

Application for QIBA Round-2 Project Funding

Title of Proposal: Personnel Support for FDG-PET Profile Completion		
QIBA Committee/Subgroup: FDG-PET/CT		
NIBIB Task Number(s) which this project addresses: #9 (Establish QIBA Profiles)		
Project Coordinator or Lead Investigator Information:		
Last Name: Perlman	First Name: Eric	Degree(s): MD
e-mail:	Tel #:	
Institution/Company: Perlman Advisory Group		
Amount Requested:		

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.

Builds on previous 2 years of QIBA efforts to define content needed in FDG-PET Profile.

Also builds off considerable effort and expertise invested in constructing the UPICT FDG-PET protocol.

Project Description

This is a proposal for expert support as a 'Profile Writer' to convert the considerable amount of material accumulated by the FDG-PET TC into a QIBA Profile.

During the past 2 years the FDG-PET TC has accumulated a considerable amount of material relevant to generating a QIBA Profile for quantitative imaging. In addition the formation of the UPICT FDG-PET Protocol has generated numerous (i.e., ~20) 'call-outs' to the FDG-PET TC for unresolved issues in quantitative PET imaging. Beginning last summer/fall we have been trying to convert this into a QIBA Profile. Efforts for the conversion started in earnest after the 2010 RSNA. Unfortunately there has been little progress. This is due to a variety of reasons, including, but not limited to the challenges of tackling a complex subject on bi-weekly conference calls, and the challenge of generating (or sorting) content when there is a lack of consensus on format. In contrast, the UPICT FDG-PET Protocol group made significant progress. This was due to the efforts of a small group of experts who dedicated time to form the initial backbone of the document.

We propose a 4-stage process to generate the first complete version:

1. A one-month (or less) effort by the Profile Writer to complete the draft version of the Profile. This will involve as-needed calls with an Internal Review Committee (IRC) of QIBA FDG-PET Technical Committee members. This IRC is initially designated to consist of TC members Kinahan, Wahl, Boellaard, and Shao.
2. A review of progress at no more than 1 month after initiation, or less if required by the Profile Writer. This review may be by email, telephone conference, or in person. The Profile Writer in consultation with the IRC and RSNA/QIBA leadership will make the choice of the format of the review process.
3. If the Profile Writer and initial review group decide it is necessary, a second iteration of steps 1-2 will occur, with completion of the second review no more than 2 months after initiation.
4. After completion of the initial draft and review, the full QIBA FDG-PET TC will be asked to review and comment on the Profile. After one further month of review by the QIBA FDG-PET TC, the Profile will be released for public comment. Management of the Profile will be undertaken by RSNA/QIBA staff.

- **Scope of work**

The primary goal is to generate the initial FDG-PET QIBA Profile.

- **Deliverables**

Initial FDG-PET QIBA Profile.

- **Timeline [must include intermediate measureable milestones.]**

- Initial draft completed 1 month after initiation. Sooner at the discretion of the Profile Writer
- A review of progress at no more than 1 month after initiation, or less if required by the Profile Writer
- If agreed upon, as described above, a second review no more than 2 months after initiation
- Review and revisions completed by FDG-PET TC three months after initial draft