

QIBA Process Committee

Tuesday, May 18, 2021 at 2 pm (CT)

Call Summary

Attendees:

Kevin O'Donnell, MASC (Chair)
Alexander Guimaraes, MD, PhD

Nancy Obuchowski, PhD
Daniel Sullivan, MD
Kay Pepin, PhD

RSNA Staff:

Joe Koudelik
Susan Stanfa

Profile Stages and Profile Conformance

- Mr. O'Donnell drafted a diagram to illustrate and clarify the nuances of Profile development vs. site (end user) conformance, which is being discussed during Q2 Coordinating Committee meetings

Claim Development at Profile Stages and Conformance at Each

- QIBA Profile Claims, values, procedures, and requirements in stage 1 or 2 Profiles are typically based on untested Claims; checklist requirements are not yet stable, and changes may be needed
- While a site has achieved a high level of image quality and has better performance as a result of meeting requirements of a stage 1-3 Profile, they cannot state that their quantitative performance will achieve the Profile Claims yet, i.e., that they have achieved conformance
- Due to the amount of data collection and validation that needs to occur throughout the Profile development process, a site can claim conformance to only Stage 4 and 5 Profiles
- To avoid Profile users "overselling" their conformance, explanatory language to be incorporated into Stage 1-3 Profiles that downplay conformance since the Claim has not yet been validated
 - To advance from stages 3 to 4, Profile assumptions need to be validated, which would require conducting a test-retest study at a small number of sites (three or more) with a high degree of confidence, e.g., 95%
 - To conform to stage 4, sites still need to demonstrate that assumptions are met before they declare they are conformant, but test-retest with a lower degree of confidence, e.g., 50%, may need to be done

Relationship between Site Practices and Performance at each Profile Stage

- Sites to be encouraged to implement stage 2 Profiles to improve performance and provide data to BCs, but they may not qualify for badge or ribbon until the Profile has advanced to stage 3
 - Sites will have achieved convergence and consistency, but would not yet be conformant to the Claim
 - Site opinion/feedback would help the BC progress toward stage 3
 - Field testing would not be redone unless significant changes are made to the checklist during advancement from stage 2 to 3 in response to site feedback (e.g., elimination of requirements that would impact performance, requirements are added, constraints were tightened, etc.)
- Discussion re: whether conformance is truly binary and whether performance of every checklist requirement needs to be demonstrated to advance from stage 2 to 3
 - It was suggested that at these stages, the focus should be on Profile evaluation and refinement of checklist requirements in response to site feedback, rather than on site performance
 - Commonality across checklist requirements during feasibility testing may indicate which requirements are critical for achieving Claims and which are not
 - If eliminating a non-critical requirement would not significantly damage performance, removal from the checklist may 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
 - Sites to be informed re: impact on performance as a result of not completing a critical requirement

- If a site provides QIBA with conformance data for a Stage 3 Profile, they cannot claim conformance to a Stage 4 Profile even though checklist requirements may be similar
- If Stage 3 checklist requirements are completed with 95% confidence, a QIBA-endorsed letter of merit could be issued in lieu of conformance to endorse site effort
- It was suggested that site performance could be the focus of stage 4 & 5 Profile implementation, utilizing a point system to evaluate success
- All QIBA Profiles include a section 4 assessment procedure to test precision, linearity, and bias (e.g., with phantoms, DROs, etc.) to ensure a 95% confidence in the measurement under the Claim value
 - Suggestion to include a description of the procedure in Stage 1 & 2 Profiles, rather than setting a pass/fail threshold
- Discussion re: agenda items for the May 20 Executive Committee meeting
 - Review of issues QIBA BCs are currently facing in progressing on QIBA Campaign initiatives
 - What it means for a Profile to be at stage 3 and 4, and when a biomarker should be reconsidered
 - Definition needed re: allowable extent of change to a checklist before a field test would need to be repeated
 - Re: conformance testing, does the BC or site decide if a specification is “not applicable?”
 - BCs to be encouraged to include exceptions or workarounds with checklist requirements, e.g., a site’s software does not perform a certain function

Action items

- Mr. O’Donnell to update boilerplate Profile text with explanatory language re: Claim development at Profile stages and conformance at each

Next Process Cmte Call: Tuesday, June 1, 2021 at 2 p.m. (CT)