

## QIBA Perfusion, Diffusion and Flow – MRI Biomarker Committee (BC) Call

Wednesday, January 31, 2018 at 11 AM (CT)

### Call Summary

#### Participants

			RSNA
Michael Boss, PhD (Co-Chair)	Jim Gimpel, RT (R)(MR)	Brian Taylor, PhD	Joe Koudelik
Thomas Chenevert, PhD	Xavier Golay, PhD	Silvina Zabala Travers, MD	Susan Weinmann
Caroline Chung, MD	Edward Jackson, PhD	Elisabeth Wilde, PhD	
Amita Dave, PhD	Hendrik Laue, PhD	Ona Wu, PhD	
James Ewing, PhD	Dariya Malyarenko, PhD	Junqian (Gordon) Xu, PhD	
Dena Flamini, RT (R)(MR)(M)	Nancy Obuchowski, PhD	Robert Young, MD	
Daniel Gembris, PhD	Samir Sharma, PhD		

Moderator: Dr. Boss

#### DCE TF Update (Drs. Laue & Chung)

- Executive summary was reviewed and is being edited
- Discussion on the status of the DCE Profile Section 2: Clinical Context and Claims
  - The Claim statements below are based on test-retest data in the literature, found during a systematic search process
    - Claim 1a: A measured change in  $K^{trans}$  of a brain lesion (GBM) of 21.3% or larger indicates that a true change has occurred with 95% confidence
    - Claim 2b: A measured change of  $K^{trans}$  of a prostate lesion of 55.7% or larger indicates that a true change has occurred with 95% confidence
  - To address the dearth of test-retest data on prostate, a white paper is being written to encourage PIs to submit/publish test-retest data; the white paper may be referenced in the DCE Profile
  - True change claim (from the DWI TF) used as a model
- Next step is to continue development of Section 3: Profile Activities, providing details for the following subsections: Site Conformance, Validation, Pre-delivery and Image Data Acquisition
- A brief overview was provided on the literature review process for the benefit of ASL TF members; article details were tracked in a Google Sheet (contact [Dr. Laue](#) or [Chung](#) for the link)
- Many sections are complete and subject matter expert volunteers, especially physicists, are needed to refine them
  - PDF-MRI BC members are encouraged to review the [DCE Profile Google Doc](#) and add comments
  - Brief discussion on FDA text regarding gadolinium agents and safety guidelines and how it is addressed in the DCE profile
  - PDF-MRI members were encouraged to attend the February 1 DCE TF t-con
- Goal is to complete this Profile draft during 1Q 2018

#### DWI Update (Dr. Boss)

- Approach to the process of addressing public comments was described
- There has been significant progress made on the resolution of comments

- Dr. Boss explained the process of establishing ground truth for DWI as well as sample preparation
  - ADC measurements regarding ground truth obtained under highly controlled conditions, mitigating typical temperature fluctuation issues
  - NMR sample (centered at RF center) was monitored at 0° C; a robust level of control under NIST
- Status of DWI Profile
  - Over 100 comments were received, including a lot of feedback from the Process Committee
  - All structural issues (including transition to latest Profile template) have been resolved
  - Current focus is on line-item comments
  - Issues related to prostate to be addressed
  - PI-RADS to be acknowledged in the Profile
  - Profile draft will be ready for review by the end of Q1 2018, followed by BC and CC voting
  - Consensus Profile to be posted on the QIBA Wiki once all feedback has been incorporated
  - Planning for the technical validation phase has begun and a checklist is being drafted
  - Questions or comments about the DWI Profile are encouraged and can be submitted to Drs. Boss and Chenevert

#### **“Importance of Test-Retest Studies in Quantitative Imaging” – White Paper on Reproducibility Study Needs**

- This effort, led by Dr. Amita Dave, is motivated by the dearth of published test-retest data and inconsistency in how the data are collected and presented, especially in some sub-modalities like DCE and DWI
- The goal is to standardize how the data are collected, analyzed and reported to be most useful for Claim development across various QIBA Profiles
- Dr. Obuchowski edited statements of: study design of test-retest studies, importance of and steps for how to measure repeatability and reproducibility and references of material from metrology workshop
- Dr. Golay referenced a large ASL test-retest study and will send the information to Dr. Dave
- Drs. Yokoo, Reeder, Sirlin and Obuchowski co-authored a PDF study with a significant amount of test-retest data as well
- While QIBA does not have policy on papers submitted for publication, authors to consult Dr. Jackson to maintain a QIBA consistent message; Dr. Jackson to provide some on behalf of QIBA leadership
- The goal is to submit a manuscript for publication in the Journal of Magnetic Resonance Imaging (JMIR) during Q1 2018; it will be presented to the editors and publication policy/guidelines/requirement information will be requested
- Dr. Dave to highlight in the introduction how the DCE TF discovered the need for this paper during its literature review
- White paper draft to be completed and shared with PDF-MRI BC members for review and feedback within a couple of weeks
- Suggestions/input for white paper can be submitted directly to Drs. Boss, Chung or Dave

**Next PDF-MRI BC Call:** Wednesday, February 14, 2018 at 11 AM CT

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