QIBA CT Angiography Biomarker Committee (BC) Call

22 October 2018 at 11 AM CT

Call Summary

On Call			**RSNA Staff**
Andrew Buckler, MS (Co-Chair)	Maros Ferencik, MD, PhD	Márton Kolossváry, PhD	Joe Koudelik
Luca Saba, MD (Co-Chair)	Alex Guimaraes, MD, PhD	Nancy Obuchowski, PhD	Julie Lisiecki
James Kevin DeMarco, MD	Philipp Hoelzer, PhD	Taylor Richards, PhD	
Svetlana Egorova, MD, PhD	Laura Jimenez-Juan, MD		

RSNA 2018 Poster:

- Mr. Buckler reviewed the draft of the CT Angiography BC poster for the QIBA Kiosk at RSNA 2018
- The poster has 3 sections:
    - Quantitative Plaque Morphology – introduction
    - Biomarker Committee activity related to the Profile
    - Examples of Groundwork, including assessment procedures for scanner hardware from Dr. Richards
        - Some details regarding the use of contrast from the subject handling section will be included
        - This is relevant due to the influence of contrast on the estimability framework measurement
- Authors added include BC members who have been actively engaged
- Mr. Buckler to distribute the draft poster for review by BC members prior to sending the final draft to RSNA
- Reminder that volunteers will be needed to mann the poster during the Meet-the-Expert sessions at the QIBA Kiosk (Learning Center – Hall D) for RSNA 2018

Update from Dr. Taylor Richards:

- Group members are trying to determine what studies need to be done to inform the Profile
- Dr. Saba has an interest in a clinical utilities study which would build on an analytical performance baseline
- More studies are being conducted regarding the assessment procedures for image acquisition hardware to identify the hyper parameter space

Parameters:

- Parameters that will be included in the Profile were discussed, including those for acquisition, reconstruction, and patient preparation
- The goal is to identify the range of acquisition parameters that enables conformant image analysis tools to fulfill the Profile's precision and bias claims for a given measurand
- Five parameter axes were agreed upon:
    - Vessel radius {1-3 mm}
    - Vessel displacement {.375 – 4 mm}
    - Image noise (σ) {30 – 70 Hounsfield Units (HU)}
    - Pixel size {.4 – 1.2 mm}
    - Spatial resolution modulation transfer function (MTF_{f50}) {.3 - .6 mm^{-1}}
- The quantitative bases for the setting will be specified in the Profile
- Dr. Richards is objectively trying to include that which can be supported by rigorous simulation backing, such as the following:
    - An established simulation framework
    - Testing with experimental studies
    - Identification of set points
        - It is important to consider what happens when the numbers change
- Dr. Ferencik noted that this approach was conceptually excellent and asked about when different models would be used

- Current work is being done at the hardware level; phantom used to better identify vessel structures
- The next level, (tissue), will include analysis software and will incorporate ex vivo clinical modeling

Quality Assessment (QA):

- Phantoms may also be needed for site quality assessment checks (QA)
    - In this case, phantoms would need to be complex enough to capture what is needed, but not so complex as to require an entirely new/specialized phantom design that may not be accessible to most end users
    - The phantoms would need to include a range of parameters that are clinically relevant and provide ground truth
    - They would be used to quantify bias and precision on machines to see if they match
- It was decided that phantom testing at sites would not be required to demonstrate a conformant operation because model-level testing of hardware and software would suffice, not necessarily on an ongoing basis
    - If a site QA is required, instructions will be incorporated into the study design
        - It will be stipulated that QA will be required only if there is a major change in software or a new machine is installed
        - A white paper will be drafted to discuss these implications
- It is possible that the group may be able to develop a 3-D printed phantom for this purpose
    - It was decided that phantom testing be limited to the vendor scanner model level (i.e., model line), not a serial number level; any performance drifting per scanner will be detected and normalized by department staff during QA procedures
    - The conformance statement would identify the scanner performance settings needed to achieve conformance
- In addition, for specific studies, phantoms would be selected based on their suitability to the study
    - This would not be a Profile dependent specific site activity
- Drs. Saba, Richards, Hoelzer and Mr. Buckler to discuss these concepts further offline, including the determination of energy (kVp) and how accurately it is determined, as it may be necessary to quantify kVp tolerance

Action items:

- All are asked to contact the co-chairs if they are interested in any particular parameters to ensure that leadership is not missing something: andrew.buckler@elucidbio.com; lucasabamd@gmail.com; schoepf@musc.edu
- Drs. Richards, Hoelzer, Kolossváry, and Obuchowski to correspond offline regarding experimental activity designs
    - Dr. Saba is planning for a clinical utility study to be underway in 6 months and would like to utilize the Profile, which is why the hardware parameter specifications and assessment and conformance procedures must be determined within the next 2 months
    - Experiments could be planned for November with analysis planned for December
- Email communications for planning will be needed; all are asked to cc Mr. Buckler and Dr. Obuchowski
- Dr. Richards to review which CT lung densitometry procedures may be applicable to the CT Angiography Profile on the next BC call

QIBA Wiki: Latest version of the Atherosclerosis Biomarkers Profile, as well as other useful documents can be found on the CT Angiography BC page at: http://qibawiki.rsna.org/index.php/CT_Angiography_Biomarker_Ctte

Next call: Monday, November 5th at 11 am CT

RSNA 2018: All are encouraged to RSVP for the QIBA Working Meeting on Wednesday, November 28th and to volunteer for Meet-the-Expert session times