

QIBA CT Angiography Biomarker Committee (BC) Call

27 June 2023 at 11 AM CT

Call Summary

In Attendance

Andrew Buckler, PhD (Co-Chair)
Matthew Budoff, MD
Jeffrey Carr, MD

James Kevin DeMarco, MD
Mathis Konrad, MSc

Michelle Williams, MBChB, PhD...
Renu Virmani, MD

RSNA Staff

Susan Stanfa

Moderator: Andrew Buckler, PhD

Discussion topics:

- Manuscript based on Profile
- Claim Confirmation (stage 4) Profile work
- Next steps

“The QIBA Profile for Atherosclerosis Biomarkers by Computed Tomography Angiography (CTA) for pharmaceutical development and clinical care” manuscript

- Modeled on QIBA FDG-PET/CT Profile article written by Dr. Kinahan and published in *Radiology*
- Has been submitted for publication and is currently under consideration

Claim Confirmation (stage 4)

- [Claim Confirmation Process page](#) of the QIBA Wiki was referenced
- Key purpose is to:
 - Evaluate the validity of the statistical assumptions underlying the Profile Claims
 - Confirm that site performance is consistent with Profile Claim performance
- The Process Committee recommends that a multi-site study is conducted with site data pooled and mean performance reported
- The CTA Profile may be updated as the field advances e.g., technologically, photon counting CT has been and continues to gain attention in terms of some of its benefits
- Discussion on whether having a common set of “known” cases might be useful to the community
- Given the objective being to generate increasing evidence regarding what is being measured, suggestions to consider the collection and documentation of that evidence is the priority going forward

Next steps

- Go on active hiatus from regularly scheduled calls and communicate offline while collecting evidence / data and working toward Claim Confirmation (Stage 4)

Next call: as needed – TBD

Links for more information:

- [Profile Stages](#) | [CTA Profiles and Resolutions](#)
- [CTA BC wiki](#) | [FDA Medical Device Development Tools](#)