

QIBA Process Committee

Tuesday, June 15, 2021, at 2 pm (CT)

Call Summary

Attendees:

Kevin O'Donnell, MAsc (Chair)

Michael Boss, PhD (Vice Chair)

Nancy Obuchowski, PhD

Kay Pepin, PhD

Daniel Sullivan, MD

Gudrun Zahlmann, PhD

RSNA Staff:

Joe Koudelik

Susan Stanfa

Performance Claim Status and Site Performance at Stage 3: Technical Confirmation

- The Stage Transitions and Conformance diagram was referenced to clarify the nuances of Profile development (QIBA) vs. site (end user) conformance
- Conformance language needs refinement, specifically (1) what a BC is asserting about a Stage 3 Profile Claim, and (2) assumptions imaging sites can make about their performance
- A site can achieve a high level of image quality/better performance as a result of using Profiles at stage 1-3, but cannot attest to meeting the Claim yet since it is still only a hypothesis
- If a Profile has successfully assessed the technical performance of a scanner, e.g., used an ice water phantom and assessed repeatability measurements, the Claim is more robust than an “educated guess”
- The FDG-PET BC, with the most-advanced QIBA Profile and pilot testing experience, developed a scoring system to address the inability for imaging sites to complete all checklist requirements
 - For example, if a site could meet nine out of ten requirements, it would need to be determined why the one requirement was not met and the BC would proceed accordingly
 - Commonality across checklist requirements during feasibility testing may indicate which requirements are/are not critical for achieving Claims
 - If eliminating a non-critical requirement would not significantly damage performance, removal from the checklist should be considered
 - Claims and requirements must be aligned, and a BC has the discretion to adjust the Claim, e.g., decrease the confidence, as necessary
- Suggestion to include a self-attestation statement in the checklist form, so sites would be required to confirm that every requirement was executed
- Profile requirements need to eventually have been “tested practical,” otherwise, Profile development would be just an academic exercise

Wording/Concept Improvements

- The performance Claim descriptor, “educated guess,” to be updated to a more scientific/rigorous term such as “hypothesis”
- Suggestion to update site performance descriptor, “better-than-average” to “literature-based estimate,” as strength varies among Profiles
- Describing stages in terms of a progression of levels of performance may be considered
- Other suggestions for wording improvements are welcome
- The boilerplate text near the Claim section in each stage 3 Profile will be updated to clarify its meaning and significance; once a Profile advances to stage 4, boilerplate text will be updated again to reflect the increase in proof, evidence, and confidence

[QIBA Profiles: Success Factors and Challenges Assessment](#)

- The goal is to solicit feedback from BCs on various Profile-related topics; detail is intended to feed into improvements of QIBA process overall, including biomarker selection criteria, onboarding process for new BCs, Profile development and milestone tracking, Profile adoption, etc.
- Definitions of a successful Profile included prompt advancement from stage 1 – 4, value added to end users (sites and clinical trials) through Profile implementation, and impact on the field, e.g., the MRE Profile
- BCs to be asked what characteristics and factors facilitated advancement to stages 3 and 4, and to identify barriers
- Process Cmte members were asked to provide input on questions and how information should be collected and assessed

Conformance Testing for Software Companies

- The QSIC has been discussing this topic and Dr. Zahlmann sought Process Cmte member feedback
- QIBA Self-Attestation (conformance assessed by the vendor or site) and QIBA Certified (conformance assessed by a 3rd party) are the current pathways for QIBA Profile conformance
- CaliberMRI manufactures a phantom and analysis software and would like to certify sites for partial conformance as a 3rd party; there was concern about QIBA's role in ensuring it will be done properly, i.e., validating the analysis software
- If a particular metric in the Profile is selected for conformance requirements, then the BC would provide the acceptable procedure for generating that metric as well as the acceptable pass/fail threshold
- The testing tools used to assess the Profile requirements would need to be evaluated
- The BC would define reference datasets and results for testing tools as well as testing sites and/or products
- CaliberMRI would need to attest that the proper procedures were followed and provide supporting documentation for BC review and approval/validation
- Mr. O'Donnell noted that testing and certifying 3rd party vendor tools and services was beyond the current scope, exposing QIBA/RSNA to greater responsibility and liability for these vendor products
- Clarification would be needed re: what the 3rd party software tool is attesting to end users (imaging sites) and what QIBA is attesting to re: the 3rd party vendor

Action items

- PC members were encouraged to add additional information to the [“QIBA Profiles - Success Factors and Challenges” Google Doc](#) and asked to think about how to collect and assess BC data
- Conflict of interest text will be reviewed during the 6/17 SC meeting
- Mr. O'Donnell to update the [Conformance Method Comparison Google Doc](#)

Next Process Cmte Call: Tuesday, July 6, 2021, at 2 p.m. (CT) **[1st & 3rd Tuesdays of each month]**