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

Monday, April 26, 2021 at 11 a.m. (CT) Call Summary

In attendance RSNA staff

Caroline Chung, MD (Co-Chair) Cristina Lavini, PhD Mark Shiroishi, MD Joe Koudelik

Hendrik Laue, PhD (Co-Chair) Nancy Obuchowski, PhD Rianne van der Heijden, MD, PhD Susan Stanfa

Michael Boss, PhD James O'Connor, MBBS, PhD Divya Yadav, MD

Update on DCE-MRI Profile

- The <u>Public Comment Resolutions Sheet</u> was referenced to address comments; details on resolutions reached through committee discussion and consensus are included
- DCE-MRI BC members are welcome to work on edits to the Profile

The following comments submitted during the public comment period were addressed:

James O'Connor, MBBS, PhD | EIBALL/The University of Manchester (UK)

- Guidance to be added for dealing with patient movement that occurs between t1W and t2W images and the dynamic series being acquired
 - o Discussion on whether to use B-Value image (500) and a hierarchical approach
 - This information will be added to the "Open Issues" section
- Suggestion to distinguish two conceptually different scenarios in therapy evaluation where K^{trans} can be considered a pharmacodynamic biomarker (focusing on mechanism of action), and where K^{trans} is a non-specific downstream biomarker (focusing on biomarker effects)
 - o Dr. O'Connor to submit explanatory text to staff for distribution to the DCE-MRI BC for additional discussion
- Dr. Laue to verify that 'true change' thresholds in Claims are accurate and that rationale is clearly stated
 - The <u>official, Public Comment (stage 1) Profile</u> was the version referenced in the public comment announcement when it was distributed to QIBA members; it is located on the <u>Profiles page</u> of the QIBA Wiki
 - o The recent, working Profile draft reflects updates made in response to comments that have been addressed
- There were several concerns related to the lack of repeatability data on DCE-MRI from clinical studies of brain tumors and prostatic tumors that inform the Profile Claims
 - If additional studies are conducted and published in the next few years, the DCE-MRI Profile will be updated
 - The DCE-MRI BC plans to conduct a literature search of recent studies to see if more data have been published since its last review
 - QIBA BCs may need to incorporate new literature into Profiles and are welcome to post maintenance drafts to their respective <u>Committee pages</u> on the QIBA Wiki
 - Provided that Profile Claims would not be substantially impacted by updates, a round of public comment would not be necessary
 - Dr. O'Connor to send a summary of ongoing test-retest studies to staff for distribution, and intended inferences for biomarker applications
- The figure in Section 3 illustrating brain requirement for true change in K^{trans} will be corrected
- Discussion of Dr. O'Connor's comments will resume during the May 10 DCE-MRI meeting

Next call: Monday, May 10, 2021 at 11 a.m. (CT) [2nd & 4th Mondays of each month]