QIBA PDF-MRI (DWI) and IMI QuIC-ConCePT T-con

Wednesday, 27-February-2013 at 11 AM CST (GMT-6)

Call Summary

Participants

Gudrun Zahlmann, PhD (Moderator) John C. Waterton, PhD (Moderator)

Michael Boss, PhD

Thomas L. Chenevert, PhD Nandita DeSouza, MD

Edward F. Jackson, PhD Alan Jackson, MD, PhD Yan Liu, PhD

Daniel Sullivan, MD

RSNA

Fiona Miller Joe Koudelik

General Discussion

Collaboration level overview (ambition level document) – Dr. Waterton

- Ambition level 1 deemed an appropriate starting level for collaboration, with Ambition levels 2 and 3 pursued in parallel
- Group members agreed that cross comparison gives accurate overview of each organization's foci
- Two ways possible for projects to interact; at the lowest level:
 - o Exchange of ideas and information to avoid duplication of effort
 - Use of QIBA protocols or clear rationale why not to use
- QuiC-ConCePT has many volunteer and patient studies underway for 2012-2013
- Both groups to identify which studies might be of benefit to each other
- QuiC-ConCePT to identify which of their trials are QIBA protocol compatible

Feedback from QIBA and proposed collaboration details - Drs. Zahlmann and Boss

- Dr. Chenevert described the current version of the QIBA ADC ice water phantom as under development, to be used for protocol quality control purposes and site qualification in addition to original QuiC-ConCePT phantom
- Dr. Chenevert indicates that QuiC-ConCePT phantom has large field-of-view and 5 compartments to allow different ADC values
- Updated QIBA protocol available but has not yet been shared; pending Dr. Chenevert's quality control (QC) section updates
- Drs. DeSouza and Liu (overseeing the current QuiC-ConCePT ice water phantom site testing) to prepare a list
 of ADC trials that are underway and identify which sites meet the minimal performance standards developed
 by QIBA
- Though Dr. Boss estimated that the ADC phantom will be available by q2 of 2013, he stressed that this should not hinder current QuiC-ConCePT site qualification efforts
- Need to determine if the ice-water phantom and protocol used by QuiC-ConCePT is compatible with the QIBA version; a comparison was suggested to determine most appropriate for future studies
- Using the same ADC phantom in Europe and the US trials was considered an ideal situation
- Phantom design agreed upon as a primary goal, with phantom data analysis a secondary goal in the future

Discussion, decision on collaboration level and next steps – Drs. Waterton and Zahlmann

Data from current QuiC-ConCePT studies could be useful for QIBA test/retest confirmation

- QuiC-ConCePT has three projects in scope and 5 clinical trials based on lung and liver, scheduled to be completed by June 2013; additional trials as part of validation studies to be completed by q4 of 2013.
- Pre-clinical vs clinical scope of ADC phantoms discussed; concern expressed over the impact on Clinical Trial design
- Anticipated that both phantom versions will be similar and provide comparable/compatible data
- New QIBA phantom 's modularity will allow multiple ADC values, compatible with spatially dependent MR readings
- Dr. Waterton suggested a target date of November 2013 (ISMRM abstract deadline for 2014 meeting) to address ADC phantom design and, if possible, the approach to data analysis which is needed for determining site qualification
- Dr. Waterton asked group to consider applicability of phantom to pre-clinical studies
 - Dr. Chenevert indicated that no plans in place to develop a pre-clinical ADC phantom but is happy to have the group adopt design for their pre- clinical work
- The future goal of collaborative data analyses was discussed
 - Need to establish threshold cut-points for acceptable performance
 - Updates will be necessary as technology evolves
 - Need to determine acceptable level of variability and repeatability, i.e., signal-to-noise

Ambition level 2:

- QuiC-ConCePT data may help QIBA with their ongoing FDA regulatory biomarker qualification efforts; this may
 prove too early for discussion, but should be kept "on the radar"
- Discussion concerning pre-competitive data sharing policy would be valuable; data exchange would be valuable to test/retest studies
- Phantom data suggested to be made available to both groups for technical validation of protocols, while governance around sharing of clinical data needs to be addressed
- Consideration could be given to have QuiC-ConCePT focus on lung and liver; a formal partnership building off the extensive QuiC-ConCePT expertize in liver studies
- Both organizations continue their interest in leveraging relationships with manufacturers

Next steps:

- Dr. Zahlmann involved in both projects and will need to liaise activities
- Summary of what has been agreed will be circulated by Dr. Zahlmann for review
- Important to keep momentum moving; additional calls will be needed
- Establish time for regular calls at six-week intervals was suggested
- Assembling at the ISMRM meeting in Salt Lake City (April 20-26, 2013) proposed; Dr. Boss to contact Roberta Kravits for meeting space for 10 people
- ISMRM 2014 abstract submission deadline in November 2013 deemed a reasonable goal
- Electronic poster submission deadline of 3 April 2013 to be considered