QIBA Contrast Enhanced Ultrasound (CEUS) Biomarker Committee (BC) Call

Friday, March 8, 2019; 11 AM CT Call Summary

Additional notes provided by Dr. Averkiou

In attendance RSNA

Mike Averkiou, PhD (Co-Chair)Eric JuangLihong Pan, PhDJoe KoudelikPaul Carson, PhDReinhard Kubale, MDThierry RognardJulie Lisiecki

Christian Greis, PhD Zaiyang Long, PhD Theresa Tuthill, PhD
Tim Hall, PhD Wayne Monsky, MD, PhD Stephanie Wilson, MD

Moderator: Dr. Averkiou

Discussion items:

- The analysis for the variability study has been completed and no more data are being collected (data will eventually be made available to anyone interested). The variability results were reviewed.
- The amplitude standardization procedure was presented and discussed. More discussion is needed on the specific parameters (including bubble concentration) for this approach. Most participants were in agreement with this approach. There were no objections or concerns.
- Vuebox and Siemens are evaluating the slightly higher amplitude variability with the new Siemens Acuson
 Sequoia system
- Results for typical TIC curves were shared with all BC members
- The phantom setup can be reviewed <u>here</u>
 - o Four systems have been used for comparison: iu22, EpiQ, GE LOGIQ E9, and Siemens Acuson Sequoia
- The goal of the variability study is standardization and to determine what needs to be adjusted among systems, software, etc., in order to provide reproducible results; the study is not a performance comparison of systems or analysis software packages.
- Technical specifications will be standardized in efforts to improve clinical performance

Proposed Next Steps / Action items:

- Dr. Averkiou plans to send an email to BC members asking for a BC consensus vote to adopt the prescribed calibration method discussed on the last few calls
- He has provided wording for BC members to review, including the proposed amplitude standardization steps
- Feedback on the proposed amplitude standardization from industry partners would be appreciated by April 5th to Dr. Averkiou: MAverk@uw.edu.
- The QIBA Sustainability Implementation Group (SIG) has drafted a letter to request support from Pharma and iCROs
- BCs were requested to identify fundable groundwork projects that would enhance Profile development in the range of ~\$50k-\$150k
- Proposals for funded groundwork projects may be sent to Drs. Hall, Garra, and Carson prior to the next CEUS BC call on April 12th: tjhall@wisc.edu; bgarra@gmail.com; Brian.Garra@fda.hhs.gov; pcarson@umich.edu

The next scheduled QIBA ultrasound calls will be as follows at 11 am CT:

- 4/12/2019 CEUS BC call
 - o (no SWS call due to AIUM, though a f2f meeting will occur at AIUM)
- 4/26/2019 US Coordinating Committee, Quarter 2 call

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