## **QIBA Process Committee Call**

Tuesday, August 21, 2018 at 3 PM CT Call Summary

Attendees:

Kevin O'Donnell, MASc (Co-Chair)

Daniel Sullivan, MD (Co-Chair)

Edward Jackson, PhD

Michael Boss, PhD

Edward Jackson, PhD

Susan Stanfa

## **QIBA Procedures**

- Mr. O'Donnell to make final revisions of the procedural guide and post to the QIBA Wiki
- Mr. O'Donnell reviewed proposed QIBA <u>meeting procedure</u> updates currently under consideration; proposals to be drafted for consideration during the September 20 QIBA Steering Cmte meeting
  - Threshold for losing voting privileges:
    - Currently, privileges are lost upon missing two consecutive meetings
    - The Process Cmte will submit a proposal to revise to missing two out of four for losing voting eligibility
  - Additional discussion is needed on whether responding to a ballot should count toward attendance/participation
  - Additional discussion is needed on whether or not the Secretariat emails the ballot notification to all BC members (regardless of voting eligibility)
    - In some cases committees have 200+ members but fewer than 10% are eligible to vote

## Addressing Subject Repeatability Conformance/Assessment

- Discussion regarding feasibility of conducting test-retest studies and whether technically-confirmed vs. clinically-confirmed processes can be separated out
- Concern regarding inability of sites to demonstrate conformance due to time and expense for testretest studies
- Minimum level of conformance is needed that will accommodate all users
- Follow up discussion with the DCE BC is needed to clarify that as long as all "Shall" statements are addressed in the Profile, an Actor will be conformant
- Vendor product validation activity typically needed only once per product line
- There are many parallels between DCE and DWI regarding Claim conformance procedures
- The MRE BC's approach which was to provide technical requirements and outline clinical claim performance assessment
- Discussion regarding sufficient procedures for demonstrating conformance
  - "Technically Confirmed (Stage 3)" and "Clinically Confirmed (Stage 5)" generally refer to <u>Profile stage</u> maturity, rather than conformance requirements
  - Stage 3 (The Profile has been found to be practical) will be a straightforward step for the DWI BC

- Stage 5 (The Profile is proven to be practical and achieve the claimed performance) will be much more expensive and time-consuming
- Ideal procedure: if groundwork done appropriately, sites/Profile users wouldn't have to conduct test-retest studies as long as each actor is within their performance envelope
- Intermediate procedure: product validation done once per product by manufacturer to test whether scanner is conformant
- If a site has met all of the "shalls" within a Profile, they are conformant
- The use of phantoms is sufficient for demonstrating conformance, but the Profile would need to be written with specific protocols for phantom studies, as the protocol for human studies differs
- For site that wants to measure performance, suggestion to include procedures in the Profile for this
  as a voluntary activity
- There is a dearth of test-retest data on prostate-specific reproducibility, but the hope is that DWI
  Profile work is an opportunity to gather more data and obtain more accurate reproducibility
  numbers
- <u>Stage 4: Claim-Confirmed</u>: The Profile has been found to achieve the claimed performance, and is ready for Clinical testing, i.e., "if you follow technical requirements, you should meet performance in Claim"
- Dr. Boss to bring the information gathered during this discussion back to the DWI BC
- In order to get funding for groundwork studies, BCs may choose to partner/collaborate with other organizations (e.g., MSK BC / Arthritis Foundation)
- Reminder that it is very efficient for vendors to pre-validate scanners to a great degree of precision; cooperation between manufacturers and QIBA groups would be beneficial
- Mr. O'Donnell to write up issues and outcomes discussed and post them as guidance in an appropriate place on the QIBA Wiki, e.g., on a "Concepts" or "Common Issues" page

Next Call: Tuesday, September 18, 2018 at 3 PM CT