Application for QIBA Project Funding

Title of Proposal: Digital Reference Object for DCE-MRI analysis software verification		
QIBA Committee/Subgroup: MRI/DCE-MRI		
NIBIB Task Number(s) which this project addresses: Task 3		
Project Coordinator or Lead Investigator Information:		
Last Name: Barboriak	First Name: Daniel	Degree(s): M.D.
Institution/Company: Duke University Medical Center		

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) committeed from other sources.

Open source DCE-MRI software from dcemri R project (http://dcemri.sourceforge.net/).
JSim modeling software from U. Washington (http://nsr.bioeng.washington.edu/jsim/).
Matlab software, computer resources from Duke Department of Radiology

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

Project Description

One barrier to implementation of dynamic contrast-enhanced (DCE) MRI in multi-center clinical trials is that available software packages used to analyze the images may differ in their approach and implementation, causing variability in the extracted quantitative parameters. Because no standardized image analysis method is available, results obtained using DCE-MRI in different laboratories are difficult to compare, and the rational choice of one software implementation over any other for use in a multi-center trial is exceedingly challenging. As a first step in providing a standardized analysis process, it is necessary to ensure that software implementations are extracting parameters accurately. In this project, we propose to create digital reference objects (DROs) using synthetic data in order to help verify software packages for use in DCE-MRI analysis, and to initiate the development of verification protocols as a method to qualify software packages for use in clinical trials of DCE-MRI.

Primary goals and objectives

The overall goal of this proposal is to aid the process of DCE-MRI analysis standardization by developing DROs simulating MRI data with known parameter values that can be used to evaluate and compare analysis implementations. This project will provide both **image datasets** and **verification protocols** which can be used to ensure that particular analysis methods can be used to extract relevant parameters such as K^{trans} and IAUGC with sufficient accuracy to meet the claims set in the QIBA DCE-MRI profile.

Deliverables

This project will use recently available open source image analysis software for DCE-MRI (dcemri for R project, http://dcemri.sourceforge.net/) as a starting point for providing a reference method for DCE-MRI parameter extraction which can be used for comparison with commercial and/or proprietary software. DROs will be created by further development of methods we have already used to create synthetic images for the QIBA DCE-MRI initiative. Our deliverables are: **1. Verification of *dcemri* package.** We propose to use DROs to begin the validation process of the open source *dcemri* package. **2. Implementation of new analysis models.** We have provided simulated image data using the extended Tofts model . DROs simulating simple Tofts model parameters across a range of K^{trans} from 0 – 0.2/min and v_e from 0.1 – 0.5 will be produced. **3. Verification of T_1 mapping procedures.** A separate DRO will be created to test T1 mapping procedures from simulated multi-flip SPGR (or FLASH) imaging. **4. Extension of simulations to generate more realistic DROs.** Advanced DROs will be produced taking into account realistic levels of image noise, less frequent imaging, and temporal jitter. Use of these DROs will give more realistic predictions of the actual performance of software in clinical applications. **5. Development of verification protocols and integration into profiling activities.** We will begin defining verification protocols – specific series of tests and levels of performance that must be achieved on each test – that can be integrated into the QIBA DCE-MRI profile and that would allow a software package to be qualified for use in a multi-center clinical trial. **6. Creation of open source archives.** A database will be created so that all digital objects associated with the activity – DROs, software, verification protocols, results, and documentation – can be available from a single web-accessible site.

Timeline [must include intermediate measureable milestones.]

DROs for deliverables 2 and 3 will be available and on line within 3 months of project initiation, and deliverable 1 by six months. Deliverable 4 and 5 will be the focus of the 6 to 12 month time interval. The open source archive (deliverable 6) will be initiated by month 3 and further developed through the project time period.