

QIBA Process Committee Call
Tuesday, January 21, 2020 at 3 p.m. CT
Call Summary

Attendees:

Kevin O'Donnell, MASC (Chair) Nicholas Petrick, PhD
Alexander Guimaraes, MD, PhD Daniel Sullivan, MD
Nancy Obuchowski, PhD

RSNA Staff:

Joe Koudelik
Susan Stanfa

Discussion Regarding Common QIBA Profile-writing Issues

- Mr. O'Donnell has observed a level of process inconsistency across multiple BCs
- A guideline/list of “dos and don'ts” regarding Profile development was previously circulated among Profile editors, but no feedback was received
- Every Profile needs to include within-subject coefficient of variation (WcV) and the user needs to conduct testing to determine whether they can meet the Claim
- There was concern that many Profiles have gone out to public comment missing crucial information in Sect 4
- Suggestion to add information to the QIBA Wiki, including a link to Section 4: Assessment Procedure of a Profile and describe how to perform a test-retest study
 - Profile editors need to be engaged in these process discussions – suggestion to add them to the Process Cmte email list
 - Process Cmte Co-chairs and Dr. Obuchowski to draft motivational wording for an invitation to help Profile editors with Section 4 and attain consistency across QIBA Profiles
 - Discussion re: “[How to Write a Profile](#)” QIBA Wiki page – suggestion to point broadly to Claim guidance, but include a bulleted list with a WcV preparation checklist
 - Concern re: overcommitment of QIBA members; those with more time to devote may not have the QIBA knowledge experience as those who are familiar with the QIBA process but have less time to contribute
 - Suggestion to add (require) one representative from each CC to the Process Cmte to better engage and share information
 - An additional step to be added to the internal BC Profile review process, requiring that Profile editors complete a “QA checklist” before a vote-to-release for public comment
 - Mr. O'Donnell and Dr. Obuchowski to create a combined checklist of process and statistical requirements, with the goal of informing Profile editors what is missing; staff to direct BC Co-chairs to complete this document
 - Dr. Guimaraes to inform CC co-chairs about this new checklist

Biomarker Adoption Steps and Supporting Materials

- Review continued of Mr. O'Donnell's [Google Document](#), which was developed to provide a common understanding of how QIBA materials are used and by whom
- There has been a move toward a separable Profile format/structure, based on the conformance checklist, conformance statement, and self-attestation package, vs. one all-encompassing Profile document
- Discussion focused on Step 4: Testing Conformance (the actors have indicated they have implemented the Profile and the assessor needs to confirm that is true) and Step 5: Record Testing (what should be recorded and made available when testing)
 - Testing Conformance – suggestions re: relevant outputs:

- Completed checklists, scores for numerical requirements, phantom scans taken during testing, detailed analysis of those scans related to assessments
 - Consider asking BCs to be explicit in the Profile about what must be recorded - some requirements are key, and the score is informative, other requirements may be generic and details not as important
 - Number of systems/people to be determined
- Testing Conformance - checklists, spreadsheets, metric generating software, semi-automated assessments, fully automated assessments
 - Continuum - Pass/Fail, Checklists, scores, datasets behind the scores
 - Discussion re: how onerous is it for sites to manage and store data
 - In efforts to avoid customer pushback, incentives for accreditation bodies to raise the performance bar may be lacking
 - Feasibility is questionable if the bar is too high, e.g. frequency of imaging phantom for each SW/HW change is challenging
 - As the breadth of testing increases, the number of passing sites goes down
 - Focus on the Lead Tech, Chief Radiologist or PI and presume that they will cascade the teaching/checking “as needed”
 - Check annually that sites/actors are using the latest version of the Profile
 - Imaging sites to periodically submit datasets and phantom work
 - Committee consensus was that an imaging site wouldn't have to test all their scanners; only those scanners used to measure the biomarker
- Record Testing:
 - Results need to be recorded and perhaps reported; some procedures involve recording certain values
 - Suggestion that an archive of testing results be made available; information would be reported in a standardized format
 - Independent person able to evaluate what happened is the purpose of record testing
- Discussion to continue during the next Process Cmte call

Next Process Cmte Call: Tuesday, February 4, 2020 at 3 p.m. CT (1st & 3rd weeks of each month)