

Application for QIBA Project Funding

Title of Proposal: Assessing Measurement Variability of Lung Lesions in Patient Data Sets		
QIBA Committee/Subgroup: Volumetric CT Technical Committee		
NIBIB Task Number(s) which this project addresses: Task 7 – Determine the minimum change that can be measured for the proposed method		
Project Coordinator or Lead Investigator Information:		
Last Name: McNitt-Gray	First Name: Michael	Degree(s): PhD
Institution/Company: David Geffen School of Medicine at UCLA, Department of Radiology		

Please check the primary category for this proposal from among the following:

- 1. Identification of Technical Characteristics and Standards
 - a. Creation and refinement of protocols for image acquisition, analysis, quality control, etc., for specific clinical utility
 - b. Phantom development and testing
 - c. Identification and assessment of intra-reader bias (1) and variance across scanners and centers
 - d. Identification and assessment of inter-reader bias and variance across scanners and centers
 - e. Other
- 2. Clinical Performance Groundwork
 - a. Assessment of intra-reader sensitivity and specificity
 - b. Assessment of inter-reader sensitivity and specificity
 - c. Other
- 3. Clinical Efficacy Groundwork
 - a. Assessment of correlation between new biomarker and ‘accepted-as-standard’ method
 - b. Characterization of value in clinical trials
 - c. Characterization of value in clinical practice
 - d. Development/merger of databases from trials in support of qualification
 - e. Other
- 4. Resources (money and/or people) committed from other sources.

This project has already utilized tremendous resources committed free of cost from a variety of sources including:

- (a) Project management resources from RadPharm (now CoreLabs)
- (b) Extensive use of radiologist resources from RadPharm (5 readers marking 32 lesions, imaged twice and measured using three different methods; additional reads were performed to assess intra-reader variability).
- (c) Reading software was modified for image markup, annotation and recording of these markups into DICOM SR and other formats
- (d) The Image data used was from the NCI funded RIDER project, which sponsored the public release of the “Coffee Break” CT experiment data which was performed by Drs. Larry Schwartz and Binsheng Zhao (data was collected while they were at Memorial Sloan Kettering Cancer Center in NY; they are currently at Columbia University in New York)

Please provide a one-page summary that includes the following information:

Project Description

The purpose of this project is to perform the statistical analysis of data collected under QIBA Volumetric CT committee's 1B experiment, which is investigating the minimum detectable change in lesion size from patient datasets imaged on CT. This project used: (a) "Coffee Break" CT image datasets from 32 NSCLC patients who were imaged twice over a short (15 minute) interval on the same scanner using thin (1.25 mm) slices; (b) one lesion was identified for each patient, (c) Image data has been marked up by five radiologists at RadPharm (now CoreLabs); (d) each reader marked the lesions on each of the repeat scans to obtain measures of volume, single longest diameter and bi-dimensional diameters. This data has all been collected and now remains to be analyzed.

Primary goals and objectives

The primary goal of this project is to perform the analysis necessary to assess the minimum detectable change using datasets in which there was effectively no change in the patient. The minimum change will be analyzed for each measurement method (volumetric, linear measurements, bi-dimensional measurements). Inter- and intra-reader variability will be assessed. Preliminary investigations (and analysis from QIBA VolCT 1A group on phantom experiments) indicates that the shape and complexity of the lesion will have a significant effect on measurement variability; therefore several subgroup analyses (which may be post-hoc analyses) may be performed to assess the effects of lesion shape and complexity on both reader variability and ultimately on minimum detectable change.

Deliverables

1. Data analysis plan, which will be presented to QIBA VolCT 1B group for approval
2. Results of data analysis, including but not limited to:
 - a. Investigation into minimum detectable change using data described above
 - b. Inter- and intra-reader variability analysis
 - c. Subgroup analysis for different lesion characteristics (e.g. variability for simple lesions vs. complex lesions vs. lesions that are attached to normal anatomic structures)
3. Internal summary report of data analysis for QIBA members
4. Submission of results to conferences (e.g. RSNA, SPIE) for presentation
5. Submission of peer-reviewed publications based on results

Timeline [must include intermediate measureable milestones.]

2011 Q1 (approx. Feb 1): Data Analysis Plan presented to QIBA VolCT 1B group and approved

2011 Q2 (approx. June 1): Data Analysis Results completed

2011 Q3 (approx. Sept 1): internal summary report completed

2011 Q4: complete submissions of results to conferences and peer-reviewed publications