In attendance
Andrew Buckler, MS (co-chair)                          James Mulshine, MD
Harris Ahmad, MD                                        Kevin O'Donnell
Thomas M. Baer, PhD                                      Michael O’Neal, MD
Kristin Borradale, MS                                    Nicholas Petrick, PhD
David A. Clunie, MBBS                                    Daniel Sullivan, MD
Patricia E. Cole, PhD, MD                                Hiro Yoshida, PhD
Charles Fenimore, PhD                                    Binsheng Zhao, DSc
John Fraunberger                                         RSNA
David Gustafson, PhD                                     Fiona Miller
Philip F. Judy, PhD                                      Susan Anderson, MLS
John Lu, PhD                                             Joe Koudelik
Mahadevappa Mahesh, MS, PhD                              

Update on **Optics Express** paper (Mr Buckler)
- Paper to be published in special issue of *Optics Express*, using online visualization tool
- Mr Buckler has received text and image files from Dr Petrick
  - Dr Petrick to re-send using DICOM format
- Dr McNitt-Gray has sent text; Drs McNitt-Gray and Zhao will upload LIDC DICOM datasets
- Dr Fenimore will upload text and images
- Mr Buckler will contact Dr Mozley re: data files
- Group decision to use DICOM rather than TIF format; DICOM format provides more information for users and is widely supported by the radiology community
- Mr Buckler will circulate completed draft to entire committee as it converges

**Group 1A analysis (Dr Petrick)**
- Dr Petrick has forwarded data table to Dr Clunie for comment
- Dr Petrick will continue work with Dr Kim on data analysis

**Group 1B (Dr Clunie)**
- RadPharm hopes to complete software change in January 2010

**Group 1C (Dr Fenimore)**
- Draft Procedures completed by Dr McNitt-Gray to characterize quality of imaging and specific resolution and noise level in collection
- FoV specifications under discussion; ACR phantom is smaller than FDA’s anthropomorphic phantom so acquisition sites may need to adapt scans based on target size; further discussion needed
- Work continues on Performance Protocol
  - Data available from 16-row detector at UCLA, U Maryland has offered data from a Philips 64-row detector; 64-row deemed to be target for most acquisition sites
  - Dr Samei (Duke) has volunteered to test on another scanner
- When testing of Performance Protocol is completed, Dr Fenimore will coordinate with Dr Petrick re FDA phantom and with sites for image collection and RadPharm for reading
• Goal is to have results fully reported by RSNA annual meeting 2010 (acquisition, analysis, manuscript preparation and submission all completed)

Roadmapping activity (Mr Buckler)
• Two documents reviewed by Mr Buckler:
  o Narrative paper *Consensus Position on the Assessment of Quantitative Imaging Biomarkers with Implication to Process Roadmap*
  o Excel spreadsheet of Roadmapping steps and activities overall and by modality
• Discussion of terminology: biomarker v. assay; suggestion to use term *imaging assay*
  o Dr Sullivan to circulate NCI document in which "assay" is used to refer to both specimen and imaging tests; the document is also available at: [http://www.cancerdiagnosis.nci.nih.gov/pdf/PACCT_Assay_Standards_Document.pdf](http://www.cancerdiagnosis.nci.nih.gov/pdf/PACCT_Assay_Standards_Document.pdf)
  o Terminology reflects continuum: assay at engineering end and biomarker at clinical end; need to be general to include imaging as an assay; how assay is used and related to clinical conclusions will be the biomarker component
  o Accurate vocabulary needed for the regulatory pathway process of the FDA
• Suggestions:
  o Begin paper with Roadmapping discussion followed by discussion (or Appendices) of phenotyping and progression concepts
  o Define terms such as *acquisition, assay, biomarker*
  o Suggestion to use term *imaging assay*
• Mr Buckler invited comment from all stakeholders

Next Steps
• Drs Petrick, Fenimore, Mozley, McNitt-Gray and Zhao to complete submissions for *Optics Express* paper
  o Mr Buckler to send text and FTP info to Dr Zhao and to contact Dr Mozley about submission
• Dr Petrick will continue with Group 1A analysis and methodology write-up
• Changes and/or suggestions requested on Roadmapping documents; submit in Track Changes mode or e-mail comments to Mr Buckler
  o Mr Buckler to draft description of pathway, validation and qualification using examples from sister technologies
  o Dr Sullivan will provide NCI document re: use of term *assay* to committee