

QIBA CT Volumetry Biomarker Committee (BC)

29 June 2022 at 2 PM (CT)

Call Summary

In attendance

Ritu Gill, MD, MPH (Co-Chair)

Rudresh Jarecha, MBBS, DNB, DMRE (Co-Chair)

Ehsan Samei, PhD (Co-Chair)

Hubert Beaumont, PhD

Heang-Ping Chan, PhD

Claudia Kirsch, MD

Mathis Konrad, MSc

James Mulshine, MD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Nicholas Petrick, PhD

Ying Tang, PhD

RSNA

Julie Lisiecki

Moderator: Dr. Jarecha

Discussion Topics:

- Ballot ratification completed
- Updated, streamlined Profile for Stage 3
- Planning for Stage 4
- Proposed harmonized data use agreement

Decisions/Action items:

- Profile change log was added, and adjustments were made for normative requirements
- Rationale for not adding bias and linearity requirement was added
- Comment re: RIDER data will require additional discussion
 - Coordinates may need to be changed to a more amenable tumor
 - Data are available on the QIDW – <https://qidw.rsna.org/> under CT modality datasets
- Dr. Obuchowski to adjust section 4.4 to account for precision and bias
- Once the claim is proven in Stage 4, a noninferiority test for the radiologist may be added
- Streamlined Profile to be published to the wiki now and additional updates can be added as the team works toward Stage 4
- Many unanswered questions remain for Stage 4 planning, e.g., site motivation, data collection, etc.
- The study design document for Stage 4 will be similar to clinical trial instructions
- **Motion Approved** to post the updated Profile on the QIBA Wiki
 - Mr. O'Donnell to post the streamlined Profile version on the BC wiki page by mid-July

Comments re: RIDER data for future discussion (Mr. O'Donnell)

- 4.4 RIDER data included some Stage 4 cases and no contrast; and some were too contiguous with the hilum or vessels. Less-than ideal statistical power since N=20.
- Criteria require clearly demarcated and unattached lesions.
 - Avoid Mediastinal examples, long attached boundaries.
- Can we identify other nodules in the 11 cases that would be better?
- TODO – Dr. Gill can lead review to find better examples.
- Mr. O'Donnell will double check with Dr. Obuchowski and Mr. Buckler to determine the ideal number

Shared Google document / stage 4 planning:

https://docs.google.com/document/d/1Wcmkzp8N_2ILL-FCyKNPwgsn1BJOs7Z9A1ZyTlkuGCo/edit

- Group editing is welcome. All are invited to share ideas.

Two possibilities for Stage 4 (Dr. Beaumont)

- Working with a hospital setting
 - Would require IRB and could be quite burdensome to document requests
- Imaging center in Monaco
 - No IRB needed
 - Sample size would be needed (# of scans to process)
 - Clear guidelines needed to determine a go/no-go decision, which would be dependent on the number of scans
 - Clarify if own phantom could be used or if a QIBA phantom would be required
 - One page written summary would be helpful for the site to outline the proposed study and requirements
- More scans may be needed for scanner calibration, in addition to the scans that test site performance
- The number of patients would be a large number
- If only testing whether the claim is correct, it may be possible to reduce the sample size significantly
- Dr. Obuchowski's revised sample size plan to be shared with Dr. Beaumont
- Harmonized data-use agreement suggested by Dr. Mulshine as it saves time and is significantly more efficient

New action items:

- Mr. O'Donnell to post the streamlined Profile version on the BC wiki page by mid-July
- Dr. Obuchowski to share previous study design with Mr. O'Donnell to add to shared Google doc
- Dr. Obuchowski to determine if a revised coefficient of variation is needed and share revised sample size plan
- Dr. Mulshine to provide info re: harmonized data-sharing agreement documents discussed on the call

Ongoing action items:

- Suggestion to build use cases for the payers (future Profile version)
- Consider guidance or training data going forward for radiologists to become better "quantitators"
- Other questions to consider:
 - Should the Profile retain repeatability requirements for the radiologist?
 - Should a test of bias and linearity be added?
- Hurdle remains obtaining the test-retest data due to subject exposure to ionizing radiation

Next Call: to be determined via doodle poll (approximately one month from now) – late July / early August