



AIUM/QIBA Ultrasound Volume Blood Flow Biomarker

Summary 04-December-2023

Attendees: Brian Fowlkes, Jim Zagzebski, Paul Carson, Cristel Baiu, Jim Jago, Jonathan Rubin, Megan Russ, Michelle Robbin, Oliver Kripfgans, Ravi Managuli, Stephen Pinter, Timothy Hall

AIUM Staff: Haylea Weiss

1. ROLL CALL (We need to do this so that the video and transcript will capture attendees)
2. Review of Previous Call Summary – 06-November-2023
3. Previous Action Items
 - 3.1. Future Round Robin at a Conference - Consider contacting company about their ability and interest in participating in a possible round robin in the future when systems are ready. Also need to determine what specifically will be gained. This needs to be an effort that would be expected to result in a publishable outcome. - On Hold while concentrating on profile.
 - 3.2. Determine need for any additional information (appendix) that would need to be provide related to Zonnebeld analysis. Consider whether there might be interest by the authors in an additional related publication. - On Hold while concentrating on profile.
 - 3.3. Brian to get pulsatility information about the phantom to Jim Zagzebski. – TBD
 - 3.4. Brian to coordinate with committee members on necessary meetings. Committee to watch for announcements regarding upcoming meetings. – ON GOING
4. Update on VBF Profile Discussions
 - 4.1. Review of comments received during voting.
 - 4.1.1. From Nancy O. - The paragraph starting with "Based on the groundwork studies..." seems to be describing a longitudinal scenario whereby the "comparison flow measurement" could be a follow-up measurement. If the "comparison flow measurement" is made without error, then the confidence statement is ok. If, however, the "comparison flow measurement" also has measurement error associated with it, then the confidence range of +/-20% is inadequate. Her proposed change: If there are two measurements being taken, then multiply the wCV by 2.77 (instead of 1.96).

- 4.1.2. BC decided on proposed revised wording for this section that will be shared with Nancy O. for feedback.
- 4.1.3. Brian forwarded the proposed changes to Nancy for her review.
- 4.1.4. Wording finalized from consultation with Nancy O.
- 4.1.5. “Based on the groundwork studies and literature review carried out by the QIBA USVBF Biomarker Committee, consider the following clinical scenario: Given initial and subsequent mean flow estimates, each with a confidence of +/- 20% of the mean value (coefficient of variation), the subsequent mean will be considered different from the initial mean based on 95% confidence limits if it lies outside of the repeatability range (i.e. if subsequent mean < (initial mean ± (0.20*initial mean)*2.77) < subsequent mean). Either pulsatile or constant flow can be used for the assessment of whether each type of flow measurement meets QIBA claims.”
- 4.1.6. In addition, delete the text “To put the above Claims in perspective, consider a site that is not conforming to the requirements in the QIBA Profile or making similar special image acquisition efforts.”
- 4.2. Work on comments from Public Comment period (now closed)
 - 4.2.1. Brian F. drafted preliminary responses to the comments.
 - 4.2.2. On 22-Nov Brian F. reviewed with the PTG comments received and modified his preliminary draft responses based on feedback.
 - 4.2.3. PTG worked through most of the comments and Brian F. marked the point at which they stopped.
5. Review current draft responses to comments.
 - 5.1. Reviewed draft responses and modified some of these based on the discussion.
 - 5.2. Brian F. will solicit input from PTG members for the remaining issues and once updates to the resolution of these is available, links to the comment resolution spreadsheet and the Profile with tracked changes will be distributed to the BC (and PTG) with request for input.
 - 5.3. Once the comment resolution spreadsheet and Profile are reviewed by the PTG on Wed. Dec 13, eligible BC members will be asked to vote.
6. Action items
 - 6.1. Solicit feedback to address outstanding public comments, aiming to resolve them and send to the Biomarker committee for vote. (See items 5.2 and 5.3 above)

Next full BC meeting is **TBD**.

Next Profile meeting is Wednesday, December 13 at 10 am EST

There will be no meeting Wednesday, December 27 at 10:00 am ET.