

QIBA Quantitative DCE-MRI Subcommittee

Wednesday, February 3, 2010

11 AM CST

Call Summary

In attendance

Edward Jackson, PhD (co-chair)
Orest Boyko, MD
Andrew J. Buckler, MS
Melanie Freed
Hendrik Laue, PhD
Jiacho Liang, PhD
Aytekin Oto, MD

David E. Purdy, PhD
Mark Rosen, MD, PhD
Annette Schmid, PhD
John Waterton, PhD

RSNA

Fiona Miller
Joe Koudelik

IRAT-QIBA Phantom Data Acquisition Update

- UPenn data acquired on Siemens VB15 and VB17 platforms; analysis of both datasets deemed useful (VB15 data analyses completed and previously presented.)
- Dr Jackson to follow-up analysis with Dr Ashton and if Dr Ashton is agreeable to analyze the VB17 data Dr Jackson will let Dr Rosen know to transmit the data to VirtualScopics and will include the results with the VB15 data (spreadsheet)
- Second phantom and protocols (Drs Jackson/Karczmar) received at Duke; ready to begin image acquisition on Philips platform
- Phantom to be shipped back to MDACC, then to UC Davis upon completion of scanning

Phantom Design (Dr Jackson)

- Dr Jackson reviewed CAD of proposed phantom design based on Dr Evelhoch's "pseudo-rotation" design
- Contains 3cm diameter (cross-section) flat-bottom centrifuge tubes; 3 pseudo-rotations (0-105-210 degrees) – 8 compartments each filled with 30 ml of NiCl₂ solutions
- Internal plates will be etched with 'TR' (Top-Right) in upper right hand corner of the top plate and 'BL' (Bottom-Left) in the lower left hand corner of the bottom plate for orientation
- Inner 8 samples to simulate vascular input function (VIF) values; $\Delta R1$ distribution from 0-28 mM⁻¹ s⁻¹
- Outer samples to simulate tissue values; $\Delta R1$ distribution from 0-11 mM⁻¹ s⁻¹
- Dr Jackson provided MDACC in-house fabrication cost: approximately \$500 (\$100 for phantom with vials and \$400 for fill solutions); RSNA agreed to finance this prototype MDACC phantom construction up to \$500
- Dr Jackson to secure materials and begin fabrication at MDACC
- ISMRM (NIST) collaboration suggested; sharing of phantom fabrication costs possible
- Quality Control process needed to monitor fill solution stability in aging phantom; element analysis could prove costly; further discussion needed

NIBIB update

- No decision or notification yet on funding but signs remain favorable

Clinical test-retest

- Interest in planning for clinical test/retest while waiting for funding decision
- Will need to engage support of statistician
- Pursuit of 'Phase 1 applications' in liver and lung lesions proposed; motion/registration issues will be challenging

Roadmap

- Consensus that it is important to define a roadmap for DCE-MRI to elucidate issues related to phantoms/scanners vs. role as biomarker
- Discuss whether DCE-MRI can be used to identify patients to treat or assess treatment response
- Readouts such as K^{trans} (not the modality technique, e.g., DCE-MRI) are the biomarkers in specific applications and should drive the acquisition protocol
- With regard to Dr Zahlmann's email query of "established biomarkers" and next steps, it was suggested that biomarkers AUC_{60} (blood normalized) and K^{trans} have established records based on Phase I/II trials; biomarkers such as v_e and v_p certainly have not been as widely reported or investigated
- Need to better harmonize the DCE-MRI and UPICT efforts

Imaging Biomarker Qualification Process Summarized (Mr Buckler)

- Targeted discussions proceeding with the FDA; QIBA efforts to be 'mapped' to the FDA regulatory process
- Qualification pathway discussed:
 - Request letter
 - Briefing Document-principal discussion document; provides structure
 - Full Data Package-results of all studies
 - Signoff Letter

Next Steps:

- Continue with UPenn Siemens VB17 analysis once Dr Rosen sends data to Dr Ashton; Dr Purdy to screen protocol for possible acquisition issues
- Dr Jackson to forward phantom prototype design to Joe for Wiki posting; group feedback encouraged
- Dr Jackson to send out VFA data (MDACC vs. UPenn) to discuss on next group call
- Dr Jackson to send 2009 reference paper concerning $NiCl_2$ to group
- Continue with Profile development activities
- Start drafting IB Qualification Process 'Briefing Document'
- Compile existing qualification evidence; engage statistician
- Next call scheduled for Wednesday, February 17, 2010 at 11 AM CST