QIBA Volumetric CT Group 1C Update WebEx
Cross-Platform / Inter-Clinical Study
Sept 9, 2009, 2:00 PM CDT
Call Summary

In attendance:

Charles Fenimore, PhD (Chair, Moderator)
Denise Aberle, MD
Kristin Borradaile, MS
Rahul Bhotika, PhD
Andrew Buckler, MS
John Lu, PhD
Michael McNitt-Gray, PhD
Kevin O'Donnell
Nicholas Petrick, PhD
Anthony Reeves, PhD

RSNA Staff
Fiona Miller
Susan Anderson, MLS
Joe Koudelik

General Discussion

Agenda:

- Collection protocol and noise characterization items
- Reading component of 1C study

vCT Profile Update (Mr O'Donnell)

- Discussions in progress with Dr Dorfman concerning incorporation of post-processing procedures
- Mr O'Donnell mapping acquisition material into post-processing, working within the UPICT template format
- Revised Profile will be ready by 9/14/09 vCT update call
    - Adding generic acquisition parameters
    - Proposed model specific parameters to be filled-in; vendors and clinical trial PI's to provide this detail
        - Vendor specific tables still needed
- Discussion of need for a clinical trials PI to act as proxy, or advocate, for QIBA Profiles, i.e. an end user with specific system knowledge
    - Drs Mozley and Mulshine have provided clinical motivation, Dr Schwartz to provide imaging content based on clinical trials
- ACRIN 6678 to be adopted for vCT, but left open for future proposed upgrades
- Branch 2 of IC study: Performance Based Protocol where sites start with specific objectives, but are free to adapt parameters to meet protocol specified noise and resolution criteria
- Protocols/profiles to separate results from methods; appendices to list specific text
- Maintain inclusive nature for vendor models not listed in tables by allowing sites to 'tweak' systems into compliance

Group 1C study Performance Branch (2) Overview

- Device industry required to maintain a level of consistency, how this is obtained is specific to the vendor
- Specified parameters would act as a starting point only, e.g. ACRIN 6678
- Need to translate parameter input on specific systems, i.e. how to comply with performance targets needs more procedure ('how') language in Branch 2 Profile
- Group 1C results will provide overall guidance

- Fill-in model specific details once obtained, e.g. kVp, mA, etc
    - Group 1C work will help determine equipment settings; placeholders can be inserted as needed
- Need expert advice to determine correct system parameters
- QIBA Profiles are to assist manufacturers to provide their own documentation to help them comply with Claims
- Profiles should not to be overly prescriptive as to constrain invention, only set limits
    - Profiles tell what to achieve, not how to achieve
- Dr Fenimore and Mr O'Donnell to revisit Branch 2 Profile offline
- Calibration nodule in phantom proposed for algorithm development and site calibration function

Group 1C Mark-up Procedures Overview

- Numbers of RadPharm readers will be determined by statistics of project design
- Drs Fenimore, Lu and James Filliben to discuss 1C study sizing offline based on:
    - 3 independent measurements: RECIST (1D), WHO (2D) and volume (3D)
    - 4 imaging sites
    - 2 study branches
    - 7 nodules + 1 calibration nodule
- 1500 measurements being done for Groups 1A and 1B, i.e. 'all lesion sizing events'
    - Consider whether this is achievable/reasonable for 1C
- Nested reader design suggested
- Group 1C to consider auto-segmenting lesions as 1A has done; 1A analysis to be done by end of September 2009

Next Steps

Dr Schwartz to provide imaging content based on clinical trials
Send specific parameter details to Dr Schwartz

- Next call date to be determined
- Implications of study design as agenda item for next call
- Dr Fenimore and Mr O'Donnell to revisit Branch 2 Profile offline
- Drs Fenimore and Lu to discuss 1C study sizing.