QIBA vCT Technical Committee Weekly Update Monday, June 22, 2009 11 am CDT

Call Summary

In attendance:

Andrew Buckler, MS (Co-Chair) P. David Mozley, MD (Co-Chair) Maria Athelogou, MD Kristin Borradaile Patricia E. Cole, PhD, MD Gary Dorfman, MD Charles Fenimore, PhD Wendy Hayes, DO Philip F. Judy, PhD Despina Kontos, PhD Michael McNitt-Gray, PhD James Mulshine, MD Nicholas Petrick, PhD Anthony P. Reeves, PhD Daniel C. Sullivan, MD Hiro Yoshida, PhD

RSNA staff

Joe Koudelik Mary Cerceo

General Discussion:

Topics for Discussion

- NIBIB Contract Proposal
- Issues Associated with 'Going Forward' Items
- Software Performance Characteristics Call
- COPD Questions raised by Dr Clunie
- Group progress- Groundwork

NIBIB Contract Proposal

Proposal not as stringent as traditional RO1 grant in structure/requirements

- No specific format
- Need to provide enough information to prove to reviewers that funding will be justified
 - $\circ~$ e.g. types of experiments the group could pursue, without being committed to if funded
- Need to establish two things:
 - Give credit what has been and what is being done
 - Encourage NIBIB that this is serious work with serious effect with many stakeholders and strong collaboration
- A "Notice of Intent of all Collaborators"

vCT Group 1A

- Dr Petrick to draft a one page appendix on preliminary Group 1A activity in efforts to draw-in RadPharm efforts (contributions)
- Items to include would be technical results, % of involvement of all group members, all data collections performed, and data analysis that remains

vCT Group 1B

- Dr McNitt-Gray to draft 2 paragraphs highlighting experimental design, including specific aims and methods
- Another appendix will list resources committed to 1B

vCT Technical Committee has benefited from Dr Reeves' (Volcano) involvement

• Dr Reeves to acknowledge efforts and draft a couple of sentences to establish connections and strengthen activities – for section C1.1

Issues Associated with 'Going Forward' Items

Fiscal Proposal

- Investment should be part of the 'going-forward'
- Investment by NIBIB could be leveraged by other professional organizations and industry
- NIBIB will only add to and accelerate that which has already been done
- Even with wealth of volunteer efforts to date, all Tech Cttes would still find funding helpful for future efforts

Need to demonstrate level of investment already made by group

- Significant contributions
 - o Number of images to be generated and contributed
 - o RadPharm efforts
 - Statistical design effects to be included
- The reality of the vCT efforts have been crafted around stakeholder needs
- Lack of hard data remains an issue
 - Data already generated/submitted by Group 1A and Merck
 - Need preliminary data to demonstrate QIBA can do the work, i.e. has the expertise
 - Data at the science-level needed

Software Performance Characteristics Call

- Dr Schwartz to lead SW inaugural call on Monday, June 29, 2009 at 9:00 AM CDT
- Decision made to push ahead even without ideal attendance; multiple calls will allow participants a degree of freedom to attend

COPD Questions raised by Dr Clunie

Q1 - Is this confined to COPD, or is asthma also in scope?

- Group to focus on COPD for now, asthma as a later step
- Quantification of matrix will be useful for other diseases, i.e. asthma

Q2 - Is the goal to determine biomarkers that are a surrogate for some other clinical measure (such as PFT), and if so is this for clinical or drug therapy evaluation (or both)?

- The COPDGene goal is to identify phenotypes that become biomarkers
 - Biomedical development must eventually go beyond pulmonary function metrics
- YES for both clinical and drug therapy evaluation but the therapy end to be of stronger focus
 - Drug therapy has historically been the first stage
 - Drs Stoel and Coxsan both involved with clinical trials now
 - Drug therapy evaluation can back-into to clinical care, but not vice versa
- Additional COPDGene Goals:
 - Include non-smoking "normals" and longitudinal studies more precise measurements needed
- Early part of QIBA activities is to set clinical context inclusive of measurements to improve this is also the efforts within COPDGene

Q3 - Who is going to determine response criteria as opposed to the single time point measurement itself (if this is out of scope of QIBA, as has been determined for other biomarkers)? UPICT?

• Answer to Q2 applies here as well

Q4 - Does the scope include bronchial wall thickening quantification, or is this confined to lung density (both would be desirable)?

YES

- Bronchial wall thickening is part of the COPDGene efforts
 - o COPD performs QA on phantoms with wall thickening quantification
 - o Not clear how this fits into clinical assessment though
 - o Once the clinical context is laid out, this will become clearer

Q5 - Is this within scope of the CT Volumetric group, or does it requires its own sub-group with equal standing to the others?

- These efforts will be part of the vCT group
- Subgroup for this disease area will meet separately (like a lung cancer group)
- No separate group will be created; only ad hoc disease groups created
- Major groups are based on modality
- COPD needs to start small and grow slowly
 - Lay out clinical context first
 - Draw from the main group moving forward
- RIDER may be helpful for COPD due to their abundant CT data (emphysema scans)

Q6 - Do we have the right stakeholders involved to make an assessment of radiation dose versus dose required for accuracy and repeatability versus the clinical benefit obtained (over other measures)?

YES

 COPDGene has access to the right stakeholders; has access to broad talent-base if needed

Group Progress-Groundwork

- vCT Group 1B has a call on Wednesday (June 24, 2009)
- Experimental design to be focus of call

vCT Group 1C had call last week (June 17, 2009)

- Group fleshed-out phantom details
- Staging collection in Washington area proposed Need good vendor/scanner representation
- Need contacts (people) at:
 - o Johns Hopkins Dr McNitt-Gray to forward contact names to Dr Fenimore
 - Georgetown Dr Murray Loew may have contact
 - George Washington Dr [Friedman ?] may provide contact
 - FDA, U Maryland and Duke have shown some interest
- Dr Fenimore offered to facilitate data collection if scans were done locally (Washington area)

Next Steps:

Mr Buckler to modify the proposal in three areas (more robust text)

- C1.1 text needs amending
- Appendix on preliminary work in vCT
- Prospective Group 1C projects

Section C1.1 Updates

- Early stage lung cancer and COPD could be added to the last paragraph of C1.1
- Dr Reeves to acknowledge efforts and draft a couple of sentences to establish connections and strengthen activities to C1.1

- Dr Mozley to suggest mark-up mode to C1.1
- Dr Schwartz to add MSK Coffee Break work to C1.1

vCT Groups 1A, 1B, 1C to draft one page content for appendices:

- 1A preliminary work overview (due by 6/22/09)
- 1B & 1C Examples to substantiate forward going spending (1B due by 6/24 & 1C by 6/26)

RSNA staff to extract a clean WORD version for the FDG-PET Wiki posted protocol and email to Dr. Dorfman