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

Friday, July 10, 2020; 11 AM CT

Call Summary

In attendance			**RSNA**
Mike Averkiou, PhD (Co-Chair)	Christian Greis, PhD	Kevin O'Donnell, MASc	Joe Koudelik
Todd Erpelding, PhD (Co-Chair)	George Kapodistrias, PhD	Michelle Robbin, MD	Susan Stanfa
Paul Carson, PhD	Reinhard Kubale, MD	Douglas Stone, PhD	
J. Brian Fowlkes, PhD	Nancy Obuchowski, PhD	Stephanie Wilson, MD	

Moderator: Dr. Averkiou

Approval of 06.12.2020 call summary

- The summary was approved as presented

Phantom Study Manuscript Updates

- Dr. Averkiou submitted the manuscript to *Investigative Radiology* for its special issue on contrast media, to be published in October
- There was skepticism re: whether the publisher would agree to publish the article on an open access platform
- Due to copyright restrictions, a link to the article on publisher's website will be provided and those who subscribe to the journal will be able to access it
- QIBA CEUS BC members were acknowledged by name in appreciation of their helpful discussions during the preparation of this manuscript
- Gratitude was also expressed to Bracco Suisse SA for the SonoVue and the use of VueBox, contributions from the Bracco team, participation from Philips, GE, and Siemens representatives, and for the use of the scanners used in this study

QIBA Profile – In progress

- Dr. Averkiou noted that he would like to encourage increased t-con attendance
- Collaborative drafting of the Profile was emphasized, as there is a need for diverse expertise
- Participation from BC members with experience and familiarity with the QIBA Profile-writing process is also crucial
- RSNA Staff created a Google form for interested BC members to sign up to co/author Profile sections
- Dr. Averkiou started compiling Profile sections using the DCE-MRI Profile v1.0 as a guide; title still to be determined
- Help is needed with clarifying the claims, as well as clinical context in particular; clinician input is vital
- An overview of the DCE-MRI claims was provided
- Determination needed re: whether to base US CEUS claims on the phantom study and/or literature
- It was noted that the DCE-MRI Profile Claim was solely based on literature since groundwork was not conducted
- Dr. Obuchowski explained the various methods to draft Claims
    - Claims can be based on groundwork studies done by PIs to obtain "gap" data
    - Claims are based on literature when funding is not available for a study
    - Dr. Carson added that nearly all claims, particularly those targeted to a specific application, should have some mention of the literature as well as groundwork data, if there is any groundwork data, or if there is any literature. That could be if only to say that the claim is much more precise or unbiased than the broadly distributed literature.
- Dr. Averkiou requested feedback on the Claims that he drafted
    - Decision needed re: whether to develop one or two claims: one based on a phantom study and the other on literature

    - It was noted that while interest for quantification in lesion characterization has been expressed, there is doubt re: whether radiologists will use quantification, however, there is clear demand for therapeutic response as a focus
    - It was noted that this draft Claim focuses on technical performance, not a cross-sectional or longitudinal Claim format
    - Variability ranges, e.g., "within-subject" or "between-subject," will need to be specified
    - Measures of variability are derived from clinical studies, whereas measures of bias and linearity come from phantom studies
- It was recommended that CEUS Profile v1.0 have a narrow focus and ensure that activities can be done uniformly across platforms and patients; future versions of the Profile may include other clinical applications, e.g., neonatal brain evaluation, kidney, prostate, breast cancer, inflammatory bowel disease, etc.
- Prior to the next US CEUS BC call, members were asked to review the Claim Guidance on the QIBA Wiki, which includes the following information:
    - Two kinds of claims adopted by QIBA: Cross-sectional Claim (the ability to measure the QIB at one time point) vs. Longitudinal Claim (the ability to measure change in the QIB over multiple time points)
    - Statistical metrics that define the technical performance of a QIB measurement, e.g., within-case standard deviation (wSD)
    - Steps for developing a claim, e.g. Step 0: Summarize Clinical Context/Use Case
    - Also provided are specific examples from various QIBA Profiles and a glossary of terms
- The Claim is the "contract" of the Profile wherein if instructions are followed, the specified performance will be achieved
- Recommendation that Claims be statistically based, succinct and focus on performance; additional details are addressed in other Profile sections
    - Suggestion to start with four Claims based on different measurement parameters; if measurements are mathematically related, one or two of the Claims could be collapsed
    - The US-CEUS BC needs to define what will be measured; a metric needs to be identified
- Recommendation to continue the Profile-writing process before considering a clinical study

Action items:

- All are asked to sign up for drafting Profile sections using the Google form
- All are asked to consider directions for the claims and to forward suggestions to the co-chairs: Drs. Averkiou, Barr, and Erpelding, to be discussed during the next call
- Dr. Averkiou to follow up with the BC for input re: whether the Claim should be based on clinical studies or phantom studies
    - Feedback also needed re: whether to use published data (conduct meta-analysis) or the phantom study
    - To encourage US CEUS BC SMEs to attend more calls to provide their expertise

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The next scheduled QIBA ultrasound calls will be as follows at 11 am CT, unless otherwise noted:

08/07	SWS BC	**09/04**	SWS BC
08/14	CEUS BC	**09/11**	CEUS BC
08/28	US Qtr. 3 Coordinating Ctte		

RSNA Staff attempt to identify and capture all committee members participating on WebEx calls. However, if multiple callers join simultaneously or call in without logging on to the WebEx, identification is not possible Call participants are welcome to contact RSNA staff at QIBA@RSNA.org if their attendance is not reflected on the call summaries.

Helpful Resources:

- Examples of **Profiles** can be found on the QIBA Wiki here: http://qibawiki.rsna.org/index.php/Profiles

- Link to the **US Shear Wave Speed Profile** – which recently completed public comment: http://qibawiki.rsna.org/images/b/b7/QIBA_US_SWS_Profile_10.21.19.pdf
- **QIBA Profile template**: http://qibawiki.rsna.org/index.php/QIBA_Profile_Template
- **How to Write a QIBA Profile**: http://qibawiki.rsna.org/index.php/How_to_Write_a_Profile
- **Claim Guidance**: http://qibawiki.rsna.org/index.php/Claim_Guidance
- All Profile Editors are encouraged to join the QIBA Process Committee to learn about QIBA writing tips and processes and network with other Profile Editors to exchange best practices

Contact information for QIBA Process Committee Leaders:

- Kevin O'Donnell, MASc (Chair): KOdonnell@MRU.MEDICAL.CANON
- Michael Boss, PhD (Co-Chair): mboss@acr.org