

**QIBA VolCT Update WebEx  
Monday, April 13, 2009  
11AM (CST)**

**Call Summary**

**In attendance:**

Andrew Buckler, MS (Co-Chair)  
P. David Mozley, MD (Co-Chair)  
Lawrence Schwartz, MD (Co-Chair)  
Kristin Borradaile  
David Clunie, MBBS  
Charles Fenimore, PhD  
David Gustafson, PhD  
Wendy Hayes, DO  
Michael McNitt-Gray, PhD  
James Mulshine, MD  
Daniel R. Nicolson

Kevin O'Donnell  
Nicholas Petrick, PhD  
Daniel Sullivan, MD  
Hiro Yoshida, PhD  
Binsheng Zhao, PhD

**RSNA**

Fiona Miller  
Susan Anderson  
Joe Koudelik

**Introduction and Agenda (Mr Buckler)**

For discussion in today's call:

- Profile review
- Discuss preparation for RSNA 2009--poster preparations
- Peer review of Buckler proposal on 'Harmonized Approach for QIBA' in advance of QIBA Steering Committee call, Thursday, Apr 16

**Review of Buckler proposal on 'Harmonized Approach for QIBA' (Mr Buckler ppt)**

- The "cloud diagram" is an emerging formalization of what we are trying to accomplish for the various stakeholders
- Captures areas of exercise the FDA, CDRH and CDER, are interested in as well as business interests
- Demonstrates similarities and differences in team approaches
- Suggestions from group:
  - Challenges may be opaque to average clinician; work on message
  - Make it a story; re-arrange to imply a flow; a logical order needed
  - Develop versions addressing views from clinicians, pharma, vendors
  - Develop a process map; will also elucidate differences between the three Technical Cttes - larger context will flow better
  - Arrange along concepts of "faster, better, cheaper"
  - Frontload with specific aims and action items
  - Broadcast to management the use in clinical practice areas
  - On slide 16 re claims for a new biomarker
    - change delta T - goal is for patients and clinical trials
    - need value-add for any efforts such as "come to objective conclusion of drug trial in a shorter timepoint"; people will then be engaged in other processes we are outlining

### **Discussion on DROs (Dr. Clunie)**

- In FDG-PET, Dr Kinahan is coordinating Digital Reference Objects (DRO) effort; important to assess variability and find ways to minimize
- In DCE-MRI, trying to establish protocol for acquisitions and devise strategies to minimize variabilities
- In VolCT, density calculation
- Could use a synthetic reference object, e.g. Monte Carlo solution, or use a phantom on multiple pieces of equipment for acquisition (empirical approach)

### **Discussion of UPICT and VolCT relationship**

- The group discussed the role of VolCT Technical Committee in vetting UPICT consensus protocol
- In the slide with cloud diagram, should arrows go in both directions between QIBA and UPICT?
- Groups 1A, 1B and 1C could validate UPICT consensus protocol; Merck could pilot the protocol; current protocol claims understood to be tentative, even hypothesis derived
- Dr Mozley suggested that groups like QIBA and UPICT should act quickly to supply pharma with a consensus protocol - specifics can be modified in the future
- Suggestion for discussion with Dr Dorfman about relationship of UPICT and QIBA Technical Committees

### **Next Steps**

- Next call scheduled for Monday, April 20, 2009 (11 AM CDT); Dr Dorfman will join call
  - Mr Buckler to send "cloud" diagram to Dr Dorfman for reference
- Discuss alternatives to scientific abstract at RSNA 2009
- The proposed July 9-10, 2009 dates for a continuation of the roadmapping process begun at the March 2009 Imaging Biomarkers Roundtable meeting are not suitable for the meeting; alternative dates will be suggested
- Group 1C call (Dr Fenimore) scheduled for April 15, 2009