

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

Thursday, August 9, 2018 at 2 PM (CT)

### Call Summary

#### Participants

Michael Boss, PhD (Co-Chair)

Edward Jackson, PhD

Nancy Obuchowski, PhD

#### RSNA

Susan Stanfa

Thomas Chenevert, PhD (Co-Chair)

Dariya Malyarenko, PhD

Moderator: Dr. Boss

#### DWI Profile Update

- Drs. Chenevert and Malyarenko presented the few remaining Profile issues discovered during the process of reconciling public comments
- Discussion on how to address subject repeatability conformance/assessment
  - Details currently located in Section 3.0.2: Site Conformance specification table
  - Clarification on wording/numbers requested from Dr. Obuchowski
  - Discussion regarding the required number of human subjects for feasibility testing
    - Obtaining 30 – 40 subjects deemed unlikely due to cost, resources, approach, etc.
    - Concern re: inability of sites to complete this study to demonstrate conformance
    - The conformance bar should be set close to the target number of n=35
    - When a small vendor test-retest study is performed, a very strong outcome is needed in order to claim conformance; with a smaller sample size, a 95% confidence interval is more difficult to reach
    - Due to committee concerns regarding associated costs with using a greater number of human subjects, Dr. Obuchowski reduced her accrual recommendation from 30 to 20
  - Discussion regarding structure of the Profile and how it would be consumed by its audience
  - Two stages of feasibility-testing:
    - Manufacturer tests to see if scanner is conformant
    - Sites test Claims
  - Most scanners deemed capable of attaining Profile conformance with minimal effort
  - Assessment procedure meant for manufacturers to consider incorporating into their products
  - Discussion regarding site vs. study; several sites with fewer subjects vs. fewer sites with more subjects
  - Discussion on how to provide guidance on demonstrating Profile conformance; for reference, the latest draft of the Assessment Procedure Guidance document can be found on the QIBA Wiki at: [http://qibawiki.rsna.org/index.php/Assessment\\_Procedure\\_Guidance](http://qibawiki.rsna.org/index.php/Assessment_Procedure_Guidance)
  - Before embarking on a clinical study, Dr. Obuchowski recommended conducting a phantom study to determine repeatability and bias
  - Specific protocols for human and phantom studies would be very different
    - Because variability is reduced by using phantoms instead of human subjects to determine test-retest at a site, suggestion to require a greater number of scans to make measurements more rigorous (can also harmonize across platforms and sites more closely)
    - Another approach is doing test-retest with human subjects but with an immediate second scan (as opposed to having the human subject leave and return to table between scans), which would result in significant amount of within-subject Coefficient of Variation (CoV) data

- Process Cmte to be consulted regarding feasibility of conducting test-retest studies of this nature and whether tech-confirmed vs. clinically-confirmed processes can be separated out
  - Discussion on replicating the MRE BC's approach which was to provide technical requirements and outline clinical claim performance assessment
  - Final decision to move assessment procedure specifications currently in Section 3 (Site Conformance) to Section 4 (Assessment Procedures), and separate into technical claim conformance and clinical claim conformance
- Drs. Chenevert and Malyarenko conducted an overall, high-level review to identify redundancies and make the Profile more concise
  - Non-DWI diffusion specs and procedures language were removed, but conformance-testing text, previously moved from the appendix to the body, lengthened Section 4 considerably
  - It was noted that moving Actor-based activities to the checklist will reduce Profile size
- Changes were made to conform to the latest Profile template
- Concern reiterated re: possible perception that the Actor-based activities within the Profile will be too difficult to accomplish due to expense, resources, approach, etc.
  - Current high standards (high performance bar) will be retained to encourage people to strive for ideal performance, following the rationale that the level of performance would decline if it is omitted

#### **Next Steps**

- Dr. Boss to review the Profile and make final edits
- Next DWI BC call will be held in September; in the meantime, an offline call among Profile editors will be scheduled
- With the new, rotating call schedule, future DWI BC calls will most likely be held one Wednesday per month at 11 AM CT; call summaries will be posted on the QIBA Wiki at: <http://qibawiki.rsna.org/index.php/Committees> for those who are unable to attend
- Dr. Boss to send email re: details on new call schedule within the next few days to RSNA staff for distribution

#### **Next DWI BC Call: TBD**

---

RSNA Staff attempt to identify and capture all committee members participating on WebEx calls. However, **if multiple callers join simultaneously or call in without logging on to the WebEx, identification is not possible.** Call participants are welcome to contact RSNA staff at [QIBA@RSNA.org](mailto:QIBA@RSNA.org) if their attendance is not reflected on the call summaries.