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