## QIBA Musculoskeletal (MSK) Biomarker Committee (BC) Call

Tuesday, August 24, 2021, at 10 a.m. CT Call Summary

Joe Koudelik

Susan Stanfa

In attendance RSNA

Xiaojuan Li, PhD (Co-Chair)

Ali Guermazi, MD, PhD

Nancy Obuchowski, PhD

Thomas Link, MD, PhD (Co-Chair)

Youngkyoo Jung, PhD, DABR

Angie Botto-van Bemden, PhD

Jason Kim, PhD

Qi Peng, PhD

Robert Boutin, MD Feliks Kogan, PhD Rianne van der Heijden, MD, PhD

Majid Chalian, MD Leon Lenchik, MD Cory Wyatt, PhD Ruud de Boer, PhD Kecheng Liu, PhD, MBA Ted Zheng, MD, PhD

Maggie Fung, MEng

RSNA Staff attempt to capture all committee members participating on Zoom calls. However, **if attendees join only by phone, or do not use a recognizable name, identification is not possible.** Participants are welcome to contact RSNA staff at QIBA@RSNA.org if their attendance is not reflected on the call summaries.

## MSK Profile Consensus Process (Dr. Link)

- Post-resolution MSK BC final evaluation/review of the Profile has been completed and remaining issues found during the MSK BC internal review were addressed and resolved
- Dr. Boutin conducted an overall review of the Profile from a clinical perspective; Drs. Hardy and Wyatt attended to
  protocol and physics aspects
- Comments from Dr. Obuchowski on statistical aspects of Section 2: Clinical Context/Claims and Section 4:
   Assessment Procedures and conformance details were discussed
  - Adjustments were made to the Claim language
  - 4.1.3 Image Analysis: In order to test the assumption underlying the Claim, N=20 healthy volunteers (reduced from 40) will be imaged, with each subject imaged twice on the same day (additionally, some of these subjects may return for a third scan within one week)
    - As sample size is reduced, confidence intervals would need to be widened; it was recommended that there be no fewer than 20 volunteers
    - "Healthy volunteers" will be changed to "patients with early-stage disease or volunteers," but it was noted that the Claims apply only to subjects with less severe cartilage loss in the knees
- Dr. Kogan conducted an overall document review from the physics/scanner perspective
  - o An acquisition device requirement was discussed and updated re: transmit/receive knee coils and flex coils
  - o Guidelines needed re: laminar evaluation and minimal acceptable spatial resolution
  - 4.1.3: Image Analysis: an issue related to further dividing regions of interest, e.g., deep and superficial layers was discussed
- Dr. Botto-van Bemden to conduct an overall document review from a clinical and physics perspective and submit comments within the next few days

## **Next Steps**

- Dr. Link to update the Profile in response to remaining issues found during the MSK BC internal review
- After the public comment resolutions document has been finalized, it will be circulated to BC voting members along
  with the updated MSK Profile and link to email ballot
- An MR CC vote will follow a successful MSK BC vote
- MSK Consensus Profile (Stage 2) and Public Comment Resolutions document to be published by the end of September
- Planning for <u>Stage 3: Technically Confirmed</u> will ensue; details can be found on the <u>Technical Confirmation Process</u>
   page of the QIBA Wiki

Next Call: Tuesday, September 28, 2021, at 10 a.m. CT [4th Tuesday of each month]