



AIUM/QIBA Ultrasound Volume Blood Flow Biomarker

Summary 06-November-2023

Attendees: Brian Fowlkes, Jim Zagzebski, Jing Gao, Mark Lockhart, Megan Russ, Nicole Lafata, Stephen Pinter, Jonathan Rubin, Timothy Hall, Rimon Tadross, Michelle Robbin

AIUM Staff: Haylea Weiss

1. Review of Previous Call Summary – 02-October-2023

2. Previous Action Items

2.1. 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.

2.2. 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.

2.3. Brian to get pulsatility information about the phantom to Jim Zagzebski. – TBD

2.4. Put comments out for sixty days and when comments are received a meeting will be set up to discuss results. – Reviewed interim comments today

2.5. Brian will get clarification about collecting data. – Not sure what this was.

2.5.1. From the 02-Oct-2023 meeting transcript: **Because clinical feasibility would imply that somebody's actually gone through their profile in a circumstance where they can collect data. That's my understanding, think you're really supposed to collect data at that time. Michelle Robbin: I wasn't aware that that we had to collect data because I had volunteered for the shearwave or for the What was it? I can't remember shearwave or**

fat quantification. But I think it was the fact. But I didn't think we had to actually get data so that I would really appreciate your clarifying that.

2.5.2. Tim Hall confirmed that the expectation is that any required imaging in the profile is actually performed to confirm the clinical feasibility of the profile.

2.6. Brian to coordinate with committee members on necessary meetings. Committee to watch for announcements regarding upcoming meetings. – ON GOING

3. Update on VBF Profile Discussions

3.1. Review of comments received during voting.

3.1.1. 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).

3.1.2. BC decided on proposed revised wording for this section that will be shared with Nancy O. for feedback.

4. Action items

- 4.1. Brian will forward the proposed changes to Nancy for her review and to discuss any additional revisions or comments.
- 4.2. The Biomarker Committee will decide on the changes based on public comments and discussions.
- 4.3. After the close of public comments on November 17th, Brian will notify the members when new comments are posted for review and discussion.
- 4.4. After comments are reviewed by the BC, send comments and proposed changes to the ultrasound coordinating committee for review and approval. If the changes are approved, the profile will move to the next stage.

Next full BC meeting is scheduled for Monday, December 4, 2023 at 12:30 pm ET. **As needed**

Next Profile meeting is Wednesday, November 8 **Canceled** and Wednesday, November 22nd at 10:00 am ET **TBD**