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

Wednesday, April 13, 2022; 2 PM CT Call Summary

In attendanceRSNADavid Fetzer, MD (Co-Chair)Anil Chauhan, MDKevin O'Donnell, MAScJoe KoudelikStephen McAleavey, PhD (Co-Chair)Jun Chen, PhDArinc Ozturk, MDJulie Lisiecki

Stephen Rosenzweig, PhD (Co-Chair)Todd Erpelding, PhD, MSEMark Palmeri, MD, PhDMichael André, PhDGiovanna Ferraioli, MDGabriela Torres, PhDRichard Barr, MD, PhDJ. Brian Fowlkes, PhDKeith Wear, PhDPaul Carson, PhDKathy Nightingale, PhD

Moderator: Dr. McAleavey

SWS BC Consensus Profile Ballot Update

- The BC vote-to-publish the revised Profile at the Consensus stage was successful.
- The ballot closed at EOB on Tuesday, April 12, 2022, with a majority (12 votes) in favor to release the Profile (N=15), with 0 "no" votes or abstentions.
- The next steps in the Profile review process are:
 - 1. to conduct a vote at the US Coordinating Committee level
 - 2. to post this updated version to the <u>Profiles QIBA Wiki page</u> along with the Public Comment resolution document.

The following were discussed:

- Revisions to the Profile based on BC Consensus voting feedback, e.g., vendor edits to appendices, changes of company affiliation
- Clarification of "shalls" (must do) vs. "shoulds" (recommended to do)
- Publication / advertising of the Profile as available for use once it reaches Technical Confirmation, including the GI community
- Technical Confirmation planning and vendor conformance statements
- Suggestions for two potential publications to be submitted to the Journal of Ultrasound in Medicine (JUM):
 - 1. "How to" use the Profile and Checklist
 - 2. Why certain checklist items were included to provide rationale to users to aid with understanding
- Politics of competing technologies in the clinical environment
- Update to the Society of Radiologists (SRU) in Ultrasound Liver Elastography Consensus Statement
- QIBA Profile focus on how to achieve technical performance and help users achieve consistent measurements

Action items (general):

- Dr. Barr offered to "pre-review" any proposed publications to aid with publication preparation
- Dr. Carson suggested that bias specifications be added to the next version of the Profile
- RSNA staff to distribute DICOM documents for comments to Mr. O'Donnell prior to June 1st
- All to bring an outline of ideas to the next call to discuss re: publications and let the co-chairs know if they are interested in being potential authors
- Vendors will use the SRU guidance to adjust machines to meet prescribed interpretation and decrease variability

Action items (Profile e-ballot):

- Mr. O'Donnell to proofread the checklist for "shalls" vs. "shoulds," and make any needed adjustments
- Co-chairs to submit a Public Comment Resolution document for wiki posting
- RSNA staff to send e-ballot to US Coordinating Committee members
- Co-Chairs were advised to talk with Dr. Timothy Hall regarding next steps for Profile publication / promotion

Next Steps per QIBA Process Committee

- Circulate the resulting Profile & Checklist for formal CC approval (email ballot) (Resolve any ballot comments)
- Publish as Stage 2: Consensus and move on to Stage 3: Technically Confirmed. (Feasibility test the new checklists.)
- Plan for Technical Confirmation will require at least 3 volunteer sites to fill out the checklist demonstrating feasibility of following the Profile (a Google form would be ideal)
 - o Ideal situation (not always possible) would be to identify sites/reps not involved with Profile development to obtain "unbiased," real-world user feedback

<u>Profile Approval Process</u>: See voting and balloting process links: http://qibawiki.rsna.org/index.php/Process Minor Profile updates do not require voting but must be documented appropriately for versioning

Next call – Wednesday, May 11th at 2 pm CT {now 2nd Wednesdays of the month}