QIBA Vol-CT Weekly Update WebEx
October 27, 2008, 11am CDT
Call Overview

In attendance:

Andrew Buckler, BSEE, MSCS (Co-Chair)
P. David Mozley, MD (Co-Chair)
Charles Fenimore, PhD
David Gustafson, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD
Samuel Richard, PhD
Chris Schaefer, BS, RT
Binsheng Zhao, PhD
Fiona Miller (RSNA)
Joe Koudelik (RSNA)

General Discussion

Business case for Pharma industry suggests that Volumetric CT will reduce the number of enrolled patients in clinical studies while shortening patient follow-up time

- Testing this hypothesis will be less expensive and be faster than anticipated if existing data can be used
    - If Merck and other companies were to donate their images to help move project along
    - NCI clinical trials group might act as a neutral broker of data
- Prospective clinical trials with multiple arms divided into two responder groups
    - Data in hand already includes patients at progression
    - "Better" and "Less" effective (treatment)
    - Merck has outcomes for these cases
    - Merck knows which treatment arm performed best/worst
    - All patients progressed (with disease leading to death)
- Academicians and diagnosticians welcome to submit additional cases
- Dr Mozley to email Dr Zhao with some simple scans to suit Pharma's hypothesis of reading cycle time (i.e., shorter time per groups)
- More Pharma data needed, including known limitations involved or needed
- Merck cases may not all fit cases needed in Vol-CT studies - i.e., subset
- Need to know what the data limitations are
- Targeting additional Pharma groups
    - Donation of data is a good way to increase momentum
    - Dr Mozley to solicit other Pharma groups to participate
        - Mechanism details needed
        - Clear path must be identified
    - QIBA endorsement needed - NCI to do this on QIBA's behalf?
    - Pharmaceutical consensus is reasonably strong (per Dr Mozley)
    - GSK, Novartis and AstraZeneca may also be supportive (per Dr Mulshine)

Other stakeholder interests

- Senior management buy-in needed for core concept
- A concrete set of objectives needed
- Dr Mozley's plan is helpful for expressing this group's goal
- Need to take the entire effort to a level of formalism to be suitable for consideration at the board level and by all stakeholders

- Need buy-in requirements from clinicians ~ Dr. McNitt-Gray to discuss with colleagues
- e.g., How will VOL-CT benefit clinical oncology and diagnostic radiology
- For instrument manufacturers hypothesis needs to be true to ensure continued participation

Business case needs modification to make it more compelling to other groups
Need a clear and compelling business case for each stakeholder

- e.g., Increased complexity of imaging analysis billing code
    - Separate charges
    - Referring / patient but-in
    - Need business case for radiologists and referring physicians

Existing databases available now (Dr Zhao)

- LIDC database useful to test
    - 84 patient datasets available now
    - Contours available for all 3mm diameter nodules
    - Four radiologists marked for each case
    - Single patient visits only; no follow-up data
    - Varying slice thickness (50% are considered thin)
    - Comparing computer vs. reader volumetric measurements useful
    - Datasets now available on NCI webpage for downloading
- Need an ideal lesion as a starting point
- Segmentation issues possible (i.e., over/under segmentation)

Need means to establish that Vol-CT is better than RECIST

- Derivation studies discussed
- Error based on current RECIST studies
- Need to decrease error range
- Length of enrolment - through studies dose progression

Moving forward

- Need all parts of the roadmap in place to get to validation
- Big picture and compelling wording needed for high level mgmt
- Specific database to solve specific questions
- Project has to be expressed in definitive terms
- Need return on investment to all players
    - e.g., Therapy would change sooner based on Vol-CT measurements
- "Necessary is not the same as sufficient" Harder question - what's sufficient?
- Clarify need to change to paradigm
- What needs to be done for the stated outcome?

Next week:

- Continue with subgroup updates (1A and 1B)
- Continue to build on this session

ACTION ITEMS:

- Dr McNitt-Gray to enquire with others in his department as to their input - reviews (buy-in by radiologists)

- Dr Mozley to email Dr Zhao some simple scans to suit Pharma's hypothesis of reading cycle time (i.e., shorter time per groups)
- Dr Mulshine to develop case for treatment response and distribute to the group