QIBA Process Committee

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

Draft Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Timothy Hall, PhD	Daniel Sullivan, MD	Fiona Miller
Michael Boss, PhD (Vice Chair)	Nancy Obuchowski, PhD	Gudrun Zahlmann, PhD	Joe Koudelik
Alexander Guimaraes, MD, PhD	Nicholas Petrick, PhD		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 metanalysis
- 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]**