

QIBA vCT Technical Committee Weekly Update
Monday, July 13, 2009
11 am CDT

Call Summary

In attendance:

James Mulshine, MD (Moderator)
P. David Mozley, MD (Co-Chair)
Maria Arthellogou, MD
Charles Fenimore, PhD
Philip Judy, PhD
Kevin O'Donnell
Nicholas Petrick, PhD

Daniel Sullivan, MD
Matthias Thorn, PhD

RSNA staff
Fiona Miller
Joe Koudelik

General Discussion:

Comment regarding Profile Claims Language (Dr Thorn)

- Clinical care is the broad and ultimate goal
- What Claims are needed for the clinical and diagnostic process?
- Clinical trials are a useful subset of clinical care
- Vendor point of view
 - Vendors can currently do solid nodule volumes in the field
 - Profiles need better defining to help compare vendor products
- Profile to define manufacturer standards and algorithms needed
- QIBA to look beyond clinical trials for analysis tools (e.g. liver tools, etc)
 - An evolving set of tools needed (to apply to 3-4 diseases)
- Task is to teach/educate radiologists the purpose of these tools, what they can do
- Profile needed to address small nodules, based on new multi-detector machines, using small recon kernel and restraining the number of sites performing study
- Profile needed to address segmentation of nodules and response assessment
- New "real-life" scenarios will be challenging
 - Clinical trials choose target lesions prospectively, easier to measure lesions this way, this is not possible in a clinical setting

Neoadjuvant Window-of-Opportunity Trials Group Overview (Dr Mulshine)

- First WebEx for the Neoadjuvant Window-of-Opportunity Trials Group was July 1, 2009
- Early confirmation of drug efficacy in clinical trials is needed by Pharma
 - Few opportunities to currently perform this
- Direct molecular targets being studied, i.e. precursors of lung cancer
 - AKT signaling
 - Epidermal Growth Factor
 - Kinase blocking steps
 - Small molecule inhibitors of IGF-1 receptor pathway
 - Cox inhibitors, etc

Initial Proof-of-Concept Trial—GSK's Pazopanib Trial—reported at ASCO 2008

- 2-3 week-long experimental drug exposure in early stage lung cancer patients
- CT scans done pre- and post- resection
- Tissue analyzed for drug efficacy
 - e.g. GSK working on pre-clinical validation and has demonstrated a reduction in nodule volume *visually*; need to support this via molecular correlation
- QIBA to improve Best Practices around this trial structure

Pharma Perspective

- This is an opportunity to move into an un-crowded area with new-candidate pipeline drugs
 - targeted therapies already developed in breast cancer
- QIBA to help define variance in the clinical setting
- Need better noise-to-signal understanding
- Clinical trial group ideally needed to push this trial design to apply to acquisition parameters and quality control measures

IASLC BOD Meeting in San Francisco (July 30-August 04, 09)

- Group composed of scientific, lung cancer faculty
- Chance for QIBA to engage the leadership in this area
- Drs Mulshine, McNitt-Gray and Mr Avila, Buckler and O'Donnell to attend this BOD meeting to review QIBA work progress

Collaborative Opportunity to host DICOM file collections with preliminary studies

- Need more professional involvement to move forward
- Tom Baer of the Optical Society of America (OSA) to be involved
 - <http://www.osa.org/aboutosa/default.aspx>
- Optics Express could post a subset of QIBA data and/or link back to the NCIA for details
 - <http://www.opticsinfobase.org/oe/Issue.cfm>
- Proposed that QIBA data be posted to both OSA and NCIA for broad research access

Early vs. Late-Stage Disease

- Late-stage disease groundwork (e.g. vCT Groups 1A, 1B, 1C) seen as a near-term challenge for most existing trials
- Early-stage disease deals closer to imaging ground layer and a longer term challenge
- Characterization of noise is very interesting; more relevant in early-stage
- More imaging issues present in early-stage assessment; groundwork may raise issues beyond those seen with late-stage
- How much additional/new work will be needed?
- Utilize existing material and tighten up constraints on performance
- Focus on standardizing the vCT acquisition protocol
 - Need to approximate optimal performance levels
 - Compare phantom with real-world data
 - Need to prove our concept

Voxel Shift and Worse Case Scenarios

- Voxel shift not addresses (by Group 1A)
- Study of nodule repositioning within the lung phantom with various attachment s not part of the Group 1A experimental design, i.e. positioning of nodules in lung with shift

Next Steps

- Dr Mulshine to forward IASLC details to Dr Schwartz for reference
- Tom Baer (OSA) to be invited to participate on vCT calls