

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

Wednesday, May 29, 2019 at 11 AM (CT)

Call Summary

Participants

Hendrik Laue, PhD (Co-Chair)
Dena Flamini, RT
Hyunki (Harrison) Kim, PhD, MBA

RSNA

Nancy Obuchowski, PhD
Mark Shiroishi, MD
Joe Koudelik
Susan Stanfa

2019 ISMRM Conference (May 11 – 16 in Toronto, Canada)

- “Open Source Initiative for Perfusion Imaging Member-Initiated Symposium” was held at 1:45pm on Monday, May 13; Dr. Laue to distribute the link

2019 QIBA Annual Meeting (June 12 – 13 at RSNA HQ in Oak Brook, IL)

- Due to budget limitations, invitation to this meeting is currently open to only cmte leaders

DCE Profile Update (Dr. Laue)

- DCE BC members were encouraged to review and comment on the updated [Profile](#)
- Dr. Laue reviewed edits he made to the Executive Summary
- “Should” and “Shall” language have been revised in various tables
- Inquiries have been submitted to vendor representatives to find out whether they plan to utilize B1 mapping correction within their analysis software; recommendations still need to be provided in the Profile
- Imaging requirements for the brain are needed from Dr. Chung for Section 2: Clinical Interpretation
 - Test-retest data with the GKM/Tofts model are still needed to set a Claim definition
 - Publications need to be cited with respect to the statement “...might indicate a disease progression or failing therapy,” regarding measured change in Ktraps of a brain lesion in the statement
 - Dr. Shiroishi to send publications to Dr. Laue for review; additional discussion is needed
- Clean up in Sections 3.1 – 3.11 continues
- If T1-dependent analysis is intended for the DCE-MRI study, the fidelity of R1 measurement should be assessed based on phantom imaging
 - Recommendation regarding R1/T1 phantom is still needed
 - Providing guidance in the Profile via specifications and a manual on how to build a phantom would be helpful for users
 - Evaluation software for phantom analysis is available in the QIDW and [the link](#) is provided in the Profile
 - The phantom situation needs to be resolved before subsections in Section 4: Assessment Procedures, can be completed
 - Section 4.2 Assessment Procedure: B1-mapping to be drafted
 - Section 4.3 Assessment Procedure: Image Analysis Software – “The requirements for the software in Image Analysis (Section 3.13) can be evaluated using digital reference object data and an evaluation software comparing the calculated results”
 - A detailed, step-by-step assessment procedure to be provided in the Profile
- The major regulatory agencies (FDA, EMA) and scientific societies have amended their guidelines regarding the use of Gadolinium-based Contrast Agents (GBCAs); information in Section 3.7 to be finalized

- Benefit vs. risk of contrast usage needs more review and citable literature; feedback expected from the Public Comment phase would be most useful
- Discussion occurred on Section 3.8: Subject Handling regarding how injection contrast through a port-a-catheter or permanent indwelling catheter is not recommended due to a high injection rate with power injector
- Investigation needed re: 3.10 Image Data Reconstruction: “No user-selected post-processing filters or image normalization methods should be used prior to data analysis as described in the next steps”
- Dr. Laue to continue to clean up the Profile and remove comments as they are addressed; he hopes to be able to add more crucial information next week
- Appendices C, D and F to be revised
- Checklists to be completed; Dr. Laue to adapt the CT Volumetry Profile checklist for the DCE Profile
- The goal is to complete the Profile within the next month, though this may be ambitious; DCE BC members were encouraged again to review and comment on the Profile

Next DCE BC Call: Monday, June 10, 2019 at 11 AM CT

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