QIBA Q-CT Committee Weekly Update
Monday, August 16, 2010
11 AM CDT

Call Summary

In Attendance
Andrew Buckler, MS (co-chair)
P. David Mozley, MD (co-chair)
Maria Athelogou, MD
Patricia Cole, PhD, MD
David Gustafson, PhD
Philip F. Judy, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD
Kevin O'Donnell
Nicholas Petrick, PhD
Anthony P. Reeves, PhD
Ganesh Saiprasad, PhD
Hiro Yoshida, PhD

RSNA
Fiona Miller
Madeleine McCoy

QIBA Project Plan (Mr Buckler)

- Review of Visio diagram as a high-level summary representation of work of the Committee
  - Technical Description of Volumetric Image Analysis using CT
  - Defines activities and readouts
- Roadmap from Imaging Biomarkers Roundtable is a shared document that structures our effort:
  - Technical and (clinical) performance groundwork are the focus of current QIBA activities and form the mainstay of resources
    - Consider removal of "clinical" from title (focus on metrology performance that is applicable in a clinical setting)
  - Clinical efficacy groundwork may be done in partnership with Biomarkers Consortium and others
    - Data needed for qualification process
  - Qualification data is structured to anticipate regulatory agency and stakeholder need's
  - Analysis tools will also need validation
  - Greater distinction needed between performance groundwork and clinical efficacy groundwork
    - Latter relates to resulting in treatment changes

Q-CT Group 3B Motivation and Purpose

- Meta-analysis of data about how treatment-induced changes in marker readouts correlate with health outcomes.
  - The data would variously include results from the published literature, retrospectively re-analyzed data from previous clinical trials, and prospectively analyzed data from trials based on our QIBA protocols and profiles
- Such analysis would directly feed efforts to complete the "full data package" for qualification as well as provide contributory evidence for de novo 510(k)s and PMAs
- With such proven biomarker tests, it could drive utilization for practicing radiologists in their use of these quantitative techniques on a more proven base than currently exists

Suggested Tractable Data Plan

1. Work with Pharma reps on best way to frame request for data
2. Work with Open Image Archives ad hoc Committee on use cases and desired attributes of archive
3. Work with NIST as "trusted broker" to handle scrubbing of institution source, sorting into bulls-eye levels, sequestering of test set, and submission of training set to public archive
4. Design the meta-analysis using results of 1A/B/C and 3A to inform statistical power analysis and for initial thresholds
5. Conduct a pilot of the meta-analysis to establish capability of the class of tests that represent the marker using the training set
6. Conduct pivotal meta-analysis on test set
7. Provide public access to training set
8. Determine services needed to provide indirect access to sequestered test data by trusted broker (e.g., NIST)

- Consider moving #4 to #1

- In addition, need data sets that provide long-term health outcomes
- Determine whether tighter rings of bull's-eye provide greater clinical benefit
- Parallels drawn to recent ADNI approached to collective data in Alzheimer's study

Technical Description of Biomarker

- Technical description needed for each workflow step to properly evaluate output measurements
- Patient prep by technologists set quality standards; quality measures needed at this stage
- RSNA to reach out to technologists and invite to assess workflow and various patient prep styles
    - RadPharm technologists may be available for feedback
- Besides expert technologists, medical physicists and the vendor application training community need to be engaged

Next Steps:

- Next calls 8/23 and 8/30 at 11 am CDT (12 pm EDT): Drs Athelogou and Colditz to present update from industry perspective concerning accuracy of volume measures and activities to broaden phantom studies beyond single algorithms and software implementations.