QIBA CT Volumetry Biomarker Committee (BC)

21 March 2023 at 11 AM (CT)

Call Summary

In attendance			**RSNA**
Ritu Gill, MD, MPH (Co-Chair)	Sean Fain, PhD	Nicholas Petrick, PhD	Joe Koudelik
Rudresh Jarecha, MBBS, DNB, DMRE (Co-Chair)	Mathis Konrad, MSc	Ying Tang, PhD	Julie Lisiecki
Maria Athelogou, PhD	James Mulshine, MD	Pierre Tervé, MS	
Hubert Beaumont, PhD	Jayant Narang, MD	Gudrun Zahlmann, PhD	
Heang-Ping Chan, PhD	Nancy Obuchowski, 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_2lLL-FCykNPwgsn1BJOs7Z9A1ZyTIkuGCo/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