QIBA Volumetric CT Technical Committee Update
Monday, April 25, 2011

Call Summary

In attendance

Andrew Buckler, MS (QIBA Program Director)
P. David Mozley, MD (Co-chair)
Lawrence Schwartz, MD (Co-chair)
Charles Fenimore, PhD
David Gustafson, PhD
Philip Judy, PhD
Hyun Grace Kim, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD
Nicholas Petrick, PhD
Anthony Reeves, PhD
Samuel Richard, PhD
Yuanxin Rong, MD, MPH
Daniel Sullivan, MD
Ying Tang, PhD
David Vining, MD
Hiro Yoshida, PhD
Binsheng Zhao, DSc

RSNA
Joe Koudelik

General Discussion Items

- QIBA Round-2 funding proposals due May 3, 2011
- Group 1B results discussed (Dr McNitt-Gray)
    - Variability of small masses for 1D, 2D and volumetry has proved higher than expected with workflow used
- Confidence interval is too wide to be of value in clinical practice and clinical trials
- Unrestrained workflow will not deliver reliability to make important decisions about individuals or drug trials; management not possible
- Proposal to expand 1B efforts to include additional workflows
    - How to expand and what the workflows will be to be determined
- "Sequential Locking" proposed to compare scans 1 and 2 side-by-side with the ability to change mark-ups
- Drs McNitt-Gray and Kim willing to pursue Round-2 funding to broaden their work with the 1B efforts
- Dr McNitt-Gray to develop Round-2 proposal outline including budget details
    - Number of cases, readers and algorithms to be determined
        - 150 time point assessments proposed
        - 5-10 readers deemed statistically minimum
        - Drs Schwartz and Zhao suggested using a second software package to help isolate possible issues associated with original analysis software used
- Plans to proceed to publication with 1B reader results; enquiry whether CoreLab Partners will assist once more to broaden assessment.
    - Dr McNitt-Gray to inquire with Dr O'Neal or Clunie at CoreLab Partners concerning extending the reader activities
- Dr Zhao suggested study to compare scans side-by-side (with no mark-up changes allowed)
- FDA may provide model study design
    - Dr Petrick to follow-up with FDA staff concerning suggestions and details for study sizing

Advanced Disease Profiling Activities

- Supporting literature analysis and appropriate lesion size discussed
- Performance specifications confirmed
    - Claims to be 26% (95% confidence interval), based on lesions size ranges of 10-82mm
    - Slice thickness of 2.5 mm, RI of 1.25

Next Steps

- Need to determine number of cases and readers for expanded 1B study
- Drs McNitt-Gray, Kim, Schwartz and Zhao to discuss 1B extension off-line
- Dr McNitt-Gray to inquire with Dr O'Neal or Clunie at CoreLab Partners concerning extending the reader activities
    - CoreLab Partners to develop rough budget to consider and possibly incorporate into the Round-2 funding proposal details
- Mr Buckler to have placeholder values inserted within the Advance Disease Profile by May 5, 2011 for group feedback
- No call next week (May 2)