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

Monday, July 22, 2019 at 11 AM (CT)

Call Summary

Participants			**RSNA**
Caroline Chung, MD (Co-Chair)	Catherine Coolens, PhD	Dariya Malyarenko, PhD	Joe Koudelik
Hendrik Laue, PhD (Co-Chair)	Amita Shukla-Dave, PhD	Nancy Obuchowski, PhD	Susan Stanfa
Michael Boss, PhD	Hyunki (Harrison) Kim, PhD, MBA		

Moderator: Dr. Laue

DCE Profile v2.0 Update (Dr. Laue)

- Discussion re: Claim definition for 3T prostate
    - Feedback and recommendations were provided by Mr. O'Donnell (QIBA Process Cmte Chair)
    - The publication informing the Prostate Claim at 3.0T, Peled et al, 2018, *Academic Radiology*, was briefly discussed and will be circulated for feedback

- Discussion on B1-mapping correction continued from previous DCE BC calls
    - If the literature used to inform the Profile Claims specifies B1-mapping correction, this should be included as a requirement in the Profile
    - Dr. Chung sent a publication re: B1-mapping to core DCE BC members

- Dr. Laue followed up with Dr. Ona Wu re: how the DSC BC addressed various Actors in their Profile; there was brief discussion on how DCE-MRI and DSC-MRI checklists would compare
- Progress update on cleaning up Profile Sections 3.1 – 3.11
    - Dr. Chung addressed and removed all outstanding comments
    - 3.2 Site Qualification: in the case of DCE-MRI, the need for contrast agent application, dynamic acquisition and the use of analysis software tools makes technical details for MRI systems extremely complicated
        - Considering the costs of an MRI system, it is generally necessary to use equipment already available at the site and the suitability of the hardware needs to be aligned with the details described in the Profile

    - 3.3 Pre-delivery: discussion regarding whether this section is redundant for the DCE-MRI Profile, as later sections also discuss QA
        - The goal of this section is for the manufacturer to perform standard scanner calibration, phantom imaging, performance assessment or validation prior to the shipping the equipment from the factory
        - The DSC-MRI BC left this section in their Profile, as it includes brief guidance re: pre-delivery testing
        - Suggestion to add text related to DCE-MRI analysis

    - 3.4 Installation: "Software" subsection was retitled to "MRI Sequence"
    - 3.5 Periodic QA: recommendation regarding a R1/T1 phantom is still needed; previously considered providing guidance in the Profile via specifications and a manual on how to build a phantom
        - In efforts to avoid quality-related issues, preparing phantom fill solutions at sites was discouraged; Profile to instruct sites to buy solutions or obtain a phantom that is fully constructed
        - Instructions on acquiring software and phantoms to be added
        - Discussion re: signal linearity; some text to be moved to 4.1.2: Assessment Procedure associated with testing sequence for signal saturation and intensity

- 3.6: Specification – no discussion occurred
- 3.7: Subject Selection – the section was reorganized, and more specific wording was added re: possible clinical scenarios
    - Gadolinium guidelines were updated, advising that the Profile user reference recent FDA safety communications when developing and considering DCE-MRI clinical trial protocols
        - Recent concerns regarding the accumulation of gadolinium in the body were noted
    - European Medicines Agency (EMA) recommendations are also included
    - In efforts to avoid frequent Profile updates, links to more specific material were added
    - Discussion re: handling of subjects, e.g., timing to intervention, positioning and time intervals from pre- to post intervention scan
        - It was noted that DEC-MRI Profile Claim statements relate only to brain and prostate
        - Different organ-specific details need to be included in this section
        - Specifications should be limited to only information directly relevant to Claim statements; additional details to be moved to the "discussion" sections

Next DCE-MRI BC Call: Monday, August 5, 2019 at 11 AM CT