

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

Thursday, September 17, 2020 at 1-3 pm (CT)

*Draft Call Summary*

### Participants

*Michael Boss, PhD (Co-chair)*

*Dariya Malyarenko, PhD (Co-chair)*

Trevor Andrews, PhD

Yoganand Balagurunathan, PhD

Ishtiaq Bercha, MSc, MSEE

Thomas Chenevert, PhD

Amita Shukla Dave, PhD

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

Daniel Margolis, MD

Nancy Obuchowski, PhD

James O'Callaghan, PhD

Savannah Partridge, PhD

Lisa Wilmes, PhD

Gudrun Zahlmann, PhD

### RSNA

Joe Koudelik

**Moderator:** Dr. Boss

### Review of Previous Call Summary

- The notes from the August 20, 2020 DWI BC t-con were approved as presented

### Profile Conformance – Technical Conformance: Next Steps (Drs. Boss, O'Callaghan and Zahlmann)

- Progress re: DWI conformance efforts over the last year was presented
- Invicro's conformance testing and process feedback (as both an iCRO and imaging site) proved most valuable to make needed Profile refinements
- A push beyond QIBA members was deemed the next step
- The Self-attestation (SA) conformance pathway was seen as a simple process, in concept
  - Draft Profile text, Actors identified, and checklist created
  - Users implement the Actor requirements outlined in the checklist
  - Users document their work
  - Users (if passed) become Registered
- Invicro used a DWI conformance template to record and submit their activities (listing which Actors were tested)
- Lessons learned based on Invicro feedback will help advance the Profile to the Technically Confirmed and perhaps the Claim Confirmed stages
  - Feedback loops are critical to create a smooth workflow process
- Dr. O'Callaghan noted that the current DWI checklist will be implementable by academic centers, but may be too rigorous for the broader imaging community, e.g., medical physics support may not be available, etc.
- Consensus was that the DWI conformance documents were not appropriate for clinical trial use as currently written; a translational step is needed for iCROs to use in clinical trials
- Separating the DWI checklist based on Actors was recommended to help clarify user requirements
- Suggestion made to develop specific guidance materials for clinical trialists; this was already underway in the FDG-PET BC
- Dr. O'Callaghan provided the Invicro user experience, noting that the Mind Map protocol shared many performance parameters with the QIBA Profile, and fell within the QIBA conformance criteria
- An ice water phantom from CalibreMD was used, but it was noted that obtaining and using such a study-specific phantom was a potential challenge
- Qualitative inspection of images was performed, as well as a quantitative analysis with the MATLAB script
- All data went into a report that was submitted to QIBA staff, which resulted in a conformance statement being issued
- Next steps re: Invicro and QIBA involve maintaining their conformance standing, repeating phantom measurements, and exploring the conformance process as a core lab, e.g., organizing a multisite study in the near future

- Next steps for the DWI Profile included pursuing Technical Confirmation, which is organ-independent and can be established with a phantom in contrast to “clinical confirmation”, which is organ-based since the claims were organ-specific. Current two conformance tests performed by InVICRO and Brazyl consortium are sufficient to advance the DWI profile to “technically confirmed” status, which Dr. Boss will bring to attention during the next QIBA MR CC call.
- Dr. Chenevert noted that in addition to fabricating the ADC phantom, Calibre MRI was developing their own automated analysis software (qCal) which would automatically address Profile measurements
  - Providing ADC phantom data to analyze with this new software package was suggested
  - If the analysis is acceptable, Calibre MRI could be the DWI BC’s 3<sup>rd</sup> party certification service, as Accumetra is for Small Lung Nodule conformance
  - A “Pass/Fail” step is still needed in the DWI conformance process
  - Dr. Chenevert was cautious and posed two questions:
    - Would qCal perform the conformance process according to QIBA requirements?
    - Would qCal or QIBA issue the conformance Mark to successful sites?
  - Model 1: Use the qCal software only to perform data analysis (link customer directly to Verellium)
  - Model 2: Allow qCal to provide the full conformance service, e.g., analyze and issue conformance
  - Follow up discussion is needed with Calibre MRI (Drs. Boss, Chenevert and Malyarenko)

**VERDICT Team Data/Collaboration: PCa ADC w SD Results (Drs. Malyarenko, Obuchowski and Margolis)**

- Dr. Malyarenko reported that ADC repeatability data and analysis has already been shared by VERDICT team
- Collaborations were ignited by a *Radiology* publication last year based on a large repeatability prostate study for VERDICT method, which did not provide wCV/wSD
- Primary aim of this collaboration is to improve the Profile ADC claims by re-analyzing this data to derive wSD/wCV; a secondary aim is to guide ROI placement and size selection by studying their effect on repeatability statistics
- Dr. Obuchowski noted a small negative correlation between ADC and ROI size and between wSD and ADC, feedback is welcome for further discussion
- No positive correlation was found between wSD and ADC, so wSD was the statistically preferred repeatability measure over wCV
- The prostate was noted for posing ROI location issues; may need to refine the prostate claim which is currently too broad. There is also notable difference in wSD between index lesions and benign lesions, and within transitional versus peripehrial zone.
- Each organ may need to be addressed in different ways due to tissue differences
- Continued collaboration with the VERDICT team stressed since they share so much data for reanalysis
- A better understanding of how VERDICT obtained test/retest data was needed; was this a “coffee break” process, or only a quick rescan of subjects?
- Focusing on index lesions and normal T2 suggested for a prospective study
- Dr. Margolis noted that ADC as a BM may not be very useful, since more complex algorithms may be required to distinguish between normal and diseased tissue. Hence, it is useful to assess repeatability and bias for alternative DWI BM.
  - Perhaps an ADC cut-off, or threshold for normal/disease would be more clinically significant depending on the b-range used for ADC calculation

- Next Steps:
  - Identify more test/retest publications to better inform PIRADS and help refine our Profile claims
  - Add repeatability to the prospective VERDICT protocol
  - Prospective study to incorporate all our knowledge and have B value ranges sampled according to PIRADS
    - The PIRADS BM was FIC, not ADC; perhaps the Profile could expand in the future to include more BMs
    - Any test/retest study design must be practical, such as a coffee break scenario (simply scanning twice is not statistically acceptable, and repeating the scan 4-5 days later may not be feasible)

### **DWI Groundwork Proposal on H&N Repeatability (Drs. Dave, Guzmán Pérez-Carrillo, and Amaro)**

- An ADC claim is needed for H&N; HN-SCC will be the focus
- Three sites will participate: Washington Univ, Albert Einstein (Sao Paulo), Memorial Sloan Kettering CC
  - MD Anderson CC volunteered as well; more discussion needed in coming months re: their capabilities
- Phase 1: Goal is to identify the bias introduced by pulse sequence approaches
- Phase 2: Claim confirmation efforts using the same three institutions would follow
  - Applying for a RSNA R&E grant was suggested, leveraging off the success of the Sao Paulo team
- Phase 3: Expanding the Profile claim beyond ADC
- Dr. Boss reported that he already submitted the groundwork project to QIBA Leadership, and it was well received
  - A multi-institution study would be of great value to QIBA
  - Two grant applications may be needed to support the study scope
  - Dr. Boss volunteered to draft this grant

### **White Paper (Drs. Boss and Malyarenko)**

- Dr. Boss noted that some progress has been made, but additional discussions will be tabled until October 15
- Feedback always welcomed

### **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
- Dr. Boss to assess R&E grant opportunities and begin drafting a grant

**Next DWI-MR BC Call: Thursday, October 15, 2020: 2 pm (CT)**

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