

## QIBA Diffusion-Weighted Imaging MR Biomarker Committee (BC) Call

Thursday, August 20, 2020 at 2-4 pm (CT)

### Call Summary

#### Participants

Michael Boss, PhD (Co-chair)

Dariya Malyarenko, PhD (Co-chair)

Edson Amaro, MD

Trevor Andrews, PhD

Ishtiaq Bercha, MSc, MSEE

Thomas Chenevert, PhD

Amita Shukla Dave, PhD

Dena Flamini, RT (R)(MR)(M)

Gloria Guzmán, MD, MSc, MPH

Annelise Malkus, PhD

Daniel Margolis, MD

Felipe Nascimento, MD

Nancy Obuchowski, PhD

Brian Taylor, PhD

Lisa Wilmes, PhD

Junqian (Gordon) Xu, PhD

#### RSNA

Joe Koudelik

Susan Stanfa

**Moderator:** Dr. Boss

#### Review of Previous Call Summary

- The notes from the July 16, 2020 DWI BC t-con were approved as presented

#### Profile Conformance – Self-Attestations Procedure (Dr. Boss)

- An overview related to the purpose of Profile conformance was provided, but further elaboration will occur by Drs. O’Callaghan and Zahlmann on an upcoming call
- QIBA Profiles that have advanced to the Consensus Stage are available to interested parties (clinical sites, CROs, equipment and/or software vendors) to demonstrate that all relevant actors of an institution or product conform to the respective Profile
- Testing sites create a structured report (or self-attestation document) including a conformance statement, assessment results, completed checklists, protocol used, numerical scores for things like noise/resolution metrics as stated in Profile and any other required materials
- The conformance-testing process demonstrates that the checklist has real-world feasibility
- To advance to Stage 3: Technically Confirmed, several sites need to have performed the Profile, found it to be practical, and expect it to achieve the claimed performance
- CROs are instrumental in helping BCs to get valuable feedback to allow them to make improvements to their Profile

#### Brazil Phantom/Patient Study Review (Drs. Amaro and Nascimento)

- The presentation, “Multi-centric standard practices in quantitative Diffusion Weighted Imaging: implementation and evaluation in clinical practice in Brazil,” was provided by PhD candidate, Felipe Barjud Pereira do Nascimento, MD and PI, Edson Amaro Júnior, MD, PhD, from Hospital Israelita Albert Einstein (São Paulo, Brazil)
- The main objective was to evaluate QIBA DWI Profile adoption in routine clinical practice; specific goals included:
  - Measure QIBA DWI Profile parameters in phantom and normal human exams and evaluate staff training
  - Measure spatial coincidence of ROIs placement in human brain MR exams
  - Measure ADC variability in phantoms and individuals
  - Develop an *in vivo* correction factor to allow common use, understanding, and benchmarking of DWI from different MR systems
- Data from two different institutions were used, encompassing eight imaging sites, 18 MR systems from three different vendors, and two magnetic fields (1.5 and 3.0 T)
- Subjects were selected retrospectively – *secondary analysis* of routine brain MR exams from participating research centers
- Inclusion and exclusion criteria and sample size were provided

- Image acquisition and image analysis methodologies were explained
- Challenges included temperature issues in phantoms and position ROIs
- Drs. Amaro and Nascimento may have demonstrated the feasibility of the DWI Profile's brain protocol
- Advancement to Profile Stage 3 requires drafting a checklist and sending it to 2-3 sites to determine whether the requirements are feasible; it is also necessary to demonstrate that conformance activities in Section 4: Assessment Procedures, can be performed
- The collected phantom and clinical data may help advance the DWI Profile to Stage 3: technical confirmation, for the brain disease site

#### **Washington University Phantom and Patient Study (Drs. Guzmán Pérez-Carrillo, Andrews)**

- A project is underway to obtain Head & Neck test-retest data and has been funded by an ASFNR foundation grant
- Phantom scanning is being conducted using default scanner parameters, rather than QIBA parameters; the rationale is to duplicate existing clinical practices to assess variability and then to normalize the data afterward
- It will be determined whether test-retest data can be obtained from real subjects, using methodology described in the Dave A, et al. *Tomography* 2019 paper
- Discussion re: how other teams have conducted test-retest scan studies on Head & Neck
  - With the ideal methodology for performing a test-retest study, the principle is to image a lesion or tissue at two different examination dates on a patient known to not have any change, with no machine recalibration between scans; this may not be feasible due to time constraints or patient illness
  - Other sources of variability/experimental noise involved in MR test-retest include positioning, shimming, landmarking, etc. can still be revealed without having the subject leave the table
- QIBA groups have had challenges obtaining vendor imaging protocol sequences, making it difficult to assess variability among different scanners
- Between the Brazil, Washington University, University of Michigan, Memorial Sloan-Kettering Cancer Center studies, there may eventually be sufficient test-retest data to add a Head & Neck Claim to the DWI Profile
- MR Physicist, Trevor Andrews, PhD, is providing his expertise with technical and quality control details for this Washington University study with Gloria Guzmán, MD, MSc, MPH
- Staff to organize an ad hoc meeting to discuss and develop a plan both for groundwork Head & Neck data (to inform a DWI Profile Claim) and prospective data that uses H&N specifications to confirm the claim from the groundwork study

#### **Discussion on VERDICT team data/collaboration, next steps (Drs. Malyarenko, Margolis, Obuchowski)**

- The DWI BC has been in contact with a research team in the UK, led by Dr. Shonit Punwani, that developed a promising quantitative technique for prostate diffusion MRI called VERDICT
- This approach yields a QIB called the intracellular volume fraction (FIC), which they compared to ADC in a test-retest study published in *Radiology*
- Dr. Malyarenko has spearheaded the collaboration with the VERDICT team to encourage a companion publication that reports on this work using wCV rather than the ICC repeatability metric employed in their original publication
- The DWI BC and VERDICT team have discussed prospective DWI data acquisition, which could provide ADC test-retest data to confirm the DWI claim
- In combination with the ACRIN 6701 study, there may now be sufficient data to refine and better support the prostate Claim with additional literature
- Because mean ADC in test-retest is not consistent from patient to patient, wCV may not be as useful as wSD
- Discussion needed re: collaboration and plans for future prospective study to lead to Claim confirmation for prostate

- VERDICT meeting with interim analysis to be organized, rather than waiting until the full analysis has been completed; potential update to occur during the Sept. 17 DWI BC call
- A path forward for Profiles with disease site-specific Claims to be determined
  - Patient data are critical to demonstrate the feasibility of the Profile
  - Obtaining funding for test-retest studies is a challenge
  - The DWI BC is hopeful that data can be obtained from additional institutions re: disease sites other than brain; there may be a prospect for an additional study in Brazil
  - Collaboration with the VERDICT team and experience with ACRIN 6701 provides encouragement that the prostate protocol is achievable
  - Discussion with MR CC Co-chairs, and perhaps EC/SC needed re: this opportunity for acquiring claim confirmation data; it was noted that no other QIBA group has achieved [Stage 4: Claim confirmed](#)

### **White Paper (Dr. Boss)**

- Dr. Boss is leading the effort to draft a white paper to inform the public about the DWI Profile, promote QIBA DWI BC efforts, and better engage the radiology community
- Due to insufficient time remaining to fully address this item, discussion will resume during the 2-hour Sept. 17 DWI BC Call

### **Next Steps**

- Staff to organize an ad hoc call to discuss and develop a plan both for groundwork Head & Neck data (to inform a DWI Profile Claim) and prospective data that use H&N specifications to confirm the Claim from the groundwork study
- Dr. Boss to confer with the Process Cmte re: next steps for advancing the DWI Profile to Stage 3: Technical Confirmation, specifically to discuss how to move forward with a multiple site Profile structure

### **Next DWI-MR BC Call: Thursday, September 17, 2020: 1 – 3 pm (CT)**

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