# QIBA CT Angiography Biomarker Committee (BC) Call

14 March 2023 at 11 AM CT Call Summary

In Attendance RSNA Staff

Julie Lisiecki

Andrew Buckler, PhD (Co-Chair)James Mulshine, MDEdwin J.R. van Beek, MD, PhD...Jeffrey Carr, MDJim O'Doherty, PhD, MScJagdish Vij, MBA, BSEEMaros Ferencik, MD, PhDKevin O'Donnell, MAScRenu Virmani, MD

Mathis Konrad, MSc Ehsan Samei, PhD Michelle Williams, MBChB, PhD...

Hugo Marques, MD, PhD

Moderator: Andrew Buckler, PhD

# **Discussion topics**:

- QIBA CT Coordinating Committee (CC) ballot results
- Review of comments made during Stage 3 (Clinically Feasible) CC vote
- Proposed manuscript
- Next steps

#### Results of QIBA CT Coordinating Committee (CC) ballot for Clinically Feasible (Stage 3)

- The QIBA CT CC vote-to-publish as Clinically Feasible (Stage 3) was successful
- As of March 6<sup>th</sup>, the CT CC ballot had a majority (10 votes) in favor to release the Profile (N=16), with 1
  abstention.

#### Reviewed high and medium priority comments from Mr. O'Donnell:

- 3.1 protocol design specification missing table
- 3.1 *image header* missing
  - o Agreed to delete these two rows as they have been addressed elsewhere in the document
- 3.1 *kilovoltage peak (kVp) optimization* want to draw attention to the fact that kVp should be optimized; however, this may differ depending on the item being discussed; agreed to delete this row
- 3.2 voxel size .625 is GE specific for in-plane voxel size; recast in terms of field of view (FOV) and matrix
- 3.3 reconstruction FOV for quantitation: agreed to remove this reference in 3.3 due to changes made in previous row
- 3.3 *claim* is perceived to be cross-sectional instead of longitudinal. Dr. Buckler thinks the claim is both and will update the wording to reflect this.
- 3.5 vessel structure mentions table for reader variability but actual tables are missing in some sections
  - Need "pass marks" to follow these requirements
  - o Recommendation to update tables with table numbers and check sections
  - Update and add note to refer to claim table
- 3.5 kVp not clear what pass/fail criteria is for kVp
  - Material response curves?
  - o Affect biomarker performance?
  - o Problem in practice?
  - o Sensitive kVp -dependence exists for lipids, etc. There is a need to calibrate for this measurement.
  - Clarification wording to be added for this and "basis of area."
- 3.5 basis of volume
  - Some tools perform analysis in 2D
  - Volumes are determined by summing method, which may be too coarse for tissue regions
  - Analysis can be done in 3D with a slice into 2D to address partial volume effects
- Dr. Buckler to edit and share clarifications with the BC for ratification; will review 'low' priority items offline
- Dr. Mulshine noted that contexts can be variable in clinical practice and that there may be tension between what it 'good' and 'perfect,' and may be considered as a guideline

### Proposed manuscript based on the Profile

- Dr. Buckler to model a CTA Profile paper on a QIBA FDG-PET/CT Profile article written by Dr. Kinahan for Radiology
- If the manuscript is accepted for publication in *Radiology*, it is hoped that reviewers from cardiology-related magazines will review it or write opinion pieces
- Endorsement of the Profile and checklist from other related societies would also be helpful to get the Profile and checklist into use

#### **Next steps**

- Following Stage 3 comment ratification, the BC will work toward Claim Confirmation (Stage 4)
- Stage 4 requires collection of evidence/ data, and without funding, will take longer to achieve than Stage 3

## **BC Meeting Frequency**

• It was proposed that the BC meetings be reduced in frequency to every 2 months once CC comments are resolved

## 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. 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 calls:**

- Tuesday, March 28<sup>th</sup> at 11 am CT
- Tuesday, April 11<sup>th</sup> 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