QIBA CT Volumetry Biomarker Committee (BC) Update Call

29 June 2015 at 11 AM CT

Call Summary

In attendance:

Samuel G. Armato III, PhD (Co-Chair)
Jenifer Siegelman, MD, MPH (Co-Chair)
Maria Athelogou, PhD
Hubert Beaumont, PhD
Andrew Buckler, MS
Heang-Ping Chan, PhD
Charles Fenimore, PhD
David Gustafson, PhD
Lubomir Hadjiyski, PhD
Hyun Grace Kim, PhD
Michael McNitt-Gray, PhD
Michael O'Connor, PhD
Kevin O'Donnell, MASc
Eric Perlman, MD
Adele Peskin, PhD
Ehsan Samei, PhD
Lawrence Schwartz, MD
Hiromitsu Tan'nai, MD
Ying Tang, PhD
Pierre Tervé, MS
Luduan Zhang, PhD

RSNA:

Joe Koudelik
Julie Lisiecki

Concerns Raised by the Committee Regarding the Round-5 Field Test Study:

- Logistic and budget constraints include IRB approval and renewal, research coordinator costs, marginal costs per scan and imaging site federal overhead costs
  - Study costs per imaging site vary widely: anywhere from $20-50K to scan 20 patients *twice*
  - Due to limited available funds, high-quality imaging at low-cost would be needed
  - Potential impact of changes in study design to budget proposal
- Site participation agreements are not yet in place
  - Cross-vendor scanners are desirable for each site, though this may prove difficult
  - Scanner capabilities (i.e. speed for test-retest), etc., not yet identified
  - Sites may be "brand-loyal" and may not have several different vendor scanners available
  - Drs. McNitt-Gray and Samei both advocated for the use of a site qualification form to outline site performance requirements
- Completion of the study as designed with solid scientific results may be difficult on such a short timeline
  - Consideration to do a pilot, or exploratory study suggested at a reduced cost with a revisit to the field test in the following year once confidence measures have been established
- Some discrepancy remains as to whether or not there would be different cohorts within the chest/ abdomen groups, i.e.:
  - Lung / liver / abdomen (with contrast)
  - Chest (no contrast)
- Additional data sets that may be available
  - Test retest datasets may be available from radiation oncology treatment planning.

Progress on Current Project and Proposed Future Project – (Dr. Samei)

- Brief recap of some of the challenges the research team has faced with the Round-4 Synthetic Lesions Project
  - The group had to recollect data due to differences in lesion insertion model used by the FDA
  - Dr. Samei's graduate student will be at the FDA for a month measuring inserted lesions
  - Dr Samei anticipates completion of this Round-4 project by the end of August
- The project for Round-5 will include creating databases of actual patient cases using true values, utilizing statistical exchangeability between hybrid and realistic datasets
- A partner research team in Denver will apply 5-6 segmentation algorithms and compare results

Action items

- Group – All to reach out to their radiation oncologists to see if daily scans are performed
- Feedback regarding the Field Test design may be sent to Dr. Siegelman: jen.siegelman@gmail.com
- Dr. Goldmacher to invite / remind presenters about upcoming presentations to the BC
- All are welcome to provide suggestions for summer call schedule topics: Gregory.Goldmacher@iconplc.com

Next Calls:

- Ad-hoc calls for physicists: Tuesday, June 30th at 11 am CT
- **TBD:** Ad-hoc calls for statisticians **|** Continuation of Field Test Planning Discussion