QIBA Quantitative DCE-MRI Subcommittee Update

Wednesday, March 3, 2010

11 AM CST

Draft Call Summary

In attendance

Gudrun Zahlmann, PhD (co-chair)
Daniel Barboriak, MD
Orest Boyko, MD
Andrew J. Buckler, MS
Geoffrey D. Clarke, PhD
Jeffrey L. Evelhoch, PhD
Melanie Freed
Alexander Guimaraes, MD, PhD
Marko Ivancevic, PhD
Gregory Karczmar, PhD
Michael Knopp, MD, PhD
Despina Kontos, PhD
Hendrik Laue, PhD
Jiachao Liang, PhD
Colin G. Miller, PhD
Mark Rosen, MD, PhD
Katherine Scott, PhD
John Waterton, PhD

RSNA

Fiona Miller
Madeleine McCoy

Phantom Update

- The Evelhoch /QIBA phantom prototype is being fabricated in the MD Anderson machine shop and should be available within the month
    - High purity NiCl2 and NaCl, polypropylene centrifuge tubes have been received.
    - RSNA will reimburse costs up to $500
    - Dr Jackson will create the mixtures based on the deltaR1 values discussed on the last tcon, taking into account Dr Rosen's suggestions of February 11th.
- 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
- Dr Ashton has agreed to process the VB17 data from UPenn, as time allows.
    - Dr Rosen to send data to Dr Ashton.
- Dr Rosen to confirm with Dr Jackson that phantom is to be sent to Dr Karczmar at UChicago (address needed)
    - Use same parameters as Duke

Roadmap

- K^{trans} as a validated biomarker is the ultimate goal
- DCE as a pharmacodynamic biomarker is evident, but not clear how to establish that impact on vasculature is related to outcome
    - Antiangiogenic approach has not been proven to affect outcome
    - Outcomes are needed to engage regulators
- Need technical assessment to ensure K^{trans} is a viable biomarker before measuring treatment response or prognostic value
- Consider whether it is necessary to be able to answer the following questions
    - Does a drop in K^{trans} indicate improved outcome?
    - Is a high K^{trans} prognostic for angiogenic treatment?
- Comparability of K^{trans} between centers not yet achievable

    - Establishing a standard and methodology will permit comparison of data from individual studies to answer the above questions
    - Standardization needed to have confidence in results
- Need to decide whether DCE-MRI is at a stage to prepare briefing document to position a pre-agreement with the FDA on work that needs to be done
- Agreement that an endpoint and roadmap need to be established
- Results of phantom studies will help identify problems
- Test-retest stage can then follow
- Dr Zahlmann to draft basic outline for review before next call
- Qualification activities not the purview of this Committee

Next Steps:

- Dr Rosen to send UPenn data to Dr Ashton for Siemens VB17 analysis
- Dr Karczmar to supply shipping address to Dr Rosen
- Dr Zahlmann to summarize next steps to be taken for group review
- Next call scheduled for Wednesday, March 31, 2010 at 11 AM CST