

QIBA Process Committee Call
Wednesday, October 18, 2017 at 3 PM CT
Call Summary

Attendees:

Kevin O'Donnell, MAsc (Co-Chair)
Daniel Sullivan, MD (Co-Chair)
Cathy Elsinger, PhD

Edward Jackson, PhD
Lisa Karam, PhD

Nancy Obuchowski, PhD
Eric Perlman, MD

RSNA Staff:

Fiona Miller
Joe Koudelik
Susan Weinmann

Review of the QIBA Assessment Procedure Guidance Document

- This document is located on the QIBA Wiki at:
http://qibawiki.rsna.org/index.php/Assessment_Procedure_Guidance
- The original purpose of this document is to test statistical assumptions underlying the Claim(s) and the composite performance of a site against the Claim(s)
- Review of Section 2: Assessment Procedure: Site Linearity, and Section 3: Assessing Individual Actors
 - Dr. Obuchowski and Mr. Buckler had discussed study design for groundwork projects that would inform how to apportion the total variability to various actors
 - Discussion on how to assess each actor separately
 - Discussion on assessment of scanner and segmentation software
 - Scanner output and segmentation method treated as a single process/actor
 - Relevant factors of segmentation of images unknown (e.g., resolution and noise)
 - Intermediate metric approach suggested to help isolate the scanner from segmentation software, e.g., raw scanner output (sonogram) data to be a separate process/actor
 - Discussion on process of assessing patient-prep to scanner interface

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

- Claim 1 is a technical performance claim
- Claims 2 a & 2 b differ from the structure of other QIBA longitudinal Claims
 - Additional discussion with PET-Amyloid BC needed regarding intention of Claims and how they will be applied; currently not clear what the Claim is trying to achieve
 - Discussion on difference between biological change and technical change
 - Amyloid BC will be requested to draft clinical interpretation text
 - Dr. Perlman to follow up with Ms. Matthews for additional information to bring back to Process Cmte
 - Ms. Matthews to be invited to attend a future Process Cmte call (TBD)

Review of Dr. Obuchowski's Notes on Statistical Considerations Document

- Purpose of this document is to provide a clinical framework for applying the Profile guidelines and resulting claims to clinical trial design
- This is a proposed response to several Profile groups that have been asking for information to assist with “translating” the statistics underlying the Claims into statistics for clinical trials (to aid statistical design of clinical trials involving QIBA Profiles)
- To be submitted for publication and made accessible to a larger audience beyond QIBA membership

- Dr. Obuchowski to draft generic language for incorporation into the Profile template by Mr. O'Donnell

Other Business

- RSNA staff sent out a Doodle poll to determine availability for a possible change to standing Process Cmte call time slot
 - Results indicated that Tuesdays at 3 PM CT would be accommodating for the majority
 - Mr. O'Donnell to follow up with Dr. Garra in regard to schedule conflicts
 - Change to go into effect after the RSNA 2017 Annual Meeting

Next Call: Wednesday, November 1, 2017 at 3 PM CT