QIBA Process Committee Call
Wednesday, November 15, 2017 at 3 PM CT
Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Co-Chair)	Dawn Matthews, MS, MBA	Eric Perlman, MD	Joe Koudelik
Daniel Sullivan, MD (Co-Chair)	Nancy Obuchowski, PhD	Nicholas Petrick, PhD	Susan Weinmann

Review of the PET-Amyloid BC's Draft Claim Structure – Claim options

- Ms. Matthews discussed the Amyloid Profile Claim structure
- The Amyloid Profile addresses only FDA-approved tracers
- Discussion regarding intention of Amyloid Claims and how they will be applied
  - Claim 1 is a technical performance claim
  - Claims 2 a & 2 b differ from the structure of other QIBA longitudinal Claims due to the lack of bias data
  - Ms. Matthews provided background history on the Amyloid BC's challenges with Claims and presented the issues that were encountered
    - Reference studies were consulted to understand variability and to identify methods for detecting variability
    - Studies that align with the Profile and provide legitimate basis for citing Coefficient of Variation were identified

- QIBA groups have used groundwork studies to estimate the level of noise statistically present in the absence of biological change in order to construct a Performance Claim
- There was some discussion on the level of trust a clinician would place in a measured difference of 8% in pair of SUVR values taken in a short time interval. This may go back to correctly interpreting the meaning of the wCV values and the corresponding 95% confidence intervals. Since a short time period would not allow for "biological change", any measured differences would reflect "measurement error" as described by the wCV. If large measured differences occur with any regularity, it is likely the profile requirements are not being followed, or the profile is missing a requirement on a significant source of variability, or the 2.9% wCV might need revising. Similarly, the form of the claim does allow for periodic (say 1 time in 20) measurement errors that are unexpectedly large.
- Many QIBA Profiles include a "Clinical Interpretation" section in the discussion below the Claims that explains how the Claims might be applied to clinical decision making; this section could be added/expanded in the Amyloid profile to provide additional clarification to clinicians on how the statistical statements in the Claim might manifest in "real life" experiences.
- Mr. O'Donnell observed that the 2.9% wCV for the SUVR seemed surprisingly small in light of the 10-14% wCV for CT volumetry measurements, but that observation was NOT based on any deep understanding of the factors affecting SUVR variability.
- Dr. Obuchowski advised the Amyloid BC to include the Technical Performance Claim in the Profile and omit the longitudinal Claims (Claims 2a & 2b) for now. A rationale for the omission can be included in the discussion section along with the clinical interpretation section which may have some advice for longitudinal cases.

- Link to Clinical Trial guidance on how to use Profiles to plan sample size to be included in the Profile template by Mr. O'Donnell
- Mr. O'Donnell to email Clinical Trial Guidance text to Ms. Matthews; document to also be posted on the QIBA Wiki
- Reminder that QIBA Profiles address measurement performance, not clinical performance

Other Business

- Process Committee call will be moving to Tuesdays at 3 PM CT, effective January 9, 2018; Dr. Garra's attendance in question until March 2018

Next Call: Wednesday, December 13, 2017 at 3 PM CT