QIBA VOL-CT Group 1A Update WebEx
March 12, 2009
12 PM CDT
Call Summary

In attendance:

Nicholas Petrick, PhD (Chair)
Kristin Borradaile
Andrew Buckler, MS
Chris Burke
Lisa Kinnard, PhD

RSNA
Susan Anderson
Joe Koudelik

General Discussion
Drs Nicholas Petrick, Lisa Kinnard and Kristin Borradaile provided a VolCT Group 1A pilot project update

- Drs Kinnard and Borradaile met at RadPharm to begin the Group 1A pilot study (early March 2009)
- Radiologist assisted automated reads performed - open case, find nodule, identify central slice
- 10 cases with 3 measurements each performed (1D, 2D 3D) by two radiologists (radiologist assisted)
- 1D and 2D reads were performed with MedStudio software
- 3D volumetric reads were performed with OncoCare software
    - Do issues arise by using two different software programs?
    - Segmentation may help determine if different software versions result in any volume bias
    - Default window/level between softwares is not the same. MedStudio will be adjusted to same window/level as lung window on OncoCare software for consistency.
- Most time spent on opening cases
    - 0.8mm slices would crash the program
    - Will limit number of slices surrounding each nodule to help reduce case loading time and to avoid software crashes that increase the study time because of need to restart.
- Correction tools needed at times
- Spiculations generally missed / overlooked by programs
    - 10-20mm spiculated nodules cause issues for program
    - How does RECIST deal with spiculated lesions?
    - Readers typically take diameter from lesion's central portion - reader dependent
- Pilot project did help to identify potential issues
- Dr Kinnard to send additional cases to RadPharm (March 12, 2009)
- Results of this pilot study to be sent to FDA week of 3/16/2009. FDA will them conduct some initial analysis and post on wiki.
- Kristin Borradaile to schedule RadPharm readers for future cases
- Reducing case number from 120 to 40 or so per reading session to avoid overly taxing readers. Each reading session will be split over multiple days.
- Limiting reads to two hour blocks over a week's time frame proposed to avoid reader burnout
- Three weeks between first and second set of reads deemed adequate

- 1 case has two lesions visible and caused confusion to the reader on which to annotate. Any cases that may be similarly confusing in the pivotal data set will be clearly annotated for the reader so that they evaluate the correct lesion.
- Preliminary assessment is next step
    - Effects of lesion and sample sizes to be studied
    - Results may lead to case modifications
    - Results of assessment to be sent to Mr Buckler and VolCT Group 1A members
- Pivotal data are not expected to be completed by RSNA 2009 submission deadline. We plan to submit an abstract using analysis of the preliminary data. Pivotal study should be completed by May, 2009.

Next Steps: Action Items Slide

- Insure viewing conditions are as consistent as possible
    - Monitor viewing angle and resolution to be set the same
    - Reading office window blinds to be drawn (room settings to be as consistent as possible).
    - Reevaluating need for calibrating the monitors before conducting the pivotal study.

Thank you to RadPharm for the generous assistance with this project!