QIBA Musculoskeletal (MSK) Biomarker Committee (BC) Call

Tuesday, October 27, 2020 at 10 a.m. CT Call Summary

In attendance

Xiaojuan Li, PhD (Co-chair) Thomas Link, MD, PhD (Co-Chair) Angie Botto-van Bemden, PhD Robert Boutin, MD John Carrino, MD, MPH Ruud de Boer, PhD Ali Guermazi, MD, PhD Youngkyoo Jung, PhD, DABR Feliks Kogan, PhD Kecheng Liu, PhD, MBA Can Wu, PhD **RSNA** Joe Koudelik Susan Stanfa

Moderator: Dr. Link

MSK Profile – Review Public Comments (Dr. Link)

- The Profile was released on June 26 for public comment and the deadline was extended to October 29
- The <u>MSK public comment resolution Google Sheet</u> is being used to document how feedback is addressed
- Discussion focused on comments submitted by The American Association of Physicists in Medicine (AAPM)
- Physicists will be listed among impacted stakeholders, as they are involved in designing/optimizing the protocols
- There was a discussion regarding the least significant change/minimum detectable change; it was discussed whether 11-14% precision may be too high
- For the different manufacturers and scanner models different scan parameters may be required because of hardware and software differences
 - o Dr. Li to investigate whether equivalent parameters should be used and provide text for the Profile
- Clarification to be added that while the emphasis of the Profile is on clinical trials, this process is also intended to apply to clinical practice
- It will be acknowledged as a limitation that while claims of T2 and T1_ρ variations are within 4-5%, there are no vendors providing T1_ρ sequences commercially
 - \circ $\;$ The Profile will be modified once manufacturers provide this as a commercial product
- A lack of reference values for the calibration phantom of T2 and $T1_{\rho}$ was cited
 - Once Dr. Li's new T1_ρ phantom from NIST is finalized during the first quarter of 2021, reference values will be provided in the Profile
- Clarification on whether the software has been validated was requested; the impact of segmentation on T2 and T1_ρ values was deemed obvious
 - \circ $\;$ It was agreed that reproducibility needs to be validated and the vendor needs to be involved
 - Though there is no standardized software available, requirement in terms of reproducibility at this stage (2-3%) may be needed
 - o Separating the analysis methods based on intra- and inter-site studies was suggested
- "Physicists" to be added to Table 1: Actors and Required Activities in Section 3: Profile Activities, as the actor who will install WIP sequences or tools, check the QC and verify the T2 and T1_p values
- Clarification was requested in re: to specifying the kinds of deviations that study sponsors and others decide to handle
 - This was boilerplate language included in the QIBA Profile template and not authored by the MSK BC; Dr. Link will reach out to QIBA Process Cmte Chair, Mr. O'Donnell

- Dr. Li to update Section 3.2: Installation, to specify that the study funded by the R01 grant is ongoing work that will solidify the protocol and that resulting data will be incorporated into the Profile
- Dr. Link has already changed "MR Physicist" to "MR Scientists/Physicists" in the 3.2 specification table and has changed "ACR Phantom" to "ACR phantom for knee coil" in Section 3.3: Periodic QA
- "Human volunteers" will be removed and only "calibration phantoms" will remain in Section 3.3: Periodic QA
- Dr. Li will send language from Osteoarthritis Initiative (OAI) protocol (Schneider et al, 2008) to Dr. Link and instructions on how to measure the eddy current and how to perform the gradient calibration will be added to the Profile
- Subject selection conditions will be added to Section 3.4: Subject Selection; Dr. Li to provide references
- The Profile can be published as <u>Stage 2: Consensus</u> on the <u>Profiles Page</u> on the QIBA Wiki once:
 - Consensus is reached on all public comments which is still work in progress
 - Completed comment resolution sheet is submitted for posting on the Comment Resolutions page
 - Checklists are updated and Conformance Procedures established
 - o BC and CC votes-to-publish are successful

Special Report for *Radiology* Manuscript (Dr. Li, on behalf of Dr. Chalian)

• Dr. Chalian has requested comments on this White Paper manuscript, which was circulated on Oct. 22; all feedback to be submitted to: <u>mchalian@uw.edu</u> by Thursday, Nov. 5

Multisite/multivendor grant and phantom development (Dr. Li)

- Dr. Li received R01 funding to perform a multi-center standardization study, which will help advance the Profile through technical and claim confirmation
- A new MSK phantom is being developed by Drs. Mirowski (Verellium, LLC) and Keenan (NIST)
- It was reported that this study is on track and is proceeding smoothly

Next Call: Tuesday, January 26, 2021 at 10 a.m. CT [4th Tuesdays of each month] No calls are scheduled for Nov/Dec

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