# QIBA CT Angiography Biomarker Committee (BC) Call

24 January 2023 at 11 AM CT Call Summary

In Attendance RSNA Staff

Andrew Buckler, PhD (Co-Chair) Seth T. Lirette, PhD Nancy Obuchowski, PhD Julie Lisiecki

James Kevin DeMarco, MD Hugo Marques, MD, PhD Todd Villines, MD

Mathis Konrad, MSc

Moderator: Andrew Buckler, PhD

### **Discussion topics:**

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

#### Profile edits reviewed:

- Profile edits and feedback from Mr. Konrad reviewed
  - o Two tables with differing information were found in section 4 (type definitions); this was revised
- It was found that only two sites participated in the feasibility testing: not the required three
  - Since the Stage 3 requirements have not been met, BC leadership will advise the CT Coordinating
     Committee of this, ask if two sites would be acceptable, or if judgement is this is a hard requirement to add a third
- Actor conformance and statistical issues were reviewed by Dr. Obuchowski and addressed in document revisions
- This Profile is focused on histology-defined definitions and some terminology that is commonly used in the
  field is not in the Profile, e.g., non-calcified plaque and low attenuation plaque. After team discussion,
  clarification was added in a footnote regarding the inclusion of tissues in plaque burden and percent
  atheroma volume measurands.

## Action items (some ongoing): please strike if complete

- RSNA Staff to prepare ballot for advancement of Profile to Stage 3 (Clinically Feasible) for CT CC vote pending Stage 3 requirements clarification from QIBA Leadership (1/26 update: once a 3<sup>rd</sup> site has provided additional response and comment resolution is received)
- 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: <u>Drs. Buckler</u>, <u>Saba</u>, and <u>Schoepf</u>.

Next call: Tuesday, February 14th 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