## QIBA Dynamic Contrast-Enhanced (DCE) MRI Biomarker Committee (BC) Call

Monday, December 9, 2019 at 11 am (CT)

Call Summary

In attendance		RSNA staff
Caroline Chung, MD (Co-Chair)	Nancy Obuchowski, PhD	Joe Koudelik
Hendrik Laue, PhD (Co-Chair)	Kyunghyun Sung, PhD	Susan Stanfa
Cristina Lavini PhD		

Moderator: Dr. Chung

## **Profile Progress**

- During previous calls, DCE-MRI BC members were asked to review Section 3 of the latest version of the <u>Profile</u>
- To avoid making edits to the text itself, feedback/comments were provided using "<u>Suggested Edit Mode</u>;" comments were also added in the margin
- Over 90% of the comments/edits that have been accumulated over numerous calls have been addressed, but there are specific outstanding discussion points and clarifications needed
- The immediate goal is to address outstanding issues and finalize the Profile for public comment in early 2020
- There was a productive Profile review during the Dec. 4 breakout session following the QIBA Working Meeting
- Dr. Laue reported that all the prostate content has been completed, but minor formatting is still needed
- Discussion re: Claim statements and methods other QIBA groups have used to choose CoV values
  - A "true change" range could be confusing and present a challenge to the Profile user in choosing a value
  - o Most groups have conducted a meta-analysis, deciding on a single mean value of CoV distribution
  - o Using a mean derived from removing the highest and the lowest performers might be another option
  - o A "true change" range in a Claim containing a cutpoint would be confusing for users
  - It was decided that the Claim should remain as is
- Section 2.1: Clinical Interpretation Dr. Laue to add missing Claim 2a and 2b examples
- Section 3.3: Pre-delivery Discussion re: whether this section is redundant with site-qualification details
  - To determine whether open MRI, with its resolution issues that would not meet Claim criteria, should be addressed
  - Dr. Chung to contact Drs. Boss and Rosen to request clarification re: intended content for sitequalification vs. pre-delivery and to determine whether to remove pre-delivery section
- Section 3.5: Periodic QA phantom and software recommendations needed
  - Dr. Laue to contact Dr. Stephen Russek at NIST to request status on the NIST phantom-lending service,
     and ask which specific phantom type would be available; this detail is critical for the Profile
- Section 3.6: Protocol and Reconstruction Design Discussion re: temporal resolution and coverage and which updates are needed;
  - Appendices may be used for process details and justification text to make the Profile more readable; Dr.
     Laue to add specified Appendix location
- Section 3.7: Subject Selection Dr. Laue to clean up text
- Section 3.8 Subject Handling Reference to be added
- Section 3.11: Image QA
  - o Offline discussion proposed re: how to address B1-mapping in Profile
  - Test-retest publications and complete vendor information is lacking
  - o Dr. Lavini's publication containing supportive B1 mapping details will be available in Feb or Mar. 2020
  - o Dec. 9 DCE-MRI BC call attendees were asked for their help in cleaning up this section

Next call: Wednesday, January 6<sup>th</sup>, 2020 at 11 a.m. CT (1<sup>st</sup> & 3<sup>rd</sup> weeks of each month)

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