

QIBA CT Angiography Biomarker Committee (BC) Call

14 February 2023 at 11 AM CT

Call Summary

In Attendance

Andrew Buckler, PhD (Co-Chair)

Matthew Budoff, MD

Mathis Konrad, MSc

Seth T. Lirette, PhD

Shant Malkasian, BS

Hugo Marques, MD, PhD

Alastair J. Moss, MD, PhD

James Mulshine, MD

Nancy Obuchowski, PhD

Renu Virmani, MD

RSNA Staff

Julie Lisiecki

Moderator: Andrew Buckler, PhD

Discussion topics:

- Review of comments made during Stage 3 (Clinically Feasible) BC vote
- Next steps

Stage 3 BC comments reviewed:

- Additional sites have completed the clinically feasible checklist review for a total of 4 sites
- Comments requiring additional discussion were reviewed and addressed
- University of Cagliari raised questions re: technologist requirements
- Some comments re: Field of View (FOV)
 - Challenge with the larger field of view, in terms of a loss of resolution and potentially higher dose
 - If only one FOV, the view encompasses only the heart due to resolution issues
 - Two FOVs could be used as follows:
 - Coronary quantification (heart FOV needed for quantification)
 - Second standard field of view of the chest, only to evaluate for an extra cardiac measure
- The Profile cannot specify all clinical issues, but footnotes will be added for clarification

BC Meeting Frequency

- If Clinically Feasible (Stage 3) is achieved, the BC will work toward Claim Confirmation (Stage 4)
- Stage 4 requires collection of evidence/ data, and without funding, will take longer to achieve than Stage 3
- It was proposed that the BC meetings be reduced in frequency to every 2 months unless CC comments need resolution

Action items (some ongoing): please strike if complete

- [Dr. Buckler](#) to send revised Profile and Clinically Feasible Resolution Spreadsheet to RSNA Staff
- [RSNA Staff](#) to prepare ballot for advancement of Profile to Stage 3 (Clinically Feasible) for CT CC vote pending Stage 3 resolution documents
- [Dr. Samei](#) to add phantom direction scanner placement to imQuest analysis software
- [Dr. Samei](#) to send paper citation to Dr. Buckler
- Questions or comments regarding the Profile may be directed to: [Drs. Buckler](#), [Saba](#), and [Schoepf](#).

Next call: In two months - Tuesday, April 11th at 11 am CT (or sooner, if CC comments need review)

Links for more information:

- [Profile Stages](#) | [CTA Profile \(March 2020 version\)](#) | [Public Comment Resolution Page](#)
- [CTA BC wiki](#) | [FDA Medical Device Development Tools](#)