

QIBA CT Volumetry Biomarker Ctte (BC) Call

21 September 2015 at 11 AM CT

Call Summary

In attendance:

Gregory Goldmacher, MD, PhD, MBA (Co-Chair)
Jenifer Siegelman, MD, MPH
Maria Athelougou, PhD
Andrew Buckler, MS
Matthew Fuld, PhD
David Gustafson, PhD

Edward Jackson, PhD
Rudresh Jarecha, MBBS, DNB, DMRE
Hyun Grace Kim, PhD
Michael McKnitt-Gray, PhD
James Mulshine, MD
Nancy Obuchowski, PhD

Michael O'Connor, PhD
Kevin O'Donnell, MASc
Eric Perlman, MD
Daniel Sullivan, MD
Ying Tang, PhD

RSNA:

Joe Koudelik
Susan Weinmann

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