QIBA PDF–MRI (DWI) and IMI QuIC-ConCePT (Quantitative Imaging in Cancer-Connecting Cellular Processes to Therapy) T-con

Monday, 10-December-2012 at 9 AM CST (GMT-5)

Call Summary

Participants

Gudrun Zahlmann, PhD (Moderator)

John C. Waterton, PhD (Moderator)

Anouk Algeier, PhD

Michael Boss, PhD

Thomas L. Chenevert, PhD

Nandita DeSouza, MD

Edward F. Jackson, PhD

Yan Liu, PhD

Ralph Sinkus, PhD

RSNA

Fiona Miller

Joe Koudelik

General Discussion

Welcome

Dr. Zahlmann welcomed all participants to this inaugural t-con to discuss areas of possible collaboration between the QIBA and IMI QuIC-ConCePT initiatives in quantitative Diffusion weighted MR imaging.

Introduction of QIBA efforts (Edward Jackson, PhD)

Dr. Jackson briefly summarized the basic premise for the QIBA (RSNA) initiative as extracting objective, quantitative results from imaging studies to improve the value of imaging in clinical practice. QIBA was organized in 2008 with the mission to improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, patients, and time.

The QIBA process involves the industrialization of biomarker use via the creation of standardized image acquisition protocols and profiles, development of metrology standards (terminology, technical performance and algorithm comparisons), and the establishment or use of an image data warehouse for storing technical committee groundwork project datasets.

Introduction of IMI QuIC-ConCePT efforts (John C. Waterton, PhD)

Drs. Waterton and DeSouza provided an overview of the Innovative Medicines Initiative (IMI) structure and mission. Currently, the IMI is the world's largest biomedical/healthcare public-private partnership initiative. A joint undertaking between the European Union and the European pharmaceutical industry association (EFPIA), this initiative supports precompetitive collaborative research to accelerate drug development and pharmaceutical innovation in Europe. A IMI budget of €2bn is provided by the European Commission and in-kind from EFPIA. IMI funds projects in 4 focus areas (efficacy, safety, training, knowledge management). QuIC-ConCePT is one of those projects and runs for 5-years (2011-2016).

Focus of QuIC-ConCePT remains on bringing imaging biomarkers (IBs) into the pharmaceutical decision making "Go/No-Go" process in early (Phase 1 / Phase 2) clinical trials. Both positive and negative (i.e., no change) IB results are deemed critical in the decision making process. Animal studies have been pursed to better understand mechanisms of IBs to inform biological validation for multicenter clinical trials. As primary metastatic sites, the focus is on liver and lungs. Human studies will be employed to demonstrate reproducibility and to determine that change in IB faithfully reports change in underlying pathology. The goal is development and evaluation of IBs of proliferation, cell death and apoptosis so that "*by 2016, drug developers will be able to incorporate these IBs in Phase I trials of investigational therapies confident that the IBs are technically valid, measured change in the IBs faithfully reflects the desired change in the underlying tumor pathology (and no change in IB means no change in*

tumor pathology), and the IBs can be deployed in multiple cancer centers in a robust, consistent, ethical, and cost-effective way acceptable to patients".

Current year-1 project status:
- Animal studies, technical validation and image analysis of primary focus
- Biological validation and reproducibility studies just beginning

DWI-ADC Discussion (Apparent Diffusion Constant)
Dr. Boss discussed background efforts related to QIBA DWI profile development focusing on both 1.5 and 3T MR scanners. Image analysis procedures and digital reference objects will also be addressed in the profile. An extensive organ-based literature search has begun to help identify technical parameters, and a modified diffusion phantom is under development. Technical Committee goal is to have the phantom and initial Profile draft completed within one year (i.e., end of 2013).

Although QIBA efforts are based on technical issues associated with quantitation and not biological qualification, consensus was that the QIBA Profile supported by literature and expert opinion will be very useful to underpin the technical validity of this biomarker, while the biological validation would be pursued by the IMI.

Much animal data has already been collected for ADC intervention, making a good test bed for image analysis. Collaboration on lung and liver organ systems, with QIBA contributing the technical validation on values for ADC with input by the QuIC-ConCePT team and IMI doing the clinical studies was identified as an area for further discussion.

Commonalities between QIBA and IMI efforts addressed
With a common image acquisition standard needed for both Europe and the US, Dr. Chenevert noted that much opportunity existed for complementary work. Collaborative activities discussed included image analysis, quality control, working to better engage vendors. Both groups to continue developing optimized acquisition protocols; once complete, these will be compared and a common protocol will be extracted for use in clinical research/clinical trials and clinical care.

Next Steps:
- Cross-effort membership was proposed as a means to keep groups informed.
- Next t-con to be schedule in January 2013. Thoughts/comments may be circulated via e-mail until then.