

QIBA CT Angiography Biomarker Committee (BC) Call

10 January 2023 at 11 AM CT

Call Summary

In Attendance

Andrew Buckler, PhD (Co-Chair)

Suhny Abbara, MD

James Kevin DeMarco, MD

Mathis Konrad, MSc

Hugo Marques, MD, PhD

James Mulshine, MD

Ehsan Samei, PhD

Renu Virmani, MD

Michelle Williams, MBChB, PhD

RSNA Staff

Julie Lisiecki

Moderator: Andrew Buckler, PhD

Discussion topics:

- Review of Profile edits made
- Planning for a vote for Profile Stage 3 (Clinically Feasible)

Profile edits reviewed:

- Profile edits and feedback reviewed from Dr. Obuchowski and Mr. Konrad
- Made journal citations consistent
- Discussion with respect to the plaque stability
 - The claim is a discrimination claim stated in terms of area under the receiver operating curves
 - Mapping between the pathologist type and one of 3 less granular types: minimal disease, stable plaque, and unstable plaque
 - Add fibroatheroma in the stable presentations to the table
 - The recommendation was to pull out the intercept to simplify it
 - The standard deviation has been made explicit to the inter-reader
- Table 3 ratio discussed
- Updates to assessment procedure to identify the bias and linearity for tissue characterization
- Phraseology has been amended to allow flexibility regarding the 90 sections
- General benchmark statement recommended that allows flexibility for regular changes
- Addition - The 2 centers must have at least one statistically significant difference in terms of the variables that pertain to generalizability, such as demographics and or comorbidities.

Planning for a vote for Profile Stage 3 (Clinically Feasible)

- Dr. Buckler moved, seconded by Dr. DeMarco, to conduct an e-ballot re: advancing the Profile to Stage 3 (Clinically Feasible)
- An e-ballot will be distributed with the clean and red-lined Profile documents to the BC and then to the QIBA CT Coordinating Committee

Action items (some ongoing): please strike if complete

- [Dr. Abbara](#) to send details to help connect Dr. Buckler with the SCCT guidelines committee chair to collaborate
- [RSNA Staff](#) to prepare ballot for advancement of Profile to Stage 3 (Clinically Feasible) for next call
- [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: Tuesday, January 24th at 11 am CT

Links for more information:

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