

QIBA Process Committee Meeting

March 7, 2023, at 2 pm (CT)

Meeting Summary

Attendees:

Kevin O'Donnell, MAsc (Chair)

Michael Boss, PhD (Vice Chair)

Timothy Hall, PhD

Nancy Obuchowski, PhD

Dan Sullivan, MD

RSNA Staff:

Susan Stanfa

Next Steps / Action Items:

Profile Publication Process

- Bullet added to staff checklist on [Publication Process QIBA Wiki page](#): “Checks that the title page and document title match the current stage and profile naming guidance”

Coordinating Committee Systematic Profile Renewal, Revision, Retirement process

- Each Modality Coordinating Committee is responsible for managing their portfolio of Profiles
- QIBA Staff to track when reviews would need to occur and notify CC Co-chairs when a Profile is approaching 5 years since its most recent publication
 - Reviews would not be triggered for actively progressing Profiles that have been republished
 - The CC would be responsible for conducting a review prior to the 5-year standard if technology or clinical practice has evolved
- If the BC/ mailing list is still active, the CC would notify BC Co-chairs of the review and a formal BC assessment/recommendation may be requested
- The CC will vote to Revise (modify, re-approve, re-publish), Renew (re-publish unchanged), or Retire (withdraw from current publication) the Profile
 - If retired, Profiles would be moved from the [Profiles page](#) to a Retired page
- Suggested criteria/considerations for CC discussion:
 - If work on a Profile is underway, a revision decision would be made to allow that process to proceed
 - If there is known adoption of a Profile, renewal or revision would be appropriate
 - If the Claim performance no longer meets current clinical needs, revision or retirement would be considered
 - If technology has advanced to the point where conformance could be made easier or be improved, revision would be considered
 - If new clinical practices or consensus emerged / shifted, Profile revision should be considered
 - The Profile should be harmonized with evolution of clinical expectations and usage
 - Partnership with other organizations and specifications, e.g., EANM, means convergence activities should be initiated
 - Change in regulatory/certification/site conformance criteria environment would trigger an update
 - New publications or trials may also inform Profile updates
 - Unadopted Profiles may be renewed if additional time is needed
- Proposal that CCs review Profiles every 5 years, including suggested criteria, guidelines, checklist, elements for discussion, etc. to be brought to the Steering Cmte during their May 9 meeting

Review and Update of Stage 4 Trial Requirements

- It was agreed that BCs should notify their modality CC Co-chairs when they plan to deviate from the guidelines
- Representation of at least two scanner vendors is a base number, but BCs should consider several factors when deciding whether to raise the standard
 - Unfairly excluding any vendor due to an arbitrary requirement

- May need to constrain to meet performance target
- Biomarker and technology should be considered when setting their target number of vendors – two vendors being able to meet the Claim does not mean that others can meet it
- The need for QIBA’s revalidation of Profiles with each individual vendor would be burdensome for the BC as well as for the vendor; additional consideration of this is needed
- Guidance on near balance in sample size between sites and vendors
 - “A QIBA-associated statistician reviews/approves the overall plan” was added as a requirement, though typically they would have been involved in the Profile drafting process
 - IRBs will often also include statistical review, due to the site’s interest rather than QIBA goals for Stage 4
 - Statistical criteria from Dr. Obuchowski’s 2022 Annual Meeting presentation to be referenced
 - Note: at Stage 4, demonstration of non-inferiority with respect to the Claim differs from confirming the Claim, e.g., if the Profile confidence interval is 10%, and Stage 4 shows 12% but spans 10%

Next Process Cmte Meeting on Tuesday, March 21, 2023, at 2 p.m. CT

- Review of Stage 4 requirements to resume with reference to a specific Profile, Claim, and criteria
- US BC reps to attend