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

Friday, January 5, 2018; 11 AM CT *Call Summary* 

In attendance RSNA
Tim Hall, PhD (Co-Chair) Al Gee Nancy Obuchowski, PhD Joe Koudelik

Andy Milkowski, MS (Co-Chair)

Rik Hansen, PhD Fellow

Paul Carson, PhD

Alpana Harisinghani, MD

Shuyan Du, PhD

Eleni Liapi, MD, ScM

Theresa Tuthill, PhD

Todd Erpelding, PhD, MSE

Mi-Jung Lee, MD, PhD

Michael Wang, PhD, MASc

Joel Gay, MSc Ravi Managuli, PhD, RDMS Keith Wear, PhD

Moderator: Dr. Hall

Review prior call summary: October 6th summary approved as submitted

## Profile update:

- The Profile was distributed to leadership for initial review, and will now be distributed to BC members for a 30-day internal review, with a deadline of Friday, February 2<sup>nd</sup>
- Members are asked to volunteer to review sections that appeal to expertise and to review checklists
  - Dr. Carson volunteered to review section 3.8, image-related QA
  - He also noted that medical physicists at UAB have volunteered to review DICOM related details
- Open issues have been documented within the Profile, as some follow up remains
- Remaining items include:
  - o Finalized checklist by Dr. Garra in Excel format, framework for future interactive electronic version
  - o List of overall pass / fail tolerances for phantoms to be provided by Dr. Lynch
  - Table of Contents suggested by Dr. Samir to aid with areas of expertise for review, as well as to help potential users of the Profile
  - o References needed for some open issues
    - Although it would be preferable to have references updated prior to sending the Profile out for public comment; these can be added in parallel
  - It would also be helpful to determine how each manufacturer specifies outliers
    - Profile to specify a coefficient of variation (COV) regarding expected performance (based on claims), but not prescribe how to obtain these; this is left to each manufacturer
  - Clean-up of remaining highlighted areas within the Profile
- The checklists are complete; however, internal group review would be appreciated
- Comments welcome to Dr. Garra: <u>Brian.Garra@fda.hhs.gov</u>; <u>Brian.Garra@va.gov</u>; <u>bgarra@gmail.com</u>
  - (Please use all three emails)
- The goal is to have the Profile out for public comment sometime in February 2018

## **Profile Approval Process Next Steps:**

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

## Next QIBA WebEx calls are as follows:

Jan 12: CEUS BCFeb 02: SWS BCFeb 09: CEUS BC

• Feb 16: Hold time for US Coordinating Ctte