QIBA Process Committee Meeting

Tuesday, March 15, 2022, at 2 pm (CT)

Meeting Summary

Attendees:

Kevin O'Donnell, MASc (Chair)

Michael Boss, PhD (Vice Chair)

Nancy Obuchowski, PhD

David Soltysik, PhD

Susan Stanfa

Daniel Sullivan, MD

Topics Discussed:

- Review of Estimates of Precision Guidance Text drafted by Dr. Obuchowski
 - Since Claim in Profile stages 1 3 is a hypothesis, it should not be cited
 - Test-retest, bias, or linearity requirements for performance not recommended except for those expected be part of site conformance when the Stage 4 Profile is published. Those need to be present in Stages 1-3 so people can comment on and/or test their practicality.
 - o In Profile stage 4, The assumptions underlying the Claim have been verified in a multi-site trial
 - To conform to stage 4 and utilize the Claim, sites use data from the trial to show non-inferiority with claimed precision and bias (showing linearity would be a BC role, not a site role)
 - Definition of non-inferiority needed, e.g., wCV not more than 1%, 2%, 3% greater than Claim
 - o In a Claim-Confirmed (stage 4) study, the Claim has been verified in a multi-site, multi-vendor study and the results are expected to be generalizable in similar settings
 - Exact number of sites and vendors to be defined
 - Test of null hypothesis that wCV > Claim vs. alternative that wCV ≤ Claim
 - This stage should include a refinement of the Claim
- Streamlined Profile Template Drs. Boss and Soltysik
 - o Use of this template has encouraged the fMRI BC to limit checklists to only items required to achieve Claim
 - Extraneous details moved to Appendix A, which was renamed to avoid confusion with checklist specifications

Next Steps / Action Items:

- Dr. Obuchowski to finish guidance text for PC review/wiki posting by the end of March re: <u>estimates of precision</u> required when Profiles advance through stages vs. when imaging sites attempt Profile conformance
 - CT Volumetry Profile ballot to be distributed to BC voters and <u>Estimates of Precision Guidance Text</u> to be posted on QIBA Wiki
- Naming convention to distinguish between same-stage Profile versions and facilitate referencing / citation
 - Year edition was suggested, though a contingency plan regarding multiple Profile updates within the same year would be needed
 - Suggestion that minor changes be indicated with .1, .2, .3, etc.
 - Profile Editors to be contacted with explanation of intentions for meetings and suggestions for topics/issues/questions and logistics/timing to be requested
 - Process Cmte leaders to reach out to CC Co-chairs for feedback on Profile versioning
 - o Profile nickname vs. formal name; how titles look and sound to reference
- Agenda items for April 5 Process Committee Meeting include:
 - <u>Streamlined Profile Template</u> fMRI BC progress toward public comment (stage 1) and barriers (Drs. Boss, Elsinger and Soltysik)
 - Profile Maintenance/Versioning/Naming (Drs. Boss, Pepin, and Yap)

- o <u>Process Committee Profile Selection Process</u>
 - Number of tasks vs. bandwidth
 - How to identify when a proposal is a practical use of time and would characterize a successful Profile
- o <u>Estimates of Precision Guidance Text</u> Dr. Obuchowski plans for wrapping up

Next Process Committee Meeting: Tuesday, April 5, 2022, at 2 p.m. (CT) [1st & 3rd Tuesdays of each month]