

QIBA MRE Biomarker Committee (BC) Call

Monday, April 9, 2018 at 3 PM CT

Call Summary

Participants

Patricia Cole, PhD, MD (Co-Chair)

Richard Ehman, MD (Co-Chair)

Edward Ashton, PhD

Paul Hockings, PhD

M. Rehan Khan, MD

Michael Middleton, MD

Frank Miller, MD

Nancy Obuchowski, PhD

Mark Palmeri, MD, PhD

Kay Pepin, PhD

Sudhakar Venkatesh, MD

RSNA

Joe Koudelik

Susan Stanfa

Moderator: Dr. Ehman

Overview

- Since the last full MRE BC t-con in January 2017, the Profile Writing Task Force worked to finalize the draft profile, which was submitted to the MR Coordinating Committee for approval to seek public review and comment. The draft profile was published in August 2017. Extensive commentary was received.
- The Profile Writing Task Force worked extensively with Dr. Pepin to organize all of the comments received during the public comment process.
- All comments have been addressed and a comments/resolution spreadsheet has been created
- Dr. Ehman highlighted the reference materials for this t-con, which included the last MRE BC call summary, a spreadsheet of the addressed public comments, a red-lined version of the Profile as well as a clean version

Profile Review

- Dr. Ehman reviewed issues that were identified during the process of addressing public comments and they are now listed in the “Open Issues” log in the Profile
- Mr. O’Donnell suggested via public comment that a separate Technical Performance Claim be added in Section 2
 - The comment reads: “The wCV value is really your fundamental technical performance Claim. Essentially, if actors follow the Profile they will achieve measurements of a wCV of 7%. Move this into an additional Claim.”
 - This specification is currently in the form of a note underneath the existing Claim that is based on technical performance estimates obtained during the literature review process
- After discussion, the MRE BC concluded that since one metric follows from the other, it may be misleading to list it as a separate claim. The committee agreed to retain the claim language as it stands since it has been extensively reviewed. Updates can be incorporated into the next Profile version
- In efforts to avoid informative text in Section 3.10 from being overlooked in figure titles, text was broken into paragraphs and referenced the figure
- This version of the Profile was sent to the MRE BC on March 23 for review and feedback
- Dr. Miller made a motion to release/publish the MRE Profile as “Consensus” (Stage 2), and Dr. Venkatesh seconded
 - Motion to recommend publication of the 1st edition of the profile to the MR Coordinating Committee passed unanimously

- The need for a conformance checklist, especially with the latest Profile template, was discussed
 - The checklist would help to determine whether sites are able to follow and use the Profile in a real-world setting
 - Dr. Pepin drafted the checklist which was distributed on April 9 for MRE BC review
 - Proposal to include check list with the current Profile
 - Dr. Ehman to follow up with QIBA leadership (Dr. Jackson) or the Process Committee (Mr. O'Donnell) on how to incorporate the checklist and next steps
 - Suggestion to poll MRE BC members for approval on the checklist in parallel to the BC vote-to-publish
 - Site capability, as opposed to intra-vendor performance is the most important aspect for MRE; the checklist template is a useful guide and QIBA groups may tailor the document as needed
 - The goal is to complete the checklist before the May QIBA Annual Meeting: input from MRE BC members within next two weeks is encouraged

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