QIBA CT Angiography Biomarker Committee (BC) Call

28 March 2023 at 11 AM CT Call Summary

In Attendance RSNA Staff

Andrew Buckler, PhD (Co-Chair) Uwe Joseph Schoepf, MD (Co-Chair) Suhny Abbara, MD James Briggs, BSc, MB, ChB, FRCR

Matthew Budoff, MD James Kevin DeMarco, MD Márton Kolossváry, PhD Mathis Konrad, MSc Hugo Marques, MD, PhD Nancy Obuchowski, PhD Edwin J.R. van Beek, MD, PhD... Michelle Williams, MBChB, PhD... Susan Staff

Moderator: Andrew Buckler, PhD

Discussion topics:

- Profile changes in response to high and medium priority comments from Mr. O'Donnell
- Proposed manuscript based on Profile
- Next steps

Profile Changes

 Dr. Buckler edited and shared clarifications with the BC for ratification (see <u>March 14, 2023 call summary</u> for details)

Draft Review of the manuscript, "The QIBA Profile for Atherosclerosis Biomarkers by Computed Tomography Angiography (CTA) for pharmaceutical development and clinical care"

- Dr. Buckler modeled this proposed manuscript draft on a QIBA FDG-PET/CT Profile article written by Dr. Kinahan and published in *Radiology*
- One goal is to outline the QIBA process so that readers can understand the Profile format and how it pertains to the subject matter
- Atherosclerosis imaging as a biomarker has not been well-described in previous literature; the "Advances in Knowledge" section seeks to elevate its status as a biomarker
- Endorsement of the Profile and checklist from other related societies, e.g., ISCT, would also be helpful to get the Profile and checklist into use

Next steps

- Work toward Claim Confirmation (Stage 4)
- Stage 4 requires collection of evidence/data, and without funding, will take longer to achieve than Stage 3

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 wiki post Stage 3 resolution documents and updated Profile once received
- Dr. Buckler to send the latest manuscript draft to staff, who will distribute to the BC for feedback
- As a past ISCT president, Dr. Budoff will reach out to Dr. Kuhn regarding endorsement of the Profile, CCing Drs. Abbara, Schoepf, and Williams
- 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: BC meetings may be reduced in frequency to every 2 months once CC comments are resolved

Tuesday, May 30th 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