QIBA CT Angiography Biomarker Committee (BC) Call

6 December 2022 at 11 AM CT Call Summary

In Attendance RSNA Staff

Andrew Buckler, PhD (Co-Chair)Mathis Konrad, MScEhsan Samei, PhDJoe KoudelikSuhny Abbara, MDHugo Marques, MD, PhDTodd Villines, MD-INMDJulie Lisiecki

Julius L. Decano, MD Nancy Obuchowski, PhD Michelle Williams, MBChB, PhD...

Márton Kolossváry, PhD

Moderator: Andrew Buckler, PhD

Discussion topics:

- Review of Profile edits made
- Review of feasibility testing feedback from three sites
- Planning for a vote for Profile Stage 3 (Clinically Feasible)

Profile edits reviewed:

- The Profile has been transferred to the new streamlined Profile template, with an actor-based format
- Dr. Samei is working on a web interface for the algorithm
- Supported measurands have been extended
- Addition of the histology-defined, high-risk, plaque phenotype classification
- Field test results have been collected for carotid and coronary scanning / performance requirements
- Dr. Samei to draft instructional text regarding imQuest usage for Section 4.1 and 4.2
 - Closing paragraph also needed regarding what users can do if they fail these sections
- A few remaining issues were discussed
 - o kVp statement to be adjusted for patient size (signal to noise ratio)
 - Dr. Samei to provide some text
 - Interaction text to be provided by Dr. Marques
 - o In-plane resolution
 - Breath hold
 - Spatial resolution for pixel

Decisions / Action items (some ongoing):

- RSNA Staff to distribute streamlined Profile to group members on last 3 calls
- 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
- Dr. Buckler to update and distribute checklist in Excel spreadsheet format
- Dr. Buckler to share details re: Metrology articles
- Questions or comments regarding the Profile may be directed to: <u>Drs. Buckler</u>, <u>Saba</u>, and <u>Schoepf</u>.

Links for more information:

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

Next call: Tuesday, January 10th at 11 am CT