QIBA CT Volumetry Biomarker Ctte (BC) Call

23 January 2020 at 11 AM CT, Thursday

Call Summary

In attendance			**RSNA**
Rudresh Jarecha, MBBS, DMRE, DNB (Co-Chair)	Heang-Ping Chan, PhD	Kevin O'Donnell, MASc	Joe Koudelik
Jenifer Siegelman, MD, MPH (Co-Chair)	Lubomir Hadjiiski, PhD	Ying Tang, PhD	Julie Lisiecki
Hubert Beaumont, PhD	Nancy Obuchowski, PhD	Pierre Tervé, MS	

Moderator: Dr. Jarecha

Discussion:

- Mr. O'Donnell mentioned the SIG conformance pilots and asked for volunteers to evaluate results and determine how the BC will proceed; he will follow up with Dr. Zahlmann for more details
    - The goal of the conformance pilots is to move the Profiles from Technically Confirmed to Claim Confirmed
    - Dr. Sullivan provided some contacts but is still searching for an appropriate clinical trial
    - Any ideas are welcome
- Dr. Siegelman asked if there might be a way for CROs to work with QIBA, as the CRO influence could help to advance QIBA Profiles
    - CROs often author clinical trial protocols for their pharma sponsors
    - The aim for QIBA is to get imaging endpoints into every trial; however, the primary endpoint for most trials is survival
    - Dr. Siegelman suggested enlisting the aid of BioClinica, ICON Medical Imaging, and other CRO partners
    - Sites, including CROs or pharma sponsors, may be willing to implement the QIBA Profiles, but not willing to share data
        - Perhaps this would be a way forward – if QIBA can agree to trust the data and partners agree to use QIBA Profiles and the QIBA Process
        - While it is desirable to have some open-source data, it may not be possible due to pushback from PIs, pharma, etc. (reluctance to share data is considered more principal than financial)
        - CROs could analyze and attest that their data collected aligned with QIBA Profiles
        - It would be very helpful to get repeatability numbers from CROs, which may prove to be one approach to achieving Claim-Confirmed (Stage 4) status with the Profile
- Questions remain regarding how to recruit partner physicists at sites to aid with implementing the QIBA Profiles
    - It was suggested that BC members use their personal contacts to try to influence site physicists to image phantoms and test the QIBA Profiles
    - Incentives may be difficult to demonstrate as this would involve more time and money on the part of those testing the Profiles
    - However, in the long run, consistent data would drive down costs and save time
    - Demonstrating the value of QIBA with those beyond QIBA will be important to this effort
    - Justifying test-retest studies on patients will prove difficult
        - Again, this may be where personal relationships will be helpful
- It was suggested that the BC contact Dr. Rick Patt from RadMD, as he may be a helpful resource
    - Dr. Patt has performed blinded reads and adjudications in a variety of trial types
    - He has held positions as both an academic and private practice radiologist
    - His experience includes research and development of contrast agents and design and training of reviewers for over 300 oncology trials
- Dr. Beaumont shared his experience with working with a hospital recently on a data-blinded study
    - He said that working with the hospital partners was easier and proved to be very valuable
- Vendors do not typically use claims for repeatability of measurements, though QIBA wants to try to validate the quality of industry practices in general

    - It is difficult to justify yet another requirement unfortunately
- Phantom studies and DROs have test-retest studies available
    - Perhaps numbers could be doubled to make them realistic for clinical use
    - While this may be a cruder measurement, it is better to have one than none at all; this may suffice for conformance testing (the available measure always beats the unavailable measure)
    - It was also recommended that the BC publish data from phantom studies since phantom data may translate to clinical data, this might allow conformance testing based on phantoms or test datasets
- There was some discussion regarding whether a DRO might be acceptable for FDA biomarker qualification
    - The FNIH and QIBA have been collaborating in trying to change the qualification framework, though this is a complicated process
- There was also a suggestion to consider comparisons between early and late contrast for bladder cancer subjects in a study similar to a retrospective coffee break

Change Proposals

- Mr. O'Donnell would like to finish the work needed on the change proposals related to testing completed by Canon physicists; he needs data regarding resolution tolerances from Dr. Samei regarding what F^{50} values would be supportable

Action items:

- Schedule next call when Dr. Samei is available – he is needed to discuss a change proposal
- Invite Dr. Schwartz to the CT CC call or the next CT Volumetry call to discuss his study

Next Call: TBD via doodle poll in two weeks or a month's time, per Dr. Samei's availability

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The next **CT Coordinating Committee Call** is scheduled for **Wednesday, February 19th** at **1 pm CT**.

- **BC Co-Chairs**: If you have not already done so, please indicate your availability to moderate/provide updates on this call by visiting: https://tinyurl.com/QIBA-CC-Calls.
- Dashboard