QIBA Musculoskeletal (MSK) Biomarker Committee (BC) Call

Tuesday, February 23, 2021 at 10 a.m. CT

Call Summary

In attendance

			RSNA
Thomas Link, MD, PhD (Co-Chair)	Ali Guermazi, MD, PhD	Nancy Obuchowski, PhD	Joe Koudelik
Michael Boss, PhD	Peter Hardy, PhD	Yuxi Pang, PhD	Susan Stanfa
Angie Botto-van Bemden, PhD	Youngkyoo Jung, PhD, DABR	Qi (Chris) Peng, PhD	
Robert Boutin, MD	Jason Kim, PhD	Cory Wyatt, PhD	
Majid Chalian, MD	Kecheng Liu, PhD, MBA	Carl Winalski, MD	
Maggie Fung, MEng			

Update on Special Report for *Radiology* Manuscript (Dr. Chalian)

- Revisions received from *Radiology* were incorporated and the paper was resubmitted
- As soon as the paper is published, it will be added to the QIBA EndNote literature collection

MSK Profile – Review Public Comments (Dr. Link)

- The public comment period closed on October 29, 2020, and MSK BC members have been using the **MSK public comment resolution Google Sheet** to document how feedback is addressed

Updates were provided regarding issues discussed during the Jan. 26 MSK BC Meeting

- Dr. Link had searched for literature to support that the MSK Profile Claim would be valid in the setting of a Kellgren-Lawrence (KL) score of 2, which can be associated with significant (advanced) cartilage loss; this will be added to the Profile as a Claim limitation
  - o It was noted that while there may be difficulty identifying supporting literature thus far, abstracts on this topic have been submitted for publication; Dr. Guermazi to send his 2021 OARSI paper reference to Drs. Li and Link
  - o Differentiation between early and severe disease would be the main distinction to be made, and there was a discussion on terminology; it was determined that "non-severe," rather than "early," was the most appropriate description
  - o Dr. Link reviewed paper, Taguchi K, et al. **Characterization of cartilage defects detected by MRI in Kellgren-Lawrence grade 0 or 1 knees**. *Orthop Sci*. 2017 Sep;22(5):868-873. doi: 10.1016/j.jos.2017.06.013
- Dr. Li received phantom-related input from Dr. Keenan (NIST) on the enquiry regarding partial pressure of oxygen changes and effect on T2 if bacteria start growing in the agarose when stored at room temperature
  - o Dr. Keenan provided details about the vial solutions and noted how the preparation process used rendered the gels free from bacteria; she also explained how potential recontamination of the gels was prevented
  - o The protocol used by NIST to create agarose + Gd-EDTA gels resulted in them remaining free of bacteria growth at +3 years (to date)
  - o Detail re: the durability of the agarose gels to be added to the Profile discussion section
- Re: Section 3.6, typical SAR values; the values used in the Profile are not too high and supporting information will be added

Discussion on unaddressed comments resumed

Samuel A. Einstein, PhD (York Hospital)

- Additional discussion is needed on the use of 500 Hz frequency of adiabatic pulses, as it is a controversial issue; the recommendation in the Profile is based on current literature

- Drs. Li and Link will standardize the technical parameters offline and will follow up with the MSK BC during an upcoming call

Eric Y Chang, MD (Staff Physician at the VA San Diego Healthcare System and Professor of Radiology at the University of California, San Diego (UCSD) Medical Center)

- In Section 3.3: Periodic QA, Dr. Hardy to address issue re: the impact of temperature on phantom T2 measurements detection electronics or overall power levels into the various system components, and will update the Profile with additional details
- The lowest end of the 20-80 age range of healthy subjects recommended for including in a normal reference database was reduced to 18
- For consistence, the test-retest conformance study subjects referred to in the assessment procedures as "normal subjects" was changed to "healthy volunteers"

Jason Kim, PhD (Arthritis Foundation)

- NIST will be consulted regarding the shelf-life of the phantom and details will be added to the Profile re: lifetime and/or a re-calibration process (see above information from Dr. Keenan)
- To address the most common spin lock frequency used (at 200 Hz) and the type of acceptable coils and other equipment, focus on a specific indication, and possibly be aligned for an FDA approval
- Application of the Claim only to the knee (no other joints) must be specified in the Profile title
- Clarification on subject handling will be provided
- While aqueous para-magnetic salt solutions are commonly used in phantoms, it will be specified that they need to be MRI-compatible
- More specifications on MR scanners, software, coils, and analysis software will be added

Ashley Williams, MS (Musculoskeletal Quantitative MRI Scientist and Engineer at Stanford University)

- Effects of metal artifact(s) from metal implants, surgical hardware, shrapnel, etc., on calculated T1rho, T2 values or on high-res GRE morphology images depend on the material; specifications will be added

Miika T. Nieminen, PhD; Mikko J. Nissi, PhD; Evelina Lammentausta, PhD; Victor Casula, PhD (Oulu University Hospital)

- Required reproducibility for manual, semi-automatic and automatic segmentation will be defined and supporting reference will be added: Stehling, et al. **A novel fast knee cartilage segmentation technique for T2 measurements at MR imaging--data from the Osteoarthritis Initiative**. *Osteoarthritis Cartilage*. 2011 Aug;19(8):984-9. doi: 10.1016/j.joca.2011.04.002
- Updated reference for Dr. Li's paper will be provided: **Multi-vendor multi-site T1ρ and T2 quantification of knee cartilage**. *Osteoarthritis Cartilage*. 2020 Dec;28(12):1539-1550. doi: 10.1016/j.joca.2020.07.005
- Calibration phantom specifications, (e.g., content, description) to be added when Dr. Li's study results are available
- Language will be checked re: landmarks and definition will be added if necessary
- Drs. Li, Hardy and other MSK BC physicists to be consulted re: fitting algorithms to accommodate noise
- About two-thirds of all comments have been addressed; to continue with comment on row #85 during March 23 call

Next Call: Tuesday, March 23, 2021 at 10 a.m. CT [4th Tuesdays of each month]