QIBA Vol-CT Weekly Update WebEx
September 8, 2008, 11am CDT
Call Overview

In attendance:

Andrew Buckler, BSEE, MSCS (Chair)
Robert Ford, MD
Ronald Gottlieb, MD, MPH
David Gustafson, PhD
Wendy Hayes, DO
Bruce Hillman, MD
Michael McNitt-Gray, PhD
P. David Mozley, MD
James Mulshine, MD
Kevin O'Donnell
Nicholas Petrick, PhD
Sandra Scheib, RN, MSN
Lawrence Schwartz, MD
Daniel Sullivan, MD
Linda Bresolin, PhD, MBA, CAE (RSNA)
Fiona Miller (RSNA)
Joe Koudelik (RSNA)

The group discussed and wordsmithed the following content for the Vol CT panel of the QIBA kiosk:

Current Activities

Develop the technical capability necessary for imaging vendors to support targeted levels of accuracy and reproducibility for use of volumetric CT as a biomarker in oncologic clinical trials. This will be achieved through the development of implementation guidelines--profiles-- for which initial groundwork will be required.

Profiles will be built up in the following layers:

1. CT Volume Quantification Profile to allow users to perform, store and analyze basic spatial measurements on acquired data.

2. CT Tumor Volume Change Profile to allow users to determine tumor volume changes to a certain level of accuracy across multiple acquisitions.

3. CT Tumor Response Profile to allow users to evaluate tumor response/progression to a certain degree of confidence.

Groundwork to enable the description of these profiles are:

- To **quantify** treatment-induced changes in anatomical structures, such as neoplastic masses, with x-ray computed tomography (CT).

- To **identify** and **create coping strategies** for all meaningful sources of variability in measurements of volume with CT.

- To **establish standards** that will eventually lead to the acceptance of 3D volumetric CT by regulatory agencies as proof of drug-induced changes in pathophysiology, aiding acceptance of future surrogate end-points for changes in the health status of patients.

Main Subgroups

The following subgroups have been formed to pursue actions:

- Retrospective analysis to characterize quantitative accuracy exploiting FDA-acquired anthropomorphic phantom images
- Retrospective analysis to characterize quantitative accuracy exploiting standard and high resolution clinical datasets (NCI-RIDER and others)
- Design and execution of prospective study to characterize reproducibility given sources of variability utilizing Phantom Study Protocol

Activities to date

A committee including practicing clinicians, professional society leaders, regulatory and governmental agencies, pharmaceutical industry representatives, academics, and imaging industry representatives is formed and has laid out a strategy, as well as commissioned the subgroups as mentioned above. First activities included completing a systems engineering analysis of the sources of variability as well as identifying the clinical focus for the effort. A process has been derived to include operational descriptions for how profiles would be written and utilized to meet the intended purpose while optimizing the imaging industry's interest and responsiveness.

Next steps

1. Identify funding mechanisms, project plans, and reporting means for the identified activities.
2. Converge on a QIBA-accepted process to be utilized by all three QIBA workgroups (i.e., PET and MR along with CT).
4. Set expectations regarding effectiveness and timing for principal objectives, supporting business models desired by pharmaceutical industry rationalized with that desired by imaging industry.
5. Conceptualize the exploitation of developed capability for diagnostic and therapeutic uses of quantitative imaging in the clinic (i.e., beyond the use in clinical trials for drug development).
6. Pharmaceutical representatives have identified their goals and interests and, along with regulatory representatives and clinicians, have identified a validation plan and set out specific means and criteria to arrive at characterized and accepted performance in the indicated biomarkers.

General Discussion

- The use of "response" in QIBA context
  - Need to define response beyond the RECIST criteria
- Clinical oncology trials
  - Starting point for Vol CT trials
  - Possible beginning of the validation process
- Groundwork

    - Groundwork required to justify what goes into the implementation guide (protocol)
    - Groundwork set-up should simply pursue validation
    - This group shouldn't pursue validation itself
- Merck looking to explore standard data sets such as in RIDER and others (Dr. David Mozley)

Vol CT Technical Committee Goal:

- Goal is to establish whether volume measurement is more useful than linear measurement in measuring change in tumor size
- This group's goal is the quantitation of size changes

QIBA Kiosk for RSNA 2008

- "IHE Process" description needed on general kiosk page
- Diagram or pictures needed on kiosk, not just text

ACTION ITEMS:

- Dr. Petrick to send Kevin O'Donnell updated document (?)
- Dr. Mozley to finish action items and forward to the group