

## QIBA CT Volumetry Biomarker Ctte (BC) Call

01 February 2016 at 11 AM CT

Draft Call Summary

### In attendance:

Samuel Armato, III, PhD (Co-Chair)

Gregory Goldmacher, MD, PhD, MBA (Co-Chair)

Jenifer Siegelman, MD, MPH (Co-Chair)

Hubert Beaumont, PhD

Andrew Buckler, MS

Heang-Ping Chan, PhD

Vadivel Devaraju, PhD

Ritu Gill, MD, MPH

David Gustafson, PhD

Lubomir Hadjiyski, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Eric Perlman, MD

Nicholas Petrick, PhD

Marthony Robins, PhD

Laura Strong, PhD

Ying Tang, PhD

### RSNA:

Joe Koudelik

Julie Lisiecki

### State of the Profile (Mr. O'Donnell)

- Performance tasks are not yet finalized and need validation; final numbers need to be determined
- Sources of variance and repeatability coefficient numbers are much too large and may not be "pure" numbers
- Discussion needed among statisticians and groundwork study leaders regarding range of numbers for the *Table of Assumptions*, as follows:
  - Mr. Buckler: Group 3A Clinical Challenge
  - Dr. Kim: Group 1B study, Group 3A Pivotal Study
  - Drs. Fenimore / Lu: Group 1C study
- Top and middle performing values (point estimates) need to be checked for accuracy
- Drs. Kim and Obuchowski to work together to set up a range of numbers using a simple calculation of difference, as demonstrated by Mr. Avila's "calculator" which he demonstrated at RSNA 2015's QIBA Working Meeting
  - As a result of reviewing these numbers, a new statement will be added in the Profile table and expected precision for alternative scenarios will be updated
  - A number in the middle of the confidence interval spectrum would be preferred
    - Dr. Goldmacher to send a request to team members to check numbers
    - Dr. Obuchowski will send Word document table to Mr. Buckler, et al.
- **Rationale for the claims:**
  - Constraints on noise, resolution, iterative reconstruction, etc. must be consistent to achieve accurate performance values
  - To-date, no systematic test has been completed across vendor platforms to evaluate model-based iterative reconstruction vs. statistical iterative reconstruction
  - Physics experts within the CT Volumetry BC will be asked to address this issue and provide guidance
- **Root issue:**
  - Question regarding what assumptions are being made based on different implementations of an algorithm
  - Mr. O'Donnell will start an email thread on this topic for BC input, with a special request to physicists for input
  - Possible solutions include:
    - Providing a range of numbers
    - Providing a specific formula to determine confidence interval of the result
    - Quote performance for lower end (e.g., 10 mm lesion) and provide an "at least" number for higher end (e.g., 30 mm lesion) of scale
- **Goal:**
  - Profile to be released for public comment / published version as soon as possible
  - Plan to publish a Profile with caveats if need be, and discussion to continue on 2/8 call

### Action items:

- Mr. O'Donnell to continue updating the Profile for BC comment and review on the next call on February 8<sup>th</sup>
- Drs. Kim and Obuchowski to confer on range of values for the confidence interval
- Statisticians / past Project PIs, i.e., Mr. Buckler, Drs. Fenimore, Kim, and Lu, to review numbers for feedback to Dr. Obuchowski
  - Plan for call on 2/22 to invite stakeholders to better understand goals of the Profile and value of QIBA

**Next Call:** Monday, Feb. 8<sup>th</sup> at 11 am CT | 2016 planning and review of the Profile and Next Steps