QIBA Process Committee

Monday, April 5, 2021 at 4 pm (CT)

Call Summary

Attendees:	**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Joe Koudelik
Michael Boss, PhD (Vice Chair)	Fiona Miller
Nancy Obuchowski, PhD	Susan Stanfa

QIBA Profile Conformance Mark Proposal

- Explanation provided re: difference between a conformance mark and progress ribbon
  - A Conformance Mark is awarded to institutions that achieve Profile Conformance, i.e., institutions that meet all QIBA Profile requirements (for all actors)
  - A Progress Ribbon is awarded to an institution when it has demonstrated partial conformance by meeting a BC-defined subset (often the checklist for a key actor or activity) of QIBA Profile requirements

- While an institution has achieved a high level of image quality, they cannot state their quantitative performance will achieve the Profile Claims since they have not adhered to all the checklist items outlined in the Profile
- Discussion on the significance of clinical site conformance vs. clinical site progress at each Profile stage as well as the differences between earning a conformance mark and progress ribbon at each Profile stage
  - Conformance to a Stage 1-2 Profile would not be useful as requirements are not yet stable and changes may be needed
  - Conformance to a Stage 3 Profile would translate into the Profile being practical in the field
  - Conformance to a Stage 4 Profile would confirm that the site Profile practices were implemented
  - Connection between site practices and performance at each Profile stage were outlined

- Self-attestation: requirements are assessed by a Profile participant who makes a formal assertion of conformance
- Certification: requirements are assessed by an independent service who makes a formal assertion of conformance
- Estimates of precision (test/retest): A test where quantitative image biomarker measurements repeated on the same subject is performed to estimate precision

Estimates of Precision (test/retest) in Profile Stages vs. when Sites Conform to Profiles

- Some BCs are using only metanalysis literature to inform Stage 1 Profile Claim values, procedures, and requirements; the Profile has not been based on test-retest study groundwork
- Discussion re: BC choice to include assessment of actors/site precision (test-retest) as a Profile conformance requirement
- All BCs include a Section 4 Assessment procedure to test linearity and bias with phantoms to ensure estimate is under the claim
- BCs will need to prove that Profile requirements have stabilized estimates to ensure that a site following the profile will also have stabilized estimates
- Discussion re: when it is important to do test-retest at Technical Confirmation (TC) (Stage 3)
  - The assumption has been that QIBA experts have developed appropriate estimates of wCV, but when Claims are based only on a metanalysis of literature (i.e., no groundwork has been done), they are untested
  - If Stage 3 (TC) appears to be a natural stopping point for Profiles, limited test/retest studies suggested as a Profile requirement to help gather data; this data could then be analyzed and may help advance the Profile to Stage 4 (Claim Confirmed) quickly
  - It was suggested that only Claim Confirmed (Stage 4) Profiles are qualified for clinical trial implementation, since previous stages are based on educated guesses only

- It needs to be determined whether Profiles should include more requirements but contain a better estimate of precision or if the test/retest should be omitted and the Claim widened accordingly
- Discussion re: whether only a BC should be required to assess precision or if each site should conduct test/retest as part of conformance
- The extent of the burden of a test/retest assessment on a site depends on the amount of data required
    - It may not be too difficult, assuming the phantom is easily accessible and when phantom data captures the variability being sought
    - Suggestion that the phantom needs to closely mimic a human subject and may need to be QIBA-approved
    - Estimating real precision may not need to be the goal; a conformance test would still be better than an educated guess based only on a literature metanalysis
    - It was noted that test-retest variability is 5% in human subjects and 2% in phantoms
    - The goal is to get the best estimate of precision that can be obtained in a reasonable fashion

- Mr. O'Donnell to draft a table with a test/retest row based on discussion with Dr. Obuchowski
    - Precision of both actor and entire site to be addressed
    - Estimation as part of QIBA Profile stage progression to be addressed
    - BC must conduct Site Estimation of Precision to reach Stages 4 and 5
    - If practical, BC might conduct Site Estimation of Precision while reaching Stage 3
    - Estimation of Precision is not really involved in reaching Stage 2 (unless it is ongoing Groundwork)
    - BC usually conducts Site and/or Actor Estimation of Precision as part of Groundwork to reach Stage 1
    - Estimation as part of conformance assessment of each site and/or actor to be addressed
    - BC choice to include assessment of actors/site precision as profile conformance requirement to be discussed; situations that would necessitate such profile requirements to be detailed

Next Process Cmte Call: Tuesday, April 20, 2021 at 2 p.m. (CT)