

QIBA Process Committee Meeting

Tuesday, April 19, 2022, at 2 pm (CT)

Meeting Summary

Attendees:

Kevin O'Donnell, MASC (Chair)
Caroline Chung, MD

Timothy Hall, PhD
Nancy Obuchowski, PhD

Nicholas Petrick, PhD
Daniel Sullivan, MD

RSNA Staff:

Fiona Miller
Susan Stanfa

Topics Discussed:

- [Streamlined Profile Template](#)
- [Profile Maintenance/Versioning/Naming](#)
 - Elements may include Profile name, stage, year, version numbers, full dates of publication
- [Estimates of Precision Guidance Text](#)
 - Key Point is communication of what the conformance means at each level

Next Steps / Action Items:

- [Profile Maintenance/Versioning/Naming](#)
 - Biomarker to be the core of the name; there may be multiple applications and a given Profile focuses on just one, e.g., Elastography for Liver
 - Identify stage, as some sites may want to use only Technically Confirmed Profiles
 - Identify primacy, as some sites may deem newest version as “best”
 - Identify equivalence, as conformance requirements, assessment procedures, and Claim may differ among versions
 - Identify generation of specifications / assumptions
 - Release notes and / or change log to communicate differences between two sequential versions
 - Guidance to specify changes to requirements, process, Claims, etc. may be added to template
- Dr. Obuchowski to finish drafting guidance text for feedback re: [estimates of precision](#) required when Profiles advance through stages vs. when imaging sites attempt Profile conformance
 - General instructions to be written to help actors/sites demonstrate conformance to a Technically Confirmed Profile Claim prior to completing a claim-confirmed study (Stage 4)
 - In Profile stage 4, assumptions underlying the Claim have been verified in a multi-site trial
 - To conform to stage 4 and utilize the Claim, sites use data from the trial to show *non-inferiority* with claimed precision and bias (showing linearity would be a BC role, not an actor/site role)
 - Definition of non-inferiority needed, e.g., wCV not more than 1%, 2%, 3% greater than Claim
 - In a Claim-Confirmed (Stage 4) study, the Claim has been verified in a multi-site, multi-vendor study and the results are expected to be generalizable in similar settings
 - Exact number of sites and vendors to be defined
 - Test of null hypothesis that $wCV > \text{Claim}$ vs. alternative that $wCV \leq \text{Claim}$
 - Claim precision may change in response to study results
 - A separate QIBA TF will be needed to work through non-inferiority aspect of guidance

[Agenda items for May 3 Process Committee Meeting](#)

Next Process Committee Meeting: Tuesday, May 3, 2022, at 2 p.m. (CT) **[1st & 3rd Tuesdays of each month]**