QIBA VOL-CT Weekly Update WebEx
Monday, January 5, 2009, 11am CST

Call Summary

In attendance:
Andrew Buckler, MS (Co-Chair)
P. David Mozley, MD (Co-Chair)
Lawrence Schwartz, MD (Co-Chair)
Rick Avila, MS
Ekta Dharaiya, MS
Charles Fenimore, PhD
Paul Licato, MS
Michael McNitt-Gray, PhD
James Mulshine, MD
Nicholas Petrick, PhD
Hiro Yoshida, PhD
Binsheng Zhao, PhD

RSNA staff
Fiona Miller
Susan Anderson
Joe Koudelik

Introduction (Mr. Buckler)

- The minutes from the 12.15.08 update call were approved without change
- Mr. Buckler reiterated the spiral model of effort, moving ahead on several fronts concurrently and using the wiki as a coordinating tool

Description of Merck trials (Dr. Mozley)

- Merck has started three clinical trials in advanced lung cancer, drawing from existing trials and specified outputs
- There is a business case for each trial which is highly concordant with risk-benefit for an individual patient
    - Why Merck is conducting trial
    - What is value returned?
    - What are endpoints to prove value?
    - Risk/benefit analysis
- Dr. Mozley will be presenting on the trials over the next few months and will continue to encourage support for the VolCT group's activities
- Dr. Mozley will also continue to highlight the NLST (low-dose lung cancer screening) and ACRIN (higher does and settings) acquisition protocols as potential standards
    - *ACRIN 6678 Quality Control Parameters for CT Scan Tumor Volumetric Measurements*
      http://www.acrin.org/Portals/0/Protocols/6678/imaging/Parameters%20Chart%20for%20CT%20Volumetric%20Measurements.pdf
- Support for standardized protocol parameters like NLST but at higher dose and setting like ACRIN 6678
- Merck has agreed to contribute cases; the image and image acquisition protocols are non-competitive; the chemical structures are the only proprietary information

Profiles

- Profiles are considered "clinical contexts"
- Dr. Mulshine will circulate a draft concerning image endpoint definitions, quality control measures, imaging criteria to use, etc., within next few weeks
- Important to insure practicality today and allow for evolution, e.g. alert users that we set a mechanism for early adapters from highest resolution settings

- Do we need high resolution or not? Although not usually done in clinical trial profiles, consider statement of what the imaging needs are in evaluating tumor response
    - Dr. Mozley will seek mgmt approval to construct statement of imaging requirements for the trial(s):
        - Level of accuracy needed
        - Type of lesions
        - Type of response
- Discussion of defined quality control measures that Merck is using related to:
    - Who is reading
    - Back-ups
    - Criteria for positive/negative interpretations
- To pilot the process:
    - Drs. Mulshine, Mozley and McNitt-Gray to work with the three Merck trials
    - Work areas: *CT Lung Nodule Volume Quantification Profile* (http://qibawiki.rsna.org/index.php?title=CT_Lung_Nodule_Volume_Quantification_Profile)
        - Dr. Mozley will work in *PROFILE CLAIMS* section including resolution of CT
        - Dr. Mulshine will work on section *PROFILE DETAILS*
- With Profiles, eventually manufacturers could certify that equipment meets the claims; trials could seek sites that have Profile-compliant equipment

Group reports

1A (Dr. Petrick)

- Will begin laying groundwork on ranges, starting point with readers concerning variability
- Protocol being written
- Data being collected
- Timeline:
    - January: preliminary study on protocol
    - February: analysis and completion
- Will use project readers at RadPharm, kindly provided by Dr. Ford

1B (Dr. McNitt-Gray)

- Extending 1A's work into retrospective patient data sets
- Additional thin-slice datasets needed
- Continued group discussion on what constitutes an acceptable baseline
- Continued group discussion on tradeoff between input/output variables
- Agreed to alternate weekly meetings with 1C

1C (Dr. Fenimore)

- Group is in early stage planning meetings
- Charged with looking at interclinic/interdevice effects
- Goal is to understand the variability attributable to different scanners
- Agreed to alternate weekly meetings with group 1B
- To encourage membership in group, announcements of calls will be sent to entire VolCT group (Next call scheduled Tuesday, Jan 13th at 2 PM EST)

Next Steps

- Continuing work on Profile
- Dr. Mozley to forward profile claims to Dr. Mulshine and update the wiki
- Dr. Mulshine to draft profile document for committee review and update the wiki with profile details
- Mr. Buckler encouraged using the QIBA wiki and adding & editing material
- Dr. Mozley to update Dr. Hayes and additional pharmaceutical company contacts and encourage their participation