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

Monday, February 1, 2021 at 11 am (CT)

Call Summary

In attendance			RSNA staff
Caroline Chung, MD (Co-Chair)	Todd Jensen, 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	Prativa Sahoo, PhD	Divya Yadav, MD	
Thomas Chenevert, PhD			

## Discussion of public comments on DCE-MRI Profile

- The <u>Public Comments Resolution 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
- Dr. Obuchowski noted that a slope of exactly one should not be expected; guidance was provided regarding the acceptable distance from one
  - The recommendation is to require actors to construct a 95% confidence interval (CI) for the slope; the CI should lie between 0.95 and 1.05
- The DCE-MRI Profile has appropriately required actors to assess linearity and the magnitude of the slope, but the claims are strongly dependent on the wCVs; an assessment of the wCV and criteria for whether the actor has/has not met the requirement is needed
  - o It was noted that the DSC-MRI BC used a static R2\*phantom
  - Test-retest on a DRO is not needed, as there would be minimal or no variability with analysis software, except in situations where versions have been changed/upgraded
  - Suggestion to consider a sensitivity calculation for Ktrans from T1
  - The DCE-MRI BC will propagate the errors from T1 to ktrans into the appendix
- Statistical justification for the last two claims needs to be added
  - DCE-MRI BC to consider stating that it is assumed that ktrans are linear in the claims
  - Other Profiles, including the DSC-MRI one will be referenced
  - Statistical assumptions will be incorporated into the Claim description
- The three Claims labelled as "2," will be updated/clarified to 2a, 2b, and 2c
- Dr. Laue will reach out to comment submitters and invite them to provide clarification during upcoming meetings
  - Dr. Sourbron to be invited to the next call on February 8; if he is unable to attend, the next commenter will be contacted
  - Drs. Chung and Laue to contact QIBA leadership and/or RSNA staff to determine contacts for QIBA-Japan
- Drs. Chung and Laue will clean up minor comments not requiring cmte discussion/consensus
- Staff to include a link to the Profile in the invitation for the next DCE-MRI BC call

Next call: Monday, February 8, 2021 at 11 am (CT) [Fixed 2<sup>nd</sup> & 4<sup>th</sup> Monday schedule is now in effect]