Quantitative Imaging Biomarkers Alliance RSNA

Application for QIBA Project Funding

Title of Proposal: QIBA FDG-PET/CT Digital Reference Object Project		
QIBA Committee/Subgroup: FDG PET/CT		
NIBIB Task Number(s) which this project addresses: 1, 2, 3 in Technical Validation Topic A.I. 'Define the variability problem, using reference objects'		
Project Coordinator or Lead Investigator Information:		
Last Name: Kinahan	First Name: Paul	Degree(s): PhD
Institution/Company: University of Washington		

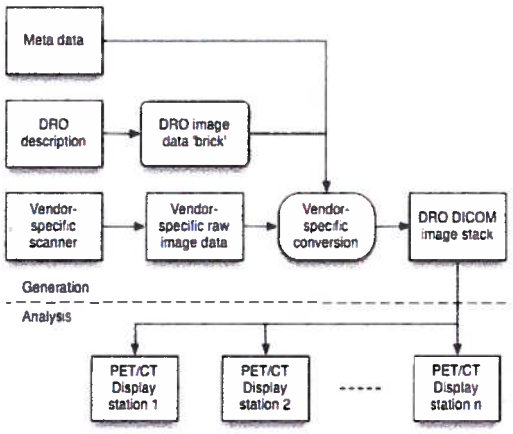
Please check the primary category for this proposal from among the following:

- ☑ 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 ëaccepted-as-standardí 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.

Supported by time and effort from
Dr David Clunie, CoreLab Partners (previously RadPharm)
Dr Dennis Nelson, MiMVista.
No funds for their support are requested.

We will use existing computer resources at the 3 sites.
Assistance of other FDG-PET TC members will be utilized for multisite testing.

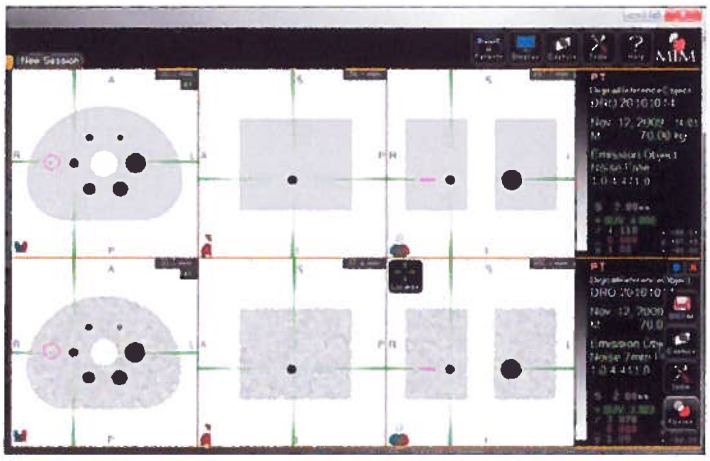
Project Description: Construct a common reference DICOM PET/CT test image (Digital reference Object or DRO) as if generated by each vendor's PET/CT scanner. This will then be read on PET/CT display stations to check SUV computation fidelity and region of interest (ROI) analysis performance. This is motivated by the vendor-specific variations in the standardized uptake value (SUV) calculations. It is well known that variations in the implementation of DICOM standards produce substantial quantitative differences in SUVs for the same image on different display stations. In addition, the behavior of ROI analysis tools (e.g. due to image interpolation) is rarely, if ever, quantitatively understood.



Process flow for the Digital Reference Object (DRO).

Primary goals and objectives: The PET/CT Digital Reference Object (DRO) will support the QIBA FDG-PET 'Technical Validation' efforts, including NIBIB tasks 1-3. This will be done by (1) evaluation / validation of SUV calculations in PET images, (2) evaluation / validation of ROI calculations and (3) providing a common reference standard that can be adopted and modified by PET/CT scanner and display station manufacturers.

Initial Results: QIBA FDG-PET/CT Subcommittees have: (1) Received completed questionnaires on SUV computation from each of the three scanner manufacturers and one 3rd party display station vendor. (2) Identified key DICOM tags for calculation of SUVs. (3) Construction of an initial DRO has proceeded at the University of Washington, with the assistance of David Clunie at CoreLab Partners and Dennis Nelson at MiMVista. This includes development of MATLAB software tools for flexible generation of DRO image data. (4) Identified key features for ROI tool performance. Progress, however, has been limited by a lack of dedicated time for development and testing



PET/CT DRO (modified NEMA NU-2) displayed in MIM with correct SUVs. Top: noise-free. Bottom: Smoothed noisy image. Both images have single voxel features for detailed ROI testing.

Deliverables: Four necessary tasks remain that will be completed in this project: (1) Extending the DRO to include multiple bed position acquisitions, (2) including attenuation (e.g. CT) images for linked PET-CT display, (3) changing DICOM encoding of parameters affecting SUV to match different scanner outputs, and (4) testing of DRO on different display stations with assistance of other QIBA FDG-PET TC members. The DRO will be transmitted to PET/CT review workstations or PACS to evaluate the properties of the DRO. The analysis phase will reveal any differences in reported SUVs between PET/CT display stations. We will iterate as necessary to incorporate known and discovered deviations from the DICOM conformance statements. Discrepancies will be noted and communicated to the relevant manufacturers.

Timeline: **Q1**: Completion of extensions to DRO generation for (1) multiple bed position acquisitions and (2) attenuation (e.g. CT) image for linked PET-CT display. **Q2**: Completion of DICOM validity testing of dual modality multibed DRO sets. **Q3**: Completion of vendor specific DRO generation. **Q4**: Completion of testing DRO on multiple display stations with assistance of QIBA FDG-PET TC members. Communication of results to manufactures. Release of white paper on recommended path for DRO extensions and adoption by manufacturers.