

QIBA VOL-CT (Part 1A) Phantom Study Protocol Update WebEx
October 9, 2008
12NN CDT
Call Summary

In attendance:

Nicholas Petrick, PhD (Chair)
Rick Avila, MS
Ekta Dharaiya, MS
Charles Fenimore, PhD

Michael McNitt-Gray, PhD
Daniel Sullivan, MD
Fiona Miller (RSNA)
Joe Koudelik (RSNA)

Dr Petrick provided an overview of the current VOL-CT Part 1A project.

Rick Avila to provide the Vol-CT Proposed Phase 1A Project update during the Monday, October 13th Vol-CT weekly call.

General Discussion

- Study to involve inter and intra-reader variability with phantom lesions/nodules
- Inter and intra-reader variability in volumetric estimates – segmentation a separate process
- Probing exercise to determine what areas RECIST breaks down may lead to a study to pursue software comparisons
- 2 measurements to begin with
 - RECIST
 - Semi-automated 3D volumetric measurements
- Three scans proposed to obtain reasonable variability of readers (what is practical and timely)
- Small lesions and fixed slices to be determined if potential issues – bias issues need to be understood
 - Need to select slice thickness – 0.75mm and 1.5mm discussed
- 6 readers to be provided by RadPharm
- Number of reading session needed to be determined
- Proposed was to pick a smaller number of cases to study, add a 20mm nodule every 8th case and have reader segment volume. This would simplify the original design and better estimate the inter-variability of readers for few cases (opposed to acquiring less reliable data based on more readers)

Issues Needing Further Discussion

- Inter reader variability bias
- Noise affects
- Shape and size effects of nodules
- Nodule placement variability (not specified)
- Should this 1A project be a pilot study to gather data?
- Current set up not complex enough to assess human readers
 - Need to understand human variability first, then determine if software is competitive
 - Humans should perform well on simple spheres and lobulated nodules
 - Software may overtake human readers on complete nodules

- 5mm slice with 10mm lesions would cause software problems, where humans are still comfortable
- Slice Thickness
 - Would algorithms perform better at 1.5mm slices?
 - What slice thickness would help peak algorithm performance?
 - 0.75mm and 1.5mm would work best with more complex lesions
 - 0.75mm and 5mm slice thickness agreed by all on call
- Can use increased speculated nodules in data set also
- Pulse Strength
 - 100mAs vs. 200mAs
 - Need to determine if 100mAs or 200mAs is needed with 0.75mm slices.
 - mAs changes per pitch used and is based on manufacturer mAs definitions – this will therefore change between manufacturers

Next Steps:

- Need additional details concerning Dr Robert Ford's offer of readers
 - Dr Robert Ford to be included on future group calls
 - What type of data should be provided to Dr Ford's readers – with or without ROI's?
 - Can images be uploaded to the RadPharm PACS?
 - How to randomize image order in the RadPharm system?
 - How upload ROI's or download segmentations and volume data?
- Small scale pilot (with readers) to identify time frame (using 2 readers)
- More segmentations using fewer nodules suggested to achieve better estimates of reader variability
- Definitive Study vs. Pilot Study discussed - Definitive study proposed and agreed upon
 - Want definitive answers to move forward
- QIBA process has leaned enough (data) to apply to clinical trials
- Submitting potential results (meetings and journals) - Need QIBA publication policy
 - ASCO – Jan 2009
 - RSNA – mid-April 2009
 - AAPM – mid-February 2009
 - ASTRO
 - NESML
 - Radiology
 - TMI Medical Physics
 - Oncology journals?
 - Project could have both technical and clinical focus to tailor to meetings
 - If patient measurements the main focus – results could go to ASCO
- Main Changes to Proposal
 - 0.75mm slice thickness (not 1.5mm)
 - Inter-reader variability
 - Proposed was decreased nodule size with single reader
 - More speculated (complex) nodules
 - Managing expectations – more discussion needed
 - Need to know what expectations of the group are

Final Thoughts

- How does this project fit into the overall QIBA picture?
- How does reader variability in a controlled trial compare to clinical trials?
 - What does this mean?
 - Is a pass/fail criteria possible?
- Lisa Kinnard, PhD and Marios Gavrielides – Dr Petrick’s lab to include these people in study
- Mr Rick Avila offered to lead the group’s next call in Dr Petrick’s absence