

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

Friday, September 6, 2019; 11 AM CT

Call Summary

In attendance

Brian Garra, MD (Co-Chair)
Karen Alton, BS, RDMS, RVT
Jun Chen, PhD
Todd Erpelding, PhD, MSE
Albert Gee

Reinhard Kubale, MD
Ravi A. Managuli, PhD, RDMS
Kathy Nightingale, PhD
Nancy Obuchowski, PhD
Arinc Ozturk, MD

Anthony Samir, MD, MPH
Theresa Tuthill, PhD
Michael Wang, PhD, MASc
Keith Wear, PhD
Jim Zagzebski, PhD

RSNA

Julie Lisiecki

Moderator: Dr. Garra

Approval of 08.02.2019 call summary

- The summary was approved as presented

Welcome to new team member

- Dr. Garra welcomed Ms. Karen Alton, a stenographer who has been testing the SWS Profile for the FDA
- Dr. Garra and Ms. Alton are working on a checklist to accompany the SWS Profile

IEC Workgroup Overview:

- The IEC Workgroup plans to standardize the user interface for equipment
- Goal is to improve confidence (data integrity) when scanning difficult/large patients
 - It would be very helpful if all practitioners used the same interface
- Dr. Palmeri had previously volunteered to join Dr. Hansen on calls for this group
- Dr. Wear volunteered to aid the group's efforts and will provide input regarding federal requirements on devices seeking FDA approval
- Drs. Hansen and Palmeri will report back to the SWS BC regarding progress or need for input
- Interested volunteers to email Drs. Hall (tjh@wisc.edu), Garra (bgarra@gmail.com), and RSNA Staff (QIBA@rsna.org)

SWS BC Profile Status:

- The Profile has been through a BC internal review
- Comments from reviewers have been incorporated and highlighted in **red font** for ease of reference
- A BC e-ballot/vote for release to Public Comment is expected soon
- Dr. Obuchowski made critical changes to the claims section, and updates were made to the tools section
- Dr. Garra to incorporate Dr. Hall's suggested edits, add line numbers to the Profile, and provide a "clean" version to RSNA Staff in preparation for public comment (vote to) release
- - Dr. Nightingale shared that there is a command in Word, which using the "help" window, allows a user to insert continuous line numbers
 - Hyperlinking is not required for this to function
- Dr. Garra and Ms. Alton are finalizing a checklist to accompany the Profile for Public Comment
- A conformance checklist will be developed later – after public comment is complete
- Profile v 1.0 has data only for elastic phantoms; v 2.0 would include a reconciliation with Fibroscan data and viscoelastic phantom data as well

Profile request: Contact email addresses for Public Comment should be provided to RSNA staff: jlisiecki@rsna.org

QIBA US Modality Poster for RSNA 2019:

- The focus of the posters this year has been changed in hopes of appealing to the broader radiological community and demonstrating how QIBA and QI are helpful, valuable, and can enhance clinical practice and clinical trials
- Each modality will only have one poster, which will be a combined effort across BCs
- The posters should be visually appealing, with more images and less text
- The focus should be on marketing QIBA and QI, including topics such as:
 - The need for QI in AI development and testing
 - Data Science
 - Clinical Trials (Pharma)
 - Standardization (equipment vendors)
 - Algorithm development (software vendors)
 - Highlight specific use cases (both clinical and research)
 - Could also highlight disease focused areas and treatment guidance
- Emphasis should be on the impact of QI and showcasing the work of QIBA
- During the 3rd Quarter US Coordinating Committee call, Dr. Carson volunteered to be the poster coordinator and to compile content; he asked for all contributions **by October 12th** so that University of Michigan graphic designers may help with design (if available)
- Dr. Ozturk volunteered to help with compiling poster content

Other topics:

- While in Peru, Dr. Garra did some informal subject testing using the Shear Wave Profile
- He was able to get within a 5% coefficient of variation with patients using the QIBA Profile
- The Profile v 1.0 only guarantees phantom numbers, but Dr. Garra would like to include patient numbers for Profile v 2.0
- Dr. Samir mentioned that he will be involved with a multi-site funded trial related to coefficient of variation for fatty liver studies, which will be moving forward in the next year
- These prospective studies will likely take place over the course of four years
- Selection will be based on what is clinically reasonable
- The protocol will be based explicitly on the QIBA Profile and will reference the Profile once published
- The study is referred to as the [Non-Invasive Biomarkers of Metabolic Liver Disease \(NIMBLE\)](#) and is funded by the Foundation for the National Institutes of Health (fNIH)
- NIMBLE will include several vendors and will measure repeatability and reproducibility
- This study will allow for technical confirmation of the SWS Profile with fatty liver disease and should certainly be included in the QIBA poster for RSNA 2019
 - Drs. Samir and Ozturk to follow up with Dr. Carson to discuss value-add wording for the poster
- Profile v 1.0 is based on hepatitis but v 2.0 could focus on fatty liver as well

Profile Approval Process Next Steps:

- See voting and balloting process links <http://qibawiki.rsna.org/index.php/Process>
- Voting to release the Profile for public comment will be done electronically

QIBA US Schedule:

09/13	CEUS BC	11/08	RSNA 2019 Poster deadline for print-ready copy
10/04	SWS BC	11/15	US Coordinating Committee at 11 am CT.
10/11	CEUS BC		