QIBA Dynamic Susceptibility Contrast (DSC-MRI) Biomarker Committee (BC) Call

Wednesday, November 13, 2019 at 11 a.m. (CT)

Call Summary

ParticipantsRSNABradley Erickson, MD, PhD (Co-Chair)Zhaoyang Fan, PhDMark Shiroishi, MDJoe KoudelikOna Wu, PhD (Co-Chair)Dariya Malyarenko, PhDYuxiang Zhou, PhDSusan StanfaThomas Chenevert, PhDNancy Obuchowski, PhD

Moderator: Dr. Wu

DSC Profile Update

- DSC-MRI BC members were asked to make notes in the <u>Profile</u>, using "<u>Suggestion Mode</u>" (rather than making direct changes to the text)
- Discussion re: acquisition protocol in the literature upon which the Profile Claims are based vs. clinical practice methods and Claim development
 - o If methodology is too strict, no one will be able to use Profile
 - Suggestion to use "acceptable" "target" and "ideal" thresholds to offer various performance levels
 - Assuming 7% CoV, or as current Claims state, expect variability to be based on Prah paper with 86% change as a real indicator of change
 - Prah MA, Stufflebeam SM, Paulson ES, et al. <u>Repeatability of Standardized and Normalized</u> <u>Relative CBV in Patients with Newly Diagnosed Glioblastoma</u>. *AJNR Am J Neuroradiol*. 2015; 36(9):1654–1661.
 - Disclaimer to be added that user will likely achieve better reproducibility results with future acquisitions based on improved protocols
 - Section 3.6: Protocol Design Specification Table
 - Coefficient of variation based on MRI parameters and contrast bolus technique
 - Previously, Dr. Schmainda's group outlined the need for more precision regarding the dosing schema
 - In response, the dosing instructions for scanning parameters were adjusted, tying the existing and emerging literature to Claims
 - One of the specifications in the Brain Tumor Imaging Protocol (BTIP) table (with highest CoV) was deemed too difficult to achieve in clinical practice and was removed
 - Suggestion that simulations be run using methodology outlined in the Prah article for acquisition to get a sense of what the CoV is, but Claims not to be based on simulation data
 - BNIDRO: Dr. Erickson's DSC-MRI simulation software; a web-based tool for creating DSC Digital Reference Objects
 - o Dr. Wu to ask Dr. Quarles to run simulations with 90° flip angle to determine the amount of improvement in CoV and compare how reality matches the simulated results
 - References provided in the Google Doc Profile comments were incorporated
 - o In preparation for the Profile (BC & CC) vote-to-release approval process, Dr. Wu requested additional internal review and feedback from DSC-MRI BC members
 - Dr. Obuchowski to review Claims and Section 4: Assessment Procedures
 - o Dr. Wu to do additional work on the BTIP

- Claims need to be based on data from test-retest studies conducted on humans; alternatives can be provided, but making recommendations will be avoided
- Concern that current Claims (supported in the literature) may be based obsolete acquisition protocols,
 i.e., protocols are improving rapidly
- o In efforts to avoid delaying the release of the Profile for public comment, Dr. Wu to edit Clinical Claim section, adding a note that Claims may be updated as new literature emerges
- Staff to follow up with Drs. Erickson and Wu re: next steps in the process toward public comment

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Next DSC-MRI BC Call: Wednesday, December 11, 2019 at 11 a.m. CT

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