QIBA CT Volumetry Biomarker Committee (BC)
21 March 2023 at 11 AM (CT)

Call Summary

In attendance
- Ritu Gill, MD, MPH (Co-Chair)
- Rudresh Jarecha, MBBS, DNB, DMRE (Co-Chair)
- Maria Athelogou, PhD
- Hubert Beaumont, PhD
- Heang-Ping Chan, PhD
- Sean Fain, PhD
- Nicholas Petrick, PhD
- Mathis Konrad, MSc
- James Mulshine, MD
- Jayant Narang, MD
- Nancy Obuchowski, PhD
- Ying Tang, PhD
- Pierre Tervé, MS
- Julie Lisiecki

RSNA
- Joe Koudelik
- Heang-Ping Chan, PhD

Moderator: Dr. Jarecha

Discussion Topics:
- Plans for Stage 4 Study (reference 11/1/2022 notes)

Updates on Progress toward Proposed Plan A – (Lung Stage 4)
- Dr. Beaumont has two sites in Europe that are willing to test the QIBA CT Volumetry Profile
  - Cancer center in France
    - Clean protocol of the study is needed
  - Site in Monaco – where no supervisory committee exists
    - Protocol with clear and simple instructions is needed
- Unresolved questions include:
  - Patient population – inclusion and exclusion criteria
  - Measurement parameters
  - Step-by-step instructions for how to make and share measurements, and use the phantom(s)
  - Place to store patient scans and data for expert review and evaluations
- Dr. Obuchowski needs a statement of objective / aim for the study to calculate necessary measurements
  - CT Vol BC wants to confirm clinically relevant use of the Profile via utilization by a clinical site
    - Hurdle is the need for patient scans
- Human clinical study protocol and proper site protocol would be needed
  - May be able to do some scanner compliance with phantom QC
- Test-retest data are needed for a large clinical study or clinical trial
  - This will be very complicated
  - Trying to consider if other Profile elements/metrics could compensate for use of patient double CT scans
- Online conformance checklist and conformance model used by QIBA FDG-PET/CT BC recommended by Dr. Zahlmann

Challenges in Developing a Conformance Program
- Scientific reviewer or review team would be needed
- This is beyond the scope of the checklist – not certain how this would be achieved
- No platform exists to acquire, store, and analyze data on a regular basis
- Human interaction needed (similar to the EARL/RadSite pilots with Dr. Jeffrey Yap and the FDG-PET/CT BC)
  - This would necessitate detailed review of submissions by sites
  - Tailored recommendations for improvement to sites in order to achieve Profile conformance
    - Email feedback and follow up dialogue with sites from scientific reviewer(s)

Link to detailed discussion notes: 11/01/2022
Proposed plans (for reference)

1) Plan A – Lung Stage 4
   a. Try to advance the Stage 3 Lung Profile to Stage 4
   b. Clinical setting needed
   c. Challenge is CT scan and re-scan of patients to measure performance
   d. May be able to apply one of Dr. Samei’s simulated datasets (see how many cases can be used for lung or liver)
   e. A public cloud-based platform is needed

2) Plan B – Liver Stage 2
   a. Expand the Profile to include lymph and liver
   b. May need to go back to Stage 2 (Consensus) to get additional details and create new Profile language
   c. Funding may be needed for this project

3) Plan C – Lung Volume – Proof of Value
   a. Demonstrate the value of existing Profile by showing use of groundwork studies
   b. Design a study to demonstrate how measurements are improved by using the QIBA Profile

New action items:
- Julie to invite small group for next meeting as discussed (3-4 weeks)

Ongoing action items: (please strike if complete)
- Drs. Jarecha and Gill to email Dr. Samei to discuss some of the questions raised on 11/1 re: his data
- Dr. Samei to follow up via email re: access to shared dataset for proposed challenges
- All to reach out to research community re: similar coffee break studies but for liver or lymph nodes
- BC leaders to contact Dr. Buckler, as his company hosted the 3A Challenge data and completed the analysis
- Permission would be requested from participants to use segmentation and volume details of the lesions for publication
- Training and clear instructions needed to provide reproducible results
- Update re: Dr. Jarecha to look for candidates to provide cross measurements to aid with determining ground truth: Dr. Narang agreed to support the cross measurements once Dr. Gill has identified the cases and lesion locations.
- Dr. Jarecha to begin drafting some study guidelines for the Stage 4 study
- Dr. Obuchowski to consider an appropriate assessment of the number of radiologists needed for approximately 31 lesions and 14 modules
- Dr. Obuchowski to email the Process Committee working document on study guidelines to Dr. Jarecha (note – this is still in process)
- Dr. Obuchowski to determine if a revised coefficient of variation is needed and share revised sample size plan
- Mr. O’Donnell will double check with Dr. Obuchowski and Mr. Buckler to determine the ideal number of cases needed from RIDER data
- Dr. Obuchowski to adjust section 4.4 to account for precision and bias
- Dr. Obuchowski’s revised sample size plan to be shared with Dr. Beaumont (for possible Stage 4 study)
- 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:** TBD via doodle poll (need Dr. Samei for next meeting – Small group identified, including
- Mr. O'Donnell, Dr. Beaumont, Dr. Samei, Dr. Gill, Dr. Jarecha, Dr. Obuchowski – in 3 weeks or so)

**Shared Google document / stage 4 planning:**
https://docs.google.com/document/d/1Wcmkzp8N_2ILL-FCykNPwgsn1BIOs7Z9A1ZyTikuGCo/edit
- Group editing is welcome. All are invited to share ideas.

**Reference:** Data are available on the QIDW – https://qidw.rsna.org/ under CT modality datasets