QIBA Volumetric CT Weekly WebEx Calls

Discussion Overview
Possible phantoms
- FDA phantom (Myers/Petrick), anatomically specific to lungs
- UC-Davis phantom(IRAT/Boone), simple design with just spheres or more complicated one with 55 modules

Clinical Issues – develop clinical efficacy recommendations
- Clinically meaningful measurements – at what point can humans pick up size differences
- Change assessment
  - Overall survival
  - Quality of life improvement

Use existing materials (phantoms and data-RIDER) and put together in a new way, assess all platforms

Merck needs DICOM3 images, provided through a transparent/public venue, willing to financially support some activities

Agenda/action items from July 7, 2008:

	What	Who	Status
	Take advantage of projects that have already been done and/or are underway to get us started:		
1	Share phantom data collected at UC Davis	John Boone	
2	Distribute overview and contacts\\for phantom measurements, including recommendation on how to move forward to leverage current data/and efforts and meet current specific purposes	Larry Clarke	
3	Guide a pre-IDE meeting with regulatory side of FDA	Lou Marzella and Nick Petrick	

4	Engage FDA and NCI on the idea of creating a PPP for funding and guiding activities like our pilot study, then moving forward into clinical trials:
	    - Consider funding mechanism for QIBA effort in volumetric CT (a sponsorship for cost recovery)
	        - need to fund pilot study design itself
	        - need to buy phantoms, other supplies?
	    - Determine standards for reviewing data (as a neutral party)
	    - Encourage commercialization of phantoms (Mike Mcnitt-Gray has ideas here)
	    - Procedure and conventions for use of RIDER and other public access methods
		Lou Marzella and Larry Clark	

4	Produce draft of study design for multi-center pilot study with phantoms: - Incorporate sources of variability from our team's matrix, augmented by Rick's insights (findings), as experimental factors (for example, do not hold algorithm constant as it is	Charles Fenimore, Wendy Hayes, Nick Petrick, John	

	indicated in the matrix as a source of variability) - Utilize phantoms as described by Nick Petrick (commercially available) and John Boone (one-of-a-kind, must be shipped across centers) … both, not just one type, to get the most data and insight from the pilot - Study design should statistically determine effects due to the factors, by prescribing how many scans to do, how many centers, etc. - Consult Wendy Hayes to add clinical value and implications on study design - Use Biochange 2008 as a pattern	Boone	
5	Recommendation on approaching clinical efficacy	Larry Clarke, Ron Gottlieb, Larry Schwartz, Jim Mulshine	

Future Agenda Topics
  - ➢ Review progress against action items
  - ➢ Consider primary vs. metastatic disease