QIBA Process Committee
Wednesday, March 9, 2016 at 3 PM CST
Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Brian Garra, MD	Lisa Karam, PhD	Joseph Koudelik
Daniel Sullivan, MD (Co-Chair)	Alexander Guimaraes, MD, PhD	Nancy Obuchowski, PhD	Susan Weinmann
Cathy Elsinger, PhD	Edward Jackson, PhD	Eric Perlman, MD	

Claim Guidance Document Review - continued (Mr. O'Donnell)

- The outlined steps for choosing technical performance values for the Claim statements were reviewed
    - Following the steps to develop a Claim statement is likely to be an iterative process
    - Step 1 (Choosing a Metric): Refer the user to a reference to obtain guidance on the kind of Groundwork Study conducted to determine whether the imaging biomarker measurements tend to be biased or unbiased
    - Step 2 (Consider Variability Sources):
        - Population vs. Technique
        - Tradeoff of broadening/narrowing performance vs. population
        - Defining when separate Profiles should be created for different organs, sites, or stage of disease
        - Approach of organ focus and what is gained by narrowing the scope of the Claim/Profile:
            - Affects sources of variability, sample sizes, factors in the groundwork
            - Affected by the therapeutic area being addressed, the nature of the clinical decisions being made and what the QIB is expected to do for them
            - The utility thresholds may vary by organ
            - The QIB may have potential for very broad clinical utility (many organs) but not everything needs to be addressed in the first Profile

    - Step 3 (Estimate the Range of Values of the Technical Performance):
        - The idea is to compare the technical performance achieved and the methods used to achieve it against the clinical requirements in Step 4 to understand whether better practices need to be targeted, whether one is in the right place, or is better than needed and can either aspire to more advanced clinical usage or relax the practices (will also feed into Step 5 and the study design for the groundwork projects, and may be used to decide whether to accept certain studies for use in meta-analysis)
        - Dr. Obuchowski to work offline to expand on this text

- Step 4 (Consider Clinical Requirements):
  - Summarizing the clinical utility might belong better as Step 1, prior to a metric being chosen (form follows function)
  - Step 4 will entail choosing the numerical threshold value for the QIB performance that would provide adequate clinical value

- Step 5 (Consider Sample Size for Conformance Test):
  - A line-by-line review of this step was conducted
    - This is actually the Assessment Procedure for the Claim itself and describes how one would confirm claim on the Profile
    - When choosing the value in one's Claim, the sample size required needs to be considered as a practical factor; if sample size would need to be large there would be less chance of confirming the Claim
    - May combine a group of studies to obtain the needed sample size**;** this advice is useful for the Section 4 assessment procedures as well as the top level claim
    - For the Assessment Procedures, sensible sample sizes should be used since there are many actors involved within the conformance process
    - A balance is needed regarding the Profile performance assessments – there needs to be a practical means to prove conformance

  - More discussion on this step is needed

- Step 6 (Choose Performance Value): Use all of the information gathered throughout the previous steps and choose a number

Next Call: Wednesday, March 23 at 3 PM CDT