

QIBA Process Committee Call
Tuesday, February 20, 2018 at 3 PM CT
Call Summary

Attendees:

Kevin O'Donnell, MASC (Co-Chair)
Daniel Sullivan, MD (Co-Chair)
Edward Jackson, PhD

Chaya Moskowitz, PhD
Nancy Obuchowski, PhD
Eric Perlman, MD

Nicholas Petrick, PhD
Brian Zimmerman, PhD

RSNA Staff:

Joe Koudelik
Susan Stanfa

Assessment Procedure Guidance

- The full title of this document is: "Guidance for Profile Authors Drafting Statistical Assumption and Composite Performance Assessment Procedures"
- The latest draft is located on the QIBA Wiki at:
http://qibawiki.rsna.org/index.php/Assessment_Procedure_Guidance
- Dr. Perlman developed a draft diagram titled, "Biomarker Production Chain Schematic"
 - Purpose was to outline the PET image analysis workflow process and to show where potential levels of variance may be introduced, e.g. the PET analysis software tools, image readers, and the interaction between these two (to visualize a bottom-up approach for setting up a performance target for each actor)
 - Similar diagram to be created for the introduction in Section 3: Assessing Individual Actor to help visually reinforce this workflow process, i.e. a visual may make the process easier to understand than text
 - Diagram to include the modality, measurement algorithm and reader
 - Suggestion to clump algorithm and reader in the same box (as a single actor), as they are considered an 'operational pair'
 - Clear definition for "algorithm" vs. "software" vs. "workstation" needed to assess as separate actors; Dr. Perlman to draft language which must be clear for clinicians
 - Mr. O'Donnell sent the latest draft of the assessment procedure guidance to Dr. Perlman to use as a reference when creating a figure/definition to explain the workstation relationship to software and algorithm (e.g. workstations contain analysis software programs that use algorithms)
 - Performance metrics may differ for each actor, e.g. noise, resolution, etc.
- Another diagram to show, for example, one image each from several patients, and how the "study design" would flow; in principle, it is easier to assess the actors compared to the site
 - PDFF to be used as an example of test-retest study design with human subjects, along with rationale for why phantoms are not being used; related paper to be referenced
 - Phantom studies are often more appropriate for the later 2.2, 2.3 (although in some BCs, e.g. PDFF, there may be an acceptable clinical "reference standard" such as *in vivo* spectroscopy (not a gold standard, but an acceptable reference measure of lipid fraction in liver, especially for bias assessment))
 - Choosing human subjects or phantoms is a judgement call for QIBA BCs, but the decision needs to be justified

- Mr. O'Donnell to send reminder to Dr. Jackson to draft text with justification for using human subjects; to be forwarded to Dr. Reeder for review
- Dr. Obuchowski to sketch figures for 2.2, 2.3 and 2.4, illustrating linearity, bias and slope for the Amyloid DRO-based approach
- Dr. Obuchowski to draft figures for Section 3.1: Bottom-Up Threshold Selection Approaches and Section 3.2: Top-Down Threshold Selection Approach
 - Rationale behind choosing top-down vs. bottom-up approach to be included
 - Dr. Obuchowski to convert into a table, the bulleted examples in Section 3.1 of types of studies that provide data on reasonable targets for performance of individual actors (and thus might provide reasonable thresholds for actor requirements in the Profile)
- Mr. O'Donnell to add a paragraph to Section 3 on choosing metrics for each actor; intent is to capture each key contribution to the final Claim performance
- It is beneficial to write a Profile containing open issues/caveats rather than to completely halt efforts; best practices are valuable to others and not all Profiles will necessarily reach the Claim-confirmed stage
- Mr. O'Donnell to edit the document and post an updated version to the QIBA Wiki at:
http://qibawiki.rsna.org/index.php/Assessment_Procedure_Guidance

Next Call: Tuesday, March 6, 2018 at 3 PM CT