QIBA Process Committee

Tuesday, September 7, 2021, at 2 pm (CT)

Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Timothy Hall, PhD	Nicholas Petrick, PhD	Angela Colmone, PhD
Michael Boss, PhD (Vice Chair)	Nancy Obuchowski, PhD	Daniel Sullivan, MD	Joe Koudelik
Cathy Elsinger, PhD	Kay Pepin, PhD	Gudrun Zahlmann, PhD	Susan Stanfa
Alexander Guimaraes, MD, PhD			

Requirements in QIBA Profiles

- There are three criteria for requirements included in a QIBA Profile; a rubric will be considered
  a) Completing the requirement results in discernable impact on the performance of the biomarker, i.e., the Claim
  b) The requirement is violated often enough in practice
  c) The impact exceeds the effort required to conform

(A) Discernable Impact on the Performance of the Biomarker, 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
- An impact case for each requirement should be able to be stated prior to Profile release for Public Comment (stage 1)
  - It was noted that the fMRI BC is currently reviewing the checklist to determine which requirements have a discernible impact on performance
  - Some fMRI BC checklist items are not required for meeting the Claim; if a hypothesis cannot be developed for a requirement, then it should not be included in the Profile checklist

- If the site believes the requirement has no discernable impact on the performance of the biomarker and the BC decides it is right, then the requirement should be removed from the checklist and the site would pass conformance-testing
  - If the site believes there has been no impact and is wrong, it should be shown how performance is affected; either the site would need to agree and conform, or decide not to conform

- A BC process for modifying checklists based on site feedback, and a formal checklist review process to be developed for inclusion in Profile stage criteria
- Discussion re: maintenance process after a BC has deemed a Profile completed
  - A flowchart was suggested, although some details/nuance may be difficult to capture in this format
  - Solidity in conformance is needed otherwise the Profile's impact is undermined, which reduces patient value
  - A clear versioning/date system is needed, as major changes made to requirements/metrics/methods, e.g., adding an organ system during Consensus (stage 2), may merit a second public comment process

- Profile development and public comment processes are significantly influenced by the academic community; broader feedback from the types of sites that would implement the Profile, e.g., CROs or CoreLabs, is crucial
- BCs should clearly identify users/stakeholders and strive to target them during public comment and technical conformance; specialized vs. common biomarker usage may be considered
  - Suggestion that CC Co-chairs solicit BC Co-chairs / Profile editor(s) re: who their stakeholders are, volume/quality of feedback received from them, and how to increase/improve response if necessary

- Discussion re: BC role (review the Profile and supporting document and confirm that the Profile meets the criteria for the stage) vs. CC role (review the overall document and verify it is understandable, not burdensome, and likely to be effective) in the Profile approval process

- BC and CC approval without appropriate evaluation is a concern; the Process Committee will address this issue with CCs
- Another critical topic is how BC controversy, e.g., an unaddressed COI, should be handled

(B) Requirement is Violated Often Enough in Practice

- Public Comment (stage 1) is an opportunity to confirm which requirements are violated most often in routine practice, and additional feasibility feedback is provided during the Technical Confirmation (TC) (stage 3) as requirements are performed by sites
- All machines at sites using many of them need to be checked, i.e., "all relevant actors"
- There are different levels of proficiency with checklist requirements among testing sites, e.g., some sites may perform a step many times daily, while others do it infrequently and with less training

(C) Impact Exceeds the Effort Required to Conform

- Since three or more testing sites need to perform checklist requirements during TC, site feedback can help a BC to determine whether the impact of a requirement is significant enough to justify the effort required to conform
- If the majority of sites conclude that the impact of a particular requirement does not justify the effort, the BC should consider omitting the requirement and modify the Claim appropriately
- If the minority of sites do not think that the effort is justified, the BC would need to decide whether they would prefer that the Profile to be more widely adoptable or whether the margin of performance is truly clinically needed
  - If the latter, the sites would not be in conformance

Discussion re: Whether Conformance is Binary

- All checklist requirements need to be met to achieve the Claim performance
- If a requirement can be omitted while still achieving the Claim, that requirement should not appear in the checklist
- The purpose of TC is to confirm that all requirements can be performed; passing all requirements is the only path to conformance
- Claim Confirmation (stage 4) involves confirming that a site's performance achieves the Claim when the checklist is followed
- Condensing multiple "partial" requirements, i.e., identifying when more fundamental requirements can be used, was recommended

Next Process Cmte Call: Tuesday, September 21, 2021, at 2 p.m. (CT) **[1st & 3rd Tuesdays of each month]**