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) Edward Jackson, PhD      Michael O’Connor, PhD  Joe Koudelik
Jenifer Siegelman, MD, MPH      Rudresh Jarecha, MBBS, DNB, DMRE  Kevin O’Donnell, MASc  Susan Weinmann
Maria Athelogou, PhD           Hyun Grace Kim, PhD                  Eric Perlman, MD
Andrew Buckler, MS             Michael McKnitt-Gray, PhD           Daniel Sullivan, MD
Matthew Fuld, PhD              James Mulshine, MD                  Ying Tang, PhD
David Gustafson, PhD           Nancy Obuchowski, 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