QIBA Dynamic Contrasted Enhanced (DCE) MRI Biomarker Committee (BC) Call

Monday, April 15, 2019 at 11 AM (CT)

Draft Call Summary

Participants

Caroline Chung, MD (Co-Chair)

Hendrik Laue, PhD (Co-Chair)

Michael Boss, PhD

RSNA

Cristina Lavini, PhD

Nancy Obuchowski, PhD

Susan Stanfa

Michael Boss, PhD

Harrison Kim, PhD, MBA

Qing Yuan, PhD

DCE Profile Update (Dr. Chung)

- DCE BC members were encouraged to review and comment on the updated Profile at: https://docs.google.com/document/d/1ytAuSsRtL2mgAlY1wq6PkVGleWvWSTdx0HGdgUu1mrA/edit?usp=sharing
- Offline discussion has occurred since the April 1 DCE BC t-con re: Section 3.6 Protocol Design; a significant amount of text re: signal linearity (SI) was eliminated
- Discussion regarding whether to move "Determination of subjects unsuitable for DCE-MRI Analysis" subsection in Section 3.7: Subject Selection elsewhere
- The long term goal for the Profile is for it to be used in clinical practice; a more immediate goal is for it to be used in clinical trials
 - o The meaning and criteria of Profile Stage 5: Clinically Confirmed are still under discussion
 - Pursuing Clinically Confirmed is beyond the scope of QIBA; but QIBA may still act as a facilitator/enabler to reach this stage
- The major regulatory agencies (FDA, EMA) and scientific societies have amended their guidelines regarding the use of GBCAs; information to be included in Section 3.7
 - The following note to be included as well: "If a patient needs adjustment in gadolinium dose and bolus injection rate beyond the recommended conditions listed in this Profile, the Claims of the Profile may not apply;" Dr. Wu, DSC BC Co-Chair to be consulted regarding how her group handled this
 - o In efforts for the DCE Profile to be applied internationally, protocol and regulatory differences between the US and EU to be considered
 - Suggestion to provide succinct synopses of the official statements
 - Discussion occurred on "<u>Gadolinium Retention: A Research Roadmap from the 2018 NIH/ACR/RSNA</u> <u>Workshop on Gadolinium Chelates</u>" publication in *Radiology* by McDonald RJ, et al.
- A checklist has been developed and placed into Appendix G
- 2019 ISMRM Conference (May 11 16 in Toronto, Canada)
 - o Dr. Huang to confirm the date that DCE members will meet during the week of this meeting
 - "Open Source Initiative for Perfusion Imaging Member-Initiated Symposium" is scheduled for 1:45pm on Monday, May 13 in Room 513A-C
- Discussion on B1-mapping continued from previous DCE BC calls
 - o Dr. Lavini made adjustments to the Profile on this topic
 - An overview was provided of a multi-scanner phantom study that demonstrated that applying B1
 mapping correction within analysis software may not solve B1 shimmy causing issues with variability and
 may actually worsen the problem for some vendor platforms
 - Recommendation made not to use B1 mapping correction at 3T in the Profile
 - o Dr. Lavini to bring additional information to share for discussion during the next DCE BC call on April 29

Next DCE BC Call: Monday, April 29, 2019 at 11 AM CT

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