

**QIBA Process Committee**  
Tuesday, May 4, 2021 at 2 pm (CT)  
*Call Summary*

**Attendees:**

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

Nancy Obuchowski, PhD  
Daniel Sullivan, MD

**RSNA Staff:**

Fiona Miller  
Joe Koudelik  
Susan Stanfa

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

- QIBA Profile Claims, values, procedures, and requirements in stage 1 or 2 Profiles are typically based on review of literature/metanalysis (i.e., no test-retest study groundwork has been done); Claims are untested
- Due to the amount of data collection and validation that would still need to occur, conformance to a stage 1, 2, or 3 Profiles does not mean that the Claim has been met; this only applies to Stage 4 and 5 Profiles
- If a site has followed best practices as a result of meeting requirements of a Profile at stage 3 or lower, they will have better than average performance (still a performance benefit), but Claim conformance cannot be declared
- Discussion re: how a software vendor would demonstrate Claim conformance to a stage 3 Profile when a multisite study has not been conducted
- All QIBA Profiles include a section 4 assessment procedure to test precision, linearity, and bias in some way (e.g., with phantoms, DROs, etc.) to ensure a 95% confidence in the measurement under the Claim
- Only after three or more sites have completed conformance testing with 95% confidence and the BC has conducted an analysis and discussed results, can a Profile advance to Claim Confirmed (Stage 4)
- A clearer distinction between a stage 3 Profile conformance and stage 4 Profile conformance needs to be made
  - Discussion re: how to award/credit/acknowledge sites for progress
  - Tracking a variety of certificates, conformance marks, colors, etc. corresponding to different types of progress may be confusing
  - A Profile Claim cannot be met, and conformance cannot be declared when a site is only partially conformant
- Commonality across specifications during conformance testing may indicate to BCs which requirements are critical for achieving Claims and which are not; site feedback to be used to simplify the Profile and associated checklist
  - This could bring conformance within reach of a site formerly unable to perform the omitted requirement
- A considerable amount of feedback on the FDG-PET Profile has resulted from the QIBA/EARL collaboration
  - There was heterogeneity among sites re: adherence/conformance to the Profile and the FDG-PET BC will assess how that impacts the Profile Claim
- Guidance on designing a Stage 3 to Stage 4 study is needed; Claims and requirements must be aligned; while a BC may decide to adjust either as necessary, the study design would need to be modified as well
- Suggestion to add language near Claims in the Profile that will correspond to its stage

**Profile Streamlining**

- Dr. Boss and Mr. O'Donnell met offline to discuss the restructuring of the DWI Profile, to be modeled after Mr. O'Donnell's modified CT Volumetry Profile
- The Section 1: Executive Summary was condensed, and the Section 2 Clinical Context and Claims will be shortened using a compact table
- Section 3 discussions, subsections, interpretations text and imaging protocol specifications were moved to the appendix
- Checklists were moved into Section 3 so that end users will be able to locate requirements more easily
- The goal is to streamline the first 10-20 pages of each QIBA Profile; subsequent sections can be left as is if BCs prefer

**Action items**

- Mr. O'Donnell to draft a proposal re: meaning of Profile stages and implications; Dr. Obuchowski to review it and provide feedback on terminology before it is forwarded to the SC
- Mr. O'Donnell to request that Dr. Zahlmann attend an upcoming PC call as there may be potential overlap with PC/Conformance TF topics

**Next Process Cmte Call:** Tuesday, May 18, 2021 at 2 p.m. (CT)