr. Garra suggested consideration of how phantoms are best used, particularly with regard to conformance for the QIBA Profile
- QIBA Steering Cmte support deemed necessary for requesting ACRIN or NIH (R01) grant funding to support a future clinical trial (being considered by Dr. Samir)

Action item: All to consider potential Round 6 projects

Notes from Dr. Garra:

SWS Clinical Task Force: Dr. Samir gave the report.

Activities:

a. Abstract submitted to ITEC, Manuscript on Round 3 submitted to *Radiology*.
b. Also abstracts submitted to AIUM and to RSNA 2017.

Collaborating Sites:

a. None have been recruited yet but there seems to be plenty of interest among the existing sites with adequate capability. The issue of what experience level should be required if any was not discussed.

Proposed Studies:

a. Technical validation proposal should be developed first and perhaps be funded by NIH. Then clinical validation study should be developed and proposed to funding sources.

Cost Projection:

a. Cost should be a factor in site selection, but actual costs depend on the study design
b. The study should be conducted as part of normal clinical usage to reduce costs to components not covered by clinical revenues such as the research coordinator time. If multiple operators must acquire then additional costs will be accrued and a central pathology reading site which is probably necessary will be costly.

Funding sources:

a. The Pharmaceutical companies are a good potential source as is NIDDK. Overseas funding sources in Europe and Asia (Korea and China and others) should also be explored. ACRIN was also suggested as a potential funding source and Dr. Garra suggested the VA and DOD as potential sources. The FDA can fund a portion probably most related to a research coordinator and supplies. Manufacturers should also be a source since they stand to gain from adoption of a standard protocol

SWS Systems/Phantoms Task Force report was given by Dr. Palmeri.

a. **Report of Activities and Progress**:

Phase II data analysis is at the stage seen in the RSNA poster which included a descriptive plot. The linear mixed model for multiple degrees of freedom has now been applied to data from phase II but now also to phase I data.

The data simulation project is still underway. A methods paper for UFFC will be submitted in March 2016. The simulated displacement data have been uploaded to the QIDW—this includes extended range data thought to be useful for some manufacturers.

Manufacturers Use of Data: Several manufacturers have used the data but no feedback from them has been obtained yet. The question arose about what metrics should be used in reporting of results obtained from use of the phantom data Expected phase velocities have been calculated but again no feedback from manufacturers for comparison with those phase velocities has been received.

Some discussion regarding the use of phase velocities vs group velocity ensued. One possibility would be to use combined or pooled group velocity estimates from all players to look at the overall variability. It was pointed out that regarding metrics it was important to get manufacturer feedback on what they wish to use.

Tim Hall suggested comparing an assumed power spectrum based on the simulation data along with the known group velocity and compare with what various manufacturers get. Mark Palmeri suggested simply comparing results across systems for a basic metric such as group velocity. A draft spreadsheet for such a comparison is being created for this purpose.

In further discussion, a report of the comparison of various FE engines for data simulation is being created and can be distributed before the next meeting for discussion.

The issue of what metrics to use when reporting results from different manufacturers for comparison with ground truth or other manufactures will be discussed at the next systems meeting.

Role of phantoms and simulated data for qualification and compliance was not discussed and will be revisited at the next SWS meeting.

Projections of future activities (goals, funding sources, work sites) was not discussed and will be held for a future SWS committee meeting.

SWS Profile Task Force:
Due to the length of the discussion of simulations and simulated data, Dr. Garra gave a very brief report explaining that a draft of the next version of the profile formatted in the new format was nearly ready for committee internal review. The claims section is not complete yet pending results from the phase II study. The profile and claims will be further discussed at the next meeting.

Review of Coordinating committee, CC leadership meeting and Steering Committee meetings: This item was deferred since no time was available.

The meeting adjourned at 1:05PM

Meetings: (Fridays, 11 am CT):

- Feb 12: US SWS Systems / Phantom Task Force
- Feb 19: US SWS Clinical Task Force
- Feb 26: US SWS Biomarker Committee
- **2016 - 2017 US Conferences**