QIBA CT Volumetry Biomarker Ctte (BC) Call
21 September 2015 at 11 AM CT
Call Summary

In attendance: **RSNA:**

Gregory Goldmacher, MD, PhD, MBA (Co-Chair)   Rudresh Jarecha, MBBS, DNB, DMRE   Michael O'Connor, PhD   Joe Koudelik

Maria Athelogou, PhD   Hyun Grace Kim, PhD   Kevin O'Donnell, MASc   Susan Weinmann

Andrew Buckler, MS   Michael McKnitt-Gray, PhD   Eric Perlman, MD

Matthew Fuld, PhD   James Mulshine, MD   Daniel Sullivan, MD

David Gustafson, PhD   Nancy Obuchowski, PhD   Ying Tang, PhD

Edward Jackson, PhD

Profile Question Re: Conformance Recommendation (continued from previous call)
- *Question:* Level at which to set the "QIBA bar" for conformance -
    - "Easier" initial conformance, with requirements increasing in complexity over time? *or*
    - "More difficult" achievement of the initial conformance standard so that it is more meaningful?

Group Discussion:
- Dr. Obuchowski provided a detailed overview of her statistical analysis of claim performance levels based on a range of introduced imaging variables
- A table of minimal detectable differences based on a 95% confidence level was discussed
- The range of expected lesion size change based on biology varied widely from 25% to 100%
    - 25% expected if using the same scanner model, reader and software package ("same-same-same")
    - 100% expected if using different scanners, readers, software ("different-different-different")
    - A mid-range of expected values existed with a combination of scanner, reader, software (actors)
- Due to the 100% lesion size change required to claim true biological change (at a 95% confidence level), the committee recommended using more stringent performance criteria in the Profile (i.e., Profile claim cannot be achieved using three different actors for scanner, reader, software)
- It was confirmed that the claim performance should be based on middle to high-end performing data
- Caution was voiced regarding the asymmetry expected between increase and decrease in lesion mass
- All sources of variance need to be outlined within the Profile
- Original performance placeholder values (i.e., claim numbers) obtained from the earlier 1B and 1C projects were acquired using a "QIBA level" of performance, thus the numbers were considered valid
- Mr. Buckler reminded the committee that the intent of the CT Profile is to push image acquisition performance to a higher standard, thus an aspirational claim (performance) should be pursued

Action items
- Dr. Samei to update the physics-related assessment procedure section text
- Mr. O'Donnell to update the performance tables with current numbers/values

Next Call:
- **Oct 5:** Continuation of CT Volumetry Conformance Recommendation
- Other topics: Progress / future planning for the Profile, RSNA 2015 QIBA poster, BC topics for the fall