Call Summary

**In attendance:**
- P. David Mozley, MD (Co-chair)
- Hubert Beaumont, PhD
- Andrew Buckler, MS
- Patricia Cole, PhD, MD
- Alden Dima, MS
- Charles Fenimore, PhD
- David Gustafson, PhD
- Philip Judy, PhD
- Michael McNitt-Gray, PhD
- David Miller, PhD
- James Mulshine, MD
- Kevin O’Donnell

**RSNA:**
- Nicholas Petrick, PhD
- Anthony Reeves, PhD
- Ehsan Samei, PhD
- Ann Scherzinger, PhD
- Daniel Sullivan, MD
- Ying Tang, PhD
- Binseng Zhao, DSc
- Joe Koudelik
- Madeleine McCoy

**Topics for discussion**
1. VolCT Tech Ctte poster update for RSNA 2011 kiosk area
2. Clinical trials guidance for the FDA responses – understanding section relationships

**VolCT Tech Ctte poster update for RSNA 2011 kiosk area**
- Dr Mozley and Mr Buckler provided an overview of the proposed 2011 VolCT TC poster layout, section by section
- Introduction is to retain purpose and aims of what the Tech Ctte is attempting to accomplish
- Need to highlight new results
- Title change proposed; “Quantifying Change in Tumor Volumes as Response to Treatment”
- “Volumetry” a new catch-term to be used
- Goal of poster is to draw in people and provide project updates without overwhelming them with detail
- Deadline for submitting material to Dr Mozley will be close-of-business on October 14, 2011, to meet the RSNA deadline of November 4th, 2011
  - Close-of-business meaning Sunday evening (Oct 16, 2011)
  - RSNA staff to distribute material received the on Oct 17th, before the 11 am (CDT) VolCT call
- [2010 QIBA Kiosk posters](#) are available on the Wiki for reference
- QIBA Kiosk area will have high-level mission, process, organizational and committee details

**Project leader updates for kiosk poster**
- Introduction – Mr Buckler and Dr Mozley to provide current activity and overview of 2010 progress
- 1A - Dr Petrick to provide latest results for the 1A study; only study that speaks towards accuracy
- 1B - Dr McNitt-Gray to provide preliminary details; methods, images, result graphics and next steps
- 1C - Dr Fenimore to provide update
- 3A - Dr Athelogou to provide statement of 3A challenge goals
- 3B - Dr Zhao to provide summary of project goals and those obtained so far
- Duke project – Dr Chen and Samei to provide update
- U Colorado project – Dr Garg/Scherzinger/Miller to provide update
Profile development – Mr O’Donnell to provide overview of what the VolCT Tech Ctte has done with Profile development (i.e., acquisition protocol, segmentation analysis, QA, certification methods, etc) “What is a Profile” detail not needed; this will be provided on the QIBA kiosk for general reference.

**FDA Clinical Trials Guidance – Mapping within Sections**
- QIBA’s one and only chance to react to the FDA’s imaging guidance request
- Influencing the FDA guidance vs. addressing gaps within QIBA Profiles/Protocols discussed; caution not to be overly detailed in response since this guidance goes beyond QIBA’s scope
- The Tech Ctte concluded to compile a conservative response with hopes that the FDA will eventually reference QIBA when discussing quantitative imaging
- Tech Ctte feedback solicited in similar format as used for Profile Public Comment; three responses submitted to Mr Buckler; comments to Mr Buckler still welcome past the Oct 3rd deadline
- Mr Buckle to draft a compiled response for review by QIBA leadership
- Response matrix (tool) to assist with QIBA responses discussed
  - FDA Guidance Text
  - Mapping to UPICT Protocol Template
  - Mapping to QIBA Profile Template
  - Feedback to FDA
- Pharmaceutical Imaging Group (PIG) response timeline reviewed
  - Draft comments done (10/0/2011)
  - Legal review (10/12/2011)
  - Finalized pharma response (10/17/2011)
  - Forward responses to FDA (10/18/2011)
- Mapping within document sections discussed
Next steps:

- Final poster content to be discussed on the next call, Monday, Oct 17, 2011, prior to handoff to the Merck graphics team
  - Deadline for submitting material to Dr Mozley will be by Sunday evening, Oct 16th
  - RSNA staff to distribute material received the morning before the 11 am (CDT) VolCT call on Oct 17th
- RSNA staff to follow-up with Drs Athelogou and Garg concerning poster details and deadlines
- FDA imaging guidance feedback needed by Mr Buckler by mid-week (Oct 5)
- Reminder: Next VolCT TC call scheduled for Monday, October 17, 2011 (no call scheduled for Oct 10th)