

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

Wednesday, July 8, 2020 at 11 a.m. (CT)

Draft Call Summary

Participants

Bradley Erickson, MD, PhD (Co-Chair)

Ona Wu, PhD (Co-Chair)

Michael Boss, PhD

Lisa Cimino, RT

James Gimpel, RT (R)(MR)

Mo Kadbi, PhD

Nancy Obuchowski, PhD

Mark Shiroishi, MD

RSNA

Joe Koudelik

Susan Stanfa

Moderators: 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 and all comments were compiled

Review of the [DSC-MRI Public Comment Resolution Sheet](#) Continued

- The latest version of the [Stage 1: Public Comment Profile](#) was referenced
- The group continued to address feedback received
- Section 3.2: Product Validation Specification Table
 - The DRO requirement was updated from, “Shall be confirmed that performance is linear and has expected wCV on digital reference objects,” to “Shall be confirmed that performance is within 20% benchmark on digital reference objects”
 - Discussion re: the need to know the slope; reference to Section 4.6 Assessment Procedure: Digital Reference Object will be added, and Dr. Erickson will continue addressing this issue
- It will be made more explicit that the Claim is only for 3T, not 1.5T
- The official Profile template includes Section 3.3: Pre-delivery and 3.4 Installation
 - Given that Periodic QA activity is included, suggestion to omit Sections 3.3 and 3.4
 - The DWI BC kept these sections with boilerplate language and it was recommended that the DSC-MRI BC do the same; Dr. Boss to send the DWI BC Profile to Dr. Wu for reference
- Dr. Wu to double check discussion sections and move any requirements to specification tables; all remaining formatting issues and typos will be addressed
- Dr. Wu to assess whether the software version has changed since the longitudinal study was completed and will add text to explain how varying software versions could impact the Claim
 - Documenting software upgrade details deemed as overly prescriptive; simply explaining the impact this may have on the Claim was suggested
 - Suggestion to reach out to Mr. O’Donnell with the proposed response, based on DSC-MRI BC feedback
- Assessing performance within vendor model benchmarks may be a common source of AUC-TN measurement variability; scanner stability for longitudinal claims can affect meeting the claim
 - Dr. Keenan’s 2019 paper to be referenced
- Dr. Wu to specify range of temporal SNR based on phantom experiments from round-robin study
- “Physicist Shall confirm number of slice locations provides optimal coverage of tumor,” requirement to be moved from Section 3.6.2: Protocol Design specification table to Section 3.8: Subject Handling specification table

- In re: to requirement in 3.6.2 Protocol Design specification table, “Shall confirm that the protocol achieves a bolus signal drop at least 10% from baseline when using specified contrast agent and dosage,” Section 4.3: Assessment Procedure Bolus Quality to be expanded and referenced
- In Section 3.7: Subject Selection: while “contraindications” and “venous access” appear as safety/best practice rather than AUC variability; with poor bolus drop, AUC can be affected
 - The DSC-MRI BC discussed replacing this language with guidance that the Profile user should make sure IV line is in the same arm as was used in the baseline study as applicable and safety concerns will be removed; it will also be noted that the right arm is better
 - In addition to Section 3.7, this information will be added to Section 3.8: Subject Handling as well
 - It was noted that the DWI Profile did not include a specification table in Section 3.7
 - The DSC-MRI BC resolved to remove the language from the specification table, but it will remain in the discussion
- It was agreed that “prescribing protocol consistent with baseline” would be more appropriate in Section 3.8: Subject Handling, rather than 3.7: Subject Selection
- Discussion has been completed and consensus has been reached on all public comments

Next Steps

- Dr. Erickson to make final updates to the Profile in response to public comments
- Dr. Wu to convert the [Profile](#) to Word and finish addressing formatting issues
- Paperpile will be rerun to update references
- Once the DSC-MRI BC completes the following, it can declare its Profile as [Stage 2: Consensus](#)
 - The completed comment resolution sheet is submitted to staff to post on the [Comment Resolutions page](#) of the QIBA Wiki
 - All *Shalls* to be sorted based on Actors for ease of use
 - Checklists to be updated and Conformance Procedures established
 - Successful BC and CC votes to publish the Profile as Stage 2: Consensus on the [Profiles Page](#) of the QIBA Wiki

Next DSC-MRI BC Call: Wednesday, August 12, 2020 at 11 a.m. CT

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