

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

Wednesday, June 10, 2020 at 11 a.m. (CT)

## Call Summary

### Participants

Bradley Erickson, MD, PhD (Co-Chair)

Ona Wu, PhD (Co-Chair)

Caroline Chung, MD

Lisa Cimino, RT

Wolter de Graaf, PhD

Zhaoyang Fan, PhD

Mo Kadbi, PhD

Nancy Obuchowski, PhD

(Christopher) Chad Quarles, PhD

### RSNA

Joe Koudelik

Susan Stanfa

Moderator: Drs. Erickson and Wu

### DSC Profile Update

- The Profile was released for public comment on March 2, 2020
  - The deadline for public comment submissions was May 15, 2020
  - All comments have been received and transferred to the [DSC-MRI public comment resolution sheet](#)

### Review of the DSC-MRI public comment resolution sheet

- The latest version of the [Stage 1: Public Comment Profile](#) was referenced
- The group addressed feedback received and consensus was reached regarding resolution
- Physicist as actor indicated for Contrast Injector – suggestion to assign task to “Physicist,” “Biomedical Engineer (or Technologist)”
  - While multiple actors could fill this role, it is ultimately the physicist’s responsibility to make sure the task is done, regardless of who performs it; consensus to leave as it
- Discussion re: MR safety
  - Many implants are MR conditional at 1.5T cylindrical bore only; at some point, guidance can be provided at 1.5T for (1) patients with 1.5T MR-conditional implants and (2) facilities with no 3T systems
  - Due to the lack of data for 1.5T, the DSC Profile focuses on 3T; no text changes will be made
- Philips acquisition - flip angle is specified as “30 or 60”, though only 60 may be more appropriate and is consistent with the other vendors; this change was suggested by another submitter and has already been made
- For multiple lesions, care must be taken if there are lesions in both hemispheres in selecting an ROI in white matter that appears normal; in addition, multiple lesions involving the same side of cerebral and cerebellar hemispheres can affect perfusion in the contralateral hemisphere if used for a reference (crossed cerebellar diaschisis)
  - Dr. Erickson to address this by adding text to the discussion section
- Cover as much of the brain as possible – proposal to cover the entire tumor
  - Multiple sites have covered the full brain and double the acquisition, causing them to double the temporal resolution
  - DSC-MRI BC priority is the keep repetition time (TR) at 1.5 ms and focus on covering the tumor; the resolution was to change to prioritize the TR and focus on tumor
- There is a reference to the use of a Preload Dose within the table in 3.6 (and a minor reference in line 528) in this section, but guidance or instructions re: the use of a preload could not be located; particularly in the checklists
  - Dr. Erickson will create new section after 3.8 called “Preload” and describe two methods, either by RT doing manual injection or via power injector
  - Appropriate delay (minimum time 5 min) to be specified; Dr. Wu to prepopulate a table

- Uncertainty what was meant by "Site Image Header" in second row of table 3.2.2, as opposed to "Image Header"; proposal to elaborate or fix; the DSC-MRI BC agreed and will correct the typo
- Confusion re: wording in 3.7.1 - "scan timing" may be confused with "scan time (e.g. sequence timing, temporal res, etc.)"; the DSC-MRI BC agreed with the recommendation to use "scan scheduling"
- No mention re: feasibility at 1.5T or why the Profile is limited to 3T; literature cited (Bell), states that, "when normalized...CBV does not differ across field strengths"
  - Recommendation to reconsider use of term and add a brief statement in the discussion on the rationale for limiting focus to 3T
  - The DSC-MRI BC discussed that there are no data on 1.5T, which is why the focus is on 3T and the paper cited is based on simulations; the resolution was to add rationale for focusing on 3T in clinical context and Claims to the introduction
- Proposal to remove template notation, and change grey text to black; the DSC-MRI BC agreed and will do so
- If feedback from users is not needed, the "Open Issues" section may be removed; the group agreed and complied
- Proposal to remove several rows in the "Closed Issues" table; the DSC-MRI BC agreed and complied
- It was agreed that "initial draft" on title page should be changed to "public comment," and it was done
- The following changes to the Executive Summary were proposed:
  - If the sentence listing actors is a useful summary to readers, it should match the actor list from Table 1; this will be verified
  - If the sentence listing activities is a useful summary to readers, it should match the activity list from Table 1; this will be verified
  - Question re: what is the purpose of the disclaimer statement and does it belong in this section?; the DSC-MRI BC agreed that text should remain, but it is not actually a "disclaimer," and that term will be removed
- Section 2: Clinical Context and Claims is intended to be only a paragraph or two stating the clinical use for Analytical ultracentrifugation (AUC); proposal to shorten
  - The DSC-MRI BC agreed and will limit text to major clinical use of auc-true negative (tn)/relative cerebral blood volume (rCBV)
- All requirements to be included in the specification tables; these should not be repeated in the body text
  - Due to BC uncertainty whether sections need to be removed, Mr. O'Donnell will be asked for clarification
- In Section 3: Profile Activities - proposed to merge rows in first column (e.g. three Acquisition Device cells) in Table 1: Actors and Required Activities; the DSC-MRI BC will comply
- Enquiry re: whether imaging site staff lacking the certifications or qualifications listed in Section 3.1: Staff Qualification is a common source of variability in AUC-TN measurements
  - If not, it was proposed that the content be removed; if so, it was proposed that the requirements focus on the specific actors and qualifications that were found to affect variability
  - Due to BC uncertainty whether text should be removed, Mr. O'Donnell will be asked for clarification
- Changes to the Section 3.2.2 specification table were proposed; the DSC-MRI BC will comply with the following:
  - Remove bullets and use only sentences
  - When copying into checklist tables, each requirement to have its own cell/row
  - Change "Site Image Header" to "Image Header"
  - Re: Contrast Media parameter, avoid embedding an incomplete MR safety/best-practices guide inside the profile; since it does not affect the Claim, removal was recommended
    - Safety language will be removed, and focus will be changed to field effect size and paramagnetic agent

- The working draft of the [Profile](#) will be converted to Word format and Paperpile will be rerun to update references
- Since the remaining comments consist of simple wording changes not requiring cmte deliberation, they will be addressed offline and reviewed during the July 8 DSC-MRI BC call

**Next DSC-MRI BC Call: Wednesday, July 8, 2020 at 11 a.m. CT**

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