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

Wednesday, April 10, 2019 at 11 AM (CT)
Call Summary

ParticipantsRSNABradley Erickson, MD, PhD (Co-Chair)Dariya Malyarenko, PhDJoe KoudelikOna Wu, PhD (Co-Chair)Nancy Obuchowski, PhDSusan Stanfa

Moderator: Dr. Erickson

DSC Profile Update

- The Profile is available to all DSC BC members through Google Drive (Google Chrome browser recommended)
- There was a brief discussion on development of draft Claims
- DSC phantom guidance will not be moved to the main body of the Profile (unlike with the DWI BC, which had a commercially-available phantom); it will remain in the appendix
 - Due to cost and limited availability, the DSC Profile uses a "homemade" phantom
 - DSC Profile users are provided guidance regarding construction of their own phantoms using High
 Precision Devices (HPD) outer shells and recipe for components from NIST
- Section 3.6: Protocol Design Specification Table
 - Coefficient of variation based on MRI parameters and contrast bolus technique
 - Need for more precision regarding the dosing schema as outlined by Dr. Schmainda's group
 - Dr. Erickson to adjust dosing instructions for scanning parameters, tying the existing and emerging literature to Claims
- 3.13.1: Image Analysis Discussion Section
 - Decision made not to specify software to be used; details to remain generic, with the primary focus on acquisition
 - The following text was added:
 - The software used to produce parametric images from the DSC acquisition is a critical element of the analysis leading to optimal clinical interpretation
 - It is typically proprietary and is updated on a regular basis; therefore, it is not possible for this Profile to specify the software analysis method, as one cannot know the implementation
 - Recommendation added to download Dr. Erickson's DROs from:
 http://qibadscdro.rsna.org/home; DROs have known values (ground truth) and can be used to assess validity of user's preferred software
 - Recommended values of the digital value when using noise and other parameters that reflect the Profile users' clinical practice were updated from to 20%, based on the noise values measured in Semmineh et al. 2018; (the figure initially cited was 10%), but Dr. Erickson to reach out to Dr. Obuchowski for guidance in methods to confirm this

- A prior discussion on confidence interval was revisited
 - References were used to develop Claims 1 & 2, which have very large within-subject COVs
 - Claim 1: "A true change in Area Under the Curve-Tissue Normalized (AUC-TN) in enhancing tumor tissue has occurred with 95% confidence if the measured change is 86% or more"
 - It was stated that the measured change must be less than 86%, because it is known for certain that 86% would be a real change
 - Once confirmed, reliable bias values in software performance to be added to the 3.13.2 specification table
- DRO parameter to be added to 3.13.2: Image Analysis Specification Table
- Dr. Erickson to complete all clinical edits and submit the Profile to Dr. Wu, who will then make final edits to the Profile technical specifications
- Once the Profile review process is completed, the DSC Profile will enter the BC approval process; next steps
 are outlined on the <u>review process page</u> of the QIBA Wiki
 - Upon DSC BC leadership request, staff will circulate a ballot, asking Biomarker Committee members to approve that the content of the Profile meets the criteria for the stage
- A QIBA BC would prepare for the public comment (PC) process only after the review process is completed
 - o BC Co-chairs review and approve that the Profile be released for public comment
 - Editor tidies up PC draft (e.g. "accept all changes" in Word) and submits to staff
 - Staff publishes PC draft on the Profiles QIBA Wiki page

QIBA Sustainability Implementation Group (SIG) Letter to Pharma

- The Sustainability Implementation Group (SIG) has requested that all QIBA CCs provide up to three groundwork projects that would help advance the current Profiles
- Project proposals to be submitted to CC Co-Chairs prior to April 15 so that they can discuss them during their
 April 24 quarterly meeting
- Dr. Quarles has a proposal related to his DRO; Dr. Wu to remind him of the deadline

Next DSC BC Call: Wednesday, May 8, 2019 at 11 AM CT

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