

QIBA Process Committee

Tuesday, September 21, 2021, at 2 pm (CT)

Call Summary

Attendees:

Kevin O'Donnell, MAsc (Chair)

Michael Boss, PhD (Vice Chair)

Alexander Guimaraes, MD, PhD

Timothy Hall, PhD

Nancy Obuchowski, PhD

Nicholas Petrick, PhD

Daniel Sullivan, MD

Gudrun Zahlmann, PhD

RSNA Staff:

Fiona Miller

Joe Koudelik

Susan Stanfa

Panel Discussion During Sept. 14 Virtual QIBA Annual Meeting: Partial Conformance

- In the early stages of Profile-writing, BCs try to identify all possible causes of variability in the biomarker, but often do not have enough data to differentiate between required and non-required checklist items; this leads to lengthy checklists resulting in unnecessary complexity for end users
- As more BCs approach the Technical Confirmation (TC) process (stage 3), there is a need for guidance regarding how best to respond to test site feedback, especially to “NO” checklist responses; in response, a flow chart will be developed, and improvements will be made to the feedback form

There are three criteria for including checklist requirements in a QIBA Profile:

(a) *Completing the requirement results in discernable **impact** on the performance of the biomarker and WcV, i.e., the Claim*

- The main goals of groundwork during stage 0 are to determine sources of variability, which factors impact performance, and to what extent
- The checklist should be filtered re: requirement vs. best practice in stage 0; if impact on the Claim is unknown, then it should be retained and hopefully addressed during the Public Comment Phase (stage 1)
- During TC:
 - if a testing site believes a requirement has **no** discernable **impact** on the performance of the biomarker and they are right, then the requirement should be removed from the checklist and the site would pass conformance-testing
 - If the site is proven wrong, it should be demonstrated how performance is negatively affected (Claim depends on it); either the site would need to agree and conform, or decide not to conform

(b) *The requirement is violated often enough in routine practice, i.e., not a **redundant** request (is the checklist item really a problem or best practice?)*

- Identifying when more fundamental requirements can be used was recommended e.g., rather than protocol parameters, resolution and noise should be constrained, i.e., the ends are the focus, not the means
- If a site completes the requirement differently, perhaps multiple conformance paths are needed; Claim Confirmation (stage 4) workload may be justified to validate each path, but complexity would be added to the Profile
- Due to different national/regional conventions, regulations, or variations, targeted feedback from international stakeholders should be sought during stage 1

(c) *The clinically relevant **benefit** exceeds the effort/time required to conform*

- If multiple sites believe it is not worth the effort and are right, the BC should consider omitting the requirement and modify the Claim appropriately, if a site is wrong, it should be demonstrated how performance is negatively affected (Claim depends on it) and the site would need to agree and conform, or decide not to conform
- Slightly loosening the requirement, e.g., scan less frequently, and relaxing the Claim should be considered

- If the requirement can be met but the assessment is burdensome, devising an easier procedure to assess the requirement should be considered
- Generating statistical estimates or modeling for partial conformance unique to each Profile was suggested, but it was noted that these data can be obtained during a metaanalysis
- Suggestion to reduce checklist items to only the most crucial, with best practices located in the appendix; items should be returned to the checklist only once conclusive evidence is gathered to support them as requirements
- If a site will be required to complete a burdensome procedure, there must be sufficient support of its effectiveness

Process Committee to Address General Checklist Issues

- Suggestion to create a “Best Practice” section for checklist items that are useful but not required, and an “Assumptions Section,” for redundant items
- Profile users should easily be able to find rationale for a checklist requirement; it was recommended that each item be accompanied by 1-2 sentences that either reference a groundwork study or explain its impact on the Claim
 - Suggestion to add a column to the checklist table that would be included in a stage 1 Profile and could then be migrated to the discussion section following public comment
- Another issue identified was the use of, “Radiologist Board Certification,” as a requirement as it does not directly impact the Claim; providing a brief description of necessary personnel qualifications or skills to complete the task, e.g., well-versed in prostate imaging,” and avoiding requiring specialized certification to perform tasks
- QIBA embodies objective quantitative requirements rather than subjective assessments; automation improves consistency of measurement, e.g., using AI
- The goal is for the radiologist to assess the adequate quality for the measurement being proposed, with the measurement being agnostic of the radiologist

Next Steps

- BC guidance on next steps when testing sites respond that they did not complete a checklist requirement will be developed in the form of a flow chart and improvements will be made to the feedback form
- BC guidance on dividing and structuring checklists for be formulated and introduced during Q4 November CC calls
- Ways to incorporate assessment services and 3rd party tooling into the processes to be discussed during upcoming Process Cmte and EC/SC meetings

Next Process Cmte Call: Tuesday, October 5, 2021, at 2 p.m. (CT) **[1st & 3rd Tuesdays of each month]**