QIBA Musculoskeletal (MSK) Biomarker Committee (BC) Meeting

Tuesday, May 24, 2022, at 10 a.m. CT Meeting Summary

Susan Stanfa

In attendance RSNA

Xiaojuan Li, PhD (Co-chair) David Rutkowski, PhD Maggie Fung, MEng Thomas Link, MD, PhD (Co-Chair) Brian Soher, PhD Ali Guermazi, MD, PhD Donald Anderson, PhD Gabby Joseph, PhD Daniel Thedens, PhD Bruce Beynnon, PhD Jason Kim, PhD Nicole Wake, PhD Angie Botto-van Bemden, PhD Kecheng Liu, PhD, MBA Carl Winalski, MD Nancy Obuchowski, PhD Cory Wyatt, PhD Robert Boutin, MD

Jean Brittain, PhD Kevin O'Donnell, MASc Jiming Zhang, PhD, DABMP(MR), MRSE

Majid Chalian, MD Chris Peng, PhD Yansong Zhao, PhD

Cathy Elsinger, PhD

Topics Discussed

- Updated RSNA QIBA MSK Profile Stage 3 and 4 Conformance Testing Scope of Work (SOW) Document (Dr. Li)
 - o Standard Operating Procedure (SOP) for stage 3 and 4: T1p and T2 Phantom MR scan
 - Proposed timeline for phantom and human scans
 - Simplified version of phantom and human subject SOP
 - o SOP will also be updated, and the new phantom (built by Calimetrix) will be implemented
 - Q&A from participating testing sites
- Review of site data collection protocol for phantom and human subjects
- Recommendation to include anonymized patient/volunteer data sharing with central site (Cleveland Clinics)
- Overview of <u>Technical Confirmation Resolutions Google Sheet</u> developed by the Process Cmte where stage 3 site feedback will be organized
- Second batch of phantoms manufactured by Calimetrix

Next Steps / Action Items

- A list of participating sites and phantoms can be found on the SOW document distributed by staff
- An overview of the adjusted timeline was provided:
 - o March May 2022: discussion on the scope of work and protocol finalization
 - June 2022: development of the second batch of NIST phantoms
 - o July 2022 January 2023: site data collection
 - February March 2023: data analysis
 - o April May 2023: publishing of results
- IRB language re: optional storage of deidentified images and data in a central database/repository to be distributed for testing site use
- Dr. Li to incorporate visuals for orientation and positioning of additional phantom types into the SOW
 - Plans to have a more detailed phantom scanning protocol as either a PDF or text file
- Acquisition QC form to be distributed to sites for collection of site documentation, e.g., phantom temperature, timing between phantom scans, etc. to pinpoint causes of variation between sites
- Overview of the Stage 3: Technical Confirmation Resolutions Google Sheet developed by the Process Cmte
 - o Information for MSK BC analysis will include:
 - Whether the site was able to conform to each requirement
 - The site's opinion on each Profile requirement and whether it is:
 - Already in routine practice
 - Feasible and not routine, but the site will change its standard practice to meet the requirements

- Feasible from a technical point of view, but practices will not be changed to do it (and why)
- Not at all feasible (and why)
- The MSK BC is doing stage 3 & 4 simultaneously; there is not yet a template for stage 4, but Dr. Obuchowski
 will consult
- Suggestion to begin stage 3 by soliciting feedback from the one site that has the phantom and is ready to proceed with data collection
- Status re: second batch of phantoms
 - Verellium, LLC has invoiced all the sites that will use this batch and payment is needed from sites for the down payment to Calimetrix to purchase the materials and make the phantoms
 - Calimetrix has been developing test batches including producing the gels, assembling the phantom, scanning (with temperature in room documented), and will send them to NIST
 - NIST to test the phantoms, provide feedback and track stability of the gels over time
 - Calimetrix to make all phantoms in the same batch and date of distribution will be based on when payment is received from sites
- This may become a two-phase project with different timelines for (1) sites that already have phantoms and are beginning data collection now, and (2) sites awaiting the second batch of phantoms
- June 28 Meeting topics:
 - Review <u>Technical Confirmation Resolutions Google Sheet</u> for providing stage 3 feedback after adaptation to MSK BC protocol (Dr. Link)
 - o Use of the modified Outerbridge grading of chondromalacia as a scale to identify grades 1-3 (Dr. Chalian)
 - Discussion of potential other applications, e.g., ligaments, muscle, and whether there could be a second MSK BC Profile or whether this would warrant a separate BC

Next Meeting: Tuesday, June 28, 2022, at 10 a.m. CT [4th Tuesday of each month]

Zoom meeting link: https://rsna-org.zoom.us/j/81459724817?pwd=TkJPYTUrOEpzKy80SnNJNnIDRC9WUT09

Meeting ID: 814 5972 4817

Passcode: MSK

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