Biomarker, Imaging, & QOL Studies Funding Program (BIQSFP)

'14 Study Checklist for Large Randomized Phase 2 and Any Phase 3 Trials with IMAGING TESTS

INSTRUCTIONS: Please submit a response to each of the criteria below and complete one Study Checklist and the Form PHS 398 Grant Budget Worksheets for each Imaging endpoint.

NOTE: One-time INTEGRATED imaging study applications must be submitted after parent concept approval and must be received within four months (16 weeks) of notification of parent concept approval. Subsequent NCI prioritization and approval for funding will be decided by CTROC after evaluation of the INTEGRATED study(s) by the respective SSC.

1. Indicate the role of the imaging test in the trial and whether it is INTEGRAL or INTEGRATED:
   A. Eligibility criterion
   B. Assignment to treatment
   C. Stratification variable
   D. Risk classifier or predictive and prognostic markers
   E. Response assessment
   F. Other (describe in detail):

2. Identify the specific individual(s) or imaging departments/sites that are being considered for conducting the imaging test for the trial.

3. Describe the imaging test:
   A. Specify the imaging devices or imaging agents.
   B. Describe any patient preparation procedures, as well as the procedures for imaging, analysis, and interpretation of the results.
   C. Describe the scoring procedures and type of data to be acquired
      - quantitative/ continuously distributed
      - semi-quantitative/ordered categorical
      - qualitative/non-ordered categorical

4. Provide data on the clinical utility of the integral/integrated imaging test as it will be used in the trial:
   A. Provide background information that justifies the use of this imaging test result as a part for this trial. For example, if the integral imaging test will be used as a stratification or treatment-determining variable, data supporting its prognostic or predictive association with a main trial endpoint should be described or referenced.
      Note: If the trial objectives include an evaluation of the association of the integral marker with a new clinical endpoint or factor not previously studied, the statistical section of the concept should explain how the magnitude of the association or effect will be measured and provide power calculations for any statistical tests that are planned.
   B. Describe the expected distribution of the imaging study results in the study population.
   C. If cutpoints will be used, specify the cutpoint(s) and describe how these will be used in the trial). Provide the rationale for the cutpoint(s) selected. What proportion of subjects is expected to have values above and below the proposed imaging cutpoints? What magnitude of effect (e.g., treatment benefit) or outcome (e.g., prognosis) is expected for patients with imaging results above and below the proposed cutpoint(s)?
   D. Describe under what conditions treating physicians and or patients will be able to access the imaging test results.

5. Provide data on the analytical performance of the imaging test.
   A. Describe the known performance characteristics of the imaging test. State and justify the limits of acceptable performance. Describe the use of positive and negative controls, calibrators, and reference standards for the imaging test.
   B. If the imaging test will be performed at more than one site, describe how inter-facility variability in the measurements will be assessed. Describe how these sources of variation will be minimized to maintain performance at all sites within acceptable limits and to prevent drift or bias in imaging test results.

6. Provide the type and number of scans. Indicate if the scan is standard of care (SOC) or investigational: e.g., 300 MRIs (SOC): 100 patients x 3 per patient; 200 FDG PET/CTs (investigational for the proposed indication/time point): 100 patients x 2 per patient; 100 F-MISO PET/CTs (investigational): 100 patients x 1 per patient.

7. The Budget Justification should include:
   A. Site/scanner qualification costs (usually done prior to patient enrollment in multi-center trials).
   B. Technical costs for each type of scan (including facility use, scanner time costs, etc.).
   C. Professional costs for each type of scan (*including cost for local radiologists / nuclear medicine physicians to interpret the images*).
   D. Image transfer costs (*includes network costs, shipping/mailing costs if physical media is used for transport*).
   E. Central imaging review costs (*if central review is performed*) for each type of scan.
   F. Real time image review costs (*if applicable*) for each type of scan.
   G. Image quality assurance costs (*additional data QA costs on top of basic interpretation or central review costs*).
   H. Imaging agent and contrast material costs, for each type of scan: (*if imaging agent costs can be further broken down into categories such as agent manufacturing, transport, or storage costs, please provide those*).
   I. Image storage costs (*includes costs for long term storage of imaging data, archiving, back-up systems, etc.*).
   J. Statistical support costs (*can include costs for services such as a contracted statistical center).*
   K. Salary support costs (*e.g. investigators, imaging technologists, research coordinators, study nurses, research assistants, etc.*).

4/13,11/13