QIBA Musculoskeletal (MSK) Biomarker Committee (BC) Meeting

Tuesday, June 28, 2022, at 10 a.m. CT

Meeting Summary

In attendance

Xiaojuan Li, PhD (Co-chair)
Thomas Link, MD, PhD (Co-Chair)
Bruce Beynnon, PhD
Angie Botto-van Bemden, PhD
Jean Brittain, PhD
Majid Chalian, MD
Ali Guermazi, MD, PhD
Gabby Joseph, PhD
Jason Kim, PhD
Feliks Kogan, PhD
Nancy Obuchowski, PhD
Yuxi Pang, PhD
Chris Peng, PhD
David Rutkowski, PhD
Rianne van der Heijden, MD, PhD
Nicole Wake, PhD
Carl Winalski, MD
Jiming Zhang, PhD, DABMP(MR), MRSE
Yansong Zhao, PhD

RSNA

Joe Koudelik
Susan Stanfa

Topics Discussed

- RSNA QIBA MSK Profile Stage 3 and 4 Conformance Testing Scope of Work Document Updates (Dr. Li)
- Technical Confirmation Feedback Resolutions Google Sheet developed by the Process Cmte where stage 3 site feedback will be organized (Dr. Link)
- IRB and data usage agreement (DUA) language for clinical data
- Anonymized patient/volunteer data sharing with Cleveland Clinic (CC) as the central processing site
- Update on phantoms manufactured by Calimetrix (Drs. Brittain and Rutkowski)

Next Steps / Action Items

- This is 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, who may choose to begin with human subject scanning
- The general IRB language distributed for testing site use on June 10, stated that data generated from this study may be sent to a central database/repository after deidentification for future data analysis by scientists/researchers/clinicians who are not involved in this study
    - Since each institution will have their own regulations, some sites may need to use different IRB and DUA language/formats
    - Dr. Chalian to share his IRB language as a reference/template
    - CC has a platform with user-friendly configuration and simple set-up that can be used to upload data to the central processing site; the data will be fully anonymized during the upload process
    - Drs. Li and Chalian to check with their legal offices re: whether data use agreements between CC and each of the twelve testing sites will be needed

- Development of the phantom prototype was an R01-funded collaborative effort involving Verellium, LLC, NIST, and CC
    - It was designed to mimic cartilage T1, T2 and T1rho; reference values at 3 Tesla will be provided by NIST, and other field strengths (1.5T and 7T) may be added in the future
    - Phantom prototype is $20,000 due to costly design, fabrication, solution testing, scanning, etc.
    - 6 additional prototype phantoms were funded through the Arthritis Foundation

- Dr. Rutkowski and his team at Calimetrix developed the vial solution samples for the second batch of phantoms and sent them to NIST for testing, scanning according to their protocols, making measurements, tracking stability of the gels over time, and providing feedback
    - Calimetrix is acting as a subcontractor of Verellium, taking on most of the design and fabrication of future phantoms
    - Calimetrix is planning to make a total of eight phantoms per single vial batch, including six for each of the six sites, one to NIST, and one stays at Calimetrix for stability evaluation

- Verellium has invoiced the six study sites; Dr. Li will follow up with the four sites from which payment is still needed
- Calimetrix needs payment from Verellium to begin manufacturing the phantoms, the date of shipment to the six sites will be about two months after down payment is received
- A round robin study using the phantom that will be sent to NIST is being considered to assess differences between vendor platforms (GE, Philips, Siemens); this will be useful to establish expected range for bias and linearity for the imaging methods and finalizing protocols for each vendor

- Reviewed the Stage 3: Technical Confirmation Resolutions Google Sheet developed by the Process Cmte
  - Dr. Link downloaded the Google Sheet into an Excel document and incorporated checklist specifications from the MSK Profile
  - Information for MSK BC analysis will include whether study sites are conformant to each requirement, as well as the sites' opinion on each requirement, such as:
    - 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)
  - Subject selection specifications may need modifications re: acceptance threshold to ensure volunteer health without requiring initial MRI scan or radiograph, the following criteria are recommended: if radiographs are available only KL0-2 subjects shall be included, if no radiographs are available, only patients below age 50 years shall be included. General exclusion criteria are: no metal, BMI >35, if reproducibility is not obtained directly after first exam (within 24 hours) patients with acute injury shall not be included.
  - Patient handling before the exam shall include 30 minutes of rest and no strenuous weight-bearing exercise for 48 hours before exam (defined as running or other strenuous weight-bearing activities (such as soccer) > 1 hour)
    - Dr. Link will update subject selection specifications for BC review during the July 26 meeting

Next Meeting: Tuesday, July 26, 2022, at 10 a.m. CT [4th Tuesday of each month]
Zoom meeting link: https://rsna-org.zoom.us/j/81459724817?pwd=TkJPYTUrOEpzKy80SnNJNnlDRC9WUT09
Meeting ID: 814 5972 4817
Passcode: MSK
