Title of Proposal: Analysis of SARC 11 Trial PET Data by PERCIST with Linkage to Clinical Outcomes		
QIBA Committee/Subgroup: FDG PET Technical Committee		
NIBIB Task Number(s) which this project addresses: 10		
Project Coordinator or Lead Investigator Information:		
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Project Description:

The insulin-like growth factor (IGF) pathway plays an important role in a variety of physiological processes in humans and animals, including normal growth and development. Additionally, this pathway has been shown to play an important role in the development of conditions like cancer. IGF signaling has been proposed to play a major role in the very aggressive nature of certain sarcomas, like Ewing's sarcoma family of tumors (ESFT) and synovial sarcomas

The SARC 11 trial prospectively evaluated the utility of an anti Insulin like Growth Factor Human Monoclonal Antibody (R1507) as monotherapy for Sarcomas of several types (Recurrent or Refractory Ewing's Sarcoma, Osteosarcoma, Synovial Sarcoma, Rhabdomyosarcoma and Other Sarcomas.) .   All patients received R1507 9mg/kg i.v. . This single arm study evaluated the efficacy and safety of **R1507** in patients with recurrent or refractory sarcoma Clinical efficacy of the trials was judged by: Objective response rate [Time Frame: Week 24, and every 12 weeks thereafter] , Progression-free survival in patients with Ewing's sarcoma [Time Frame: Week 18] , Duration of response, PFS, and overall survival.

 In this multicenter study, a baseline PET scan was obtained as well as a PET scan at approximately 9 days post therapy initiation. A follow up scan at 12-18 weeks was obtained in those remaining on study. A total of 311 patients entered the study. Importantly, the PET was not used to alter the therapy. Thus, the PET data can be used to determine prognostic ability. Accrual to the study is now complete and the full PET data set have been collected and are available in DICOM form for analysis. Details of the SARC 11 trial and the rationale for anti IGF antibody therapy are detailed at Clinical Trials. gov and the SARC website.

http://www.clinicaltrials.gov/ct2/show/related/NCT00642941?term=r1507 and
http://www.sarctrials.org/SARC011r1507

We propose to analyze the PET data quantitatively (and qualitatively) using PERCIST and EORTC response criteria to determine how predictive PET, notably changes in PET signal between baseline and the first follow up scan, is of clinical outcomes. We will also examine inter-observer consistency. We will apply commercial software and our in house developed software for analysis.   This trial is particularly suitable for analysis of PET data as they are not biased by management alterations from the PET results, a key and essential element to evaluating a potential biomarker.