

Essential Biomarker, Imaging and Quality
of Life Studies
Funding Program (BIQSFP)

CTAC Meeting

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Biomarker, Imaging and QOL Studies Funding Program (BIQSFP)

- **Purpose**
 - Ensure that the most important correlative science and quality of life studies can be initiated in a timely manner in association with clinical trials
 - Intent is to fund studies conducted in association with phase 3 trials when cost is too high to be covered by Cooperative Group mechanisms

BIQSFP: Prioritization Criteria

- **Prioritization Criteria**
 - **Correlative science (essential marker and imaging)**

Developed by the Task Force of the Program for the Assessment of Clinical Cancer Tests (PACCT) and approved by CTAC in July 2007
 - **Quality of Life and Symptom Management**

Developed by the Symptom Management and Health-Related QOL (SxQOL) Steering Committee and approved by CTAC in November 2007

Prioritization: Integral and Integrated Studies

- 1. *Integral* studies:** a test that must be performed in order for the trial to proceed
 - Test to establish patient eligibility
 - Test for patient stratification
 - Test to assign patient to treatment arm, including early response endpoints for assignment of treatment during a trial
- 2. *Integrated* studies:** studies that are intended to identify or validate markers and imaging tests or QOL instruments that might be used in future trials
 - Study plans clearly described in trial protocol
 - Tests performed on all cases although results not used to guide decisions in current trial

Prioritization of Essential Marker and Imaging Studies in Clinical Trials

- *Other correlative studies:* studies to develop markers/assays or imaging tests that are performed retrospectively
 - Exploratory in nature
 - Do not meet the criteria for *integral* or *integrated* studies
- Will not be eligible for funding

BIQSFP: Eligible Trials 2008

- Essential biomarker, imaging, and QOL studies associated with:
 - Cooperative Group Studies
 - Phase 3 Treatment
 - Phase 3 Prevention
 - Symptom Management Studies

2008 BQSF Funded Applications

- *NSABP: Biobehavioral Mechanisms of Fatigue in Patients Treated on NSABP-B-45*
- *COG: Phase III Randomized Trial of Gemtuzumab Combined with Conventional Chemotherapy for De Novo Acute Myeloid Leukemia (AML) in Children, Adolescents, and Young Adults*
- *GOG: Validation of PROMIS Tool For Fatigue in Conjunction with Treatment for Endometrial CA*

BIQSFP Changes for 2009

- Funding 2009 – at least \$5M
- Cooperative Group and CCOP Research Base studies with integral and integrated biomarker, imaging, or QOL studies associated with **new concepts**:
 - Phase 3 Prevention
 - Phase 3 Treatment
 - Symptom Management
- Exceptions for extraordinary BIQSFP proposals embedded in pre-existing approved concepts or protocols that are in early stages of accrual

BIQSFP Changes for 2009

- New additional requirement for data characterizing the precision, reproducibility and validation of the assay, test or assessment tools involved in the BIQSFP study
- Program for the Assessment of Clinical Cancer Tests (PACCT) has prepared a document on “**Performance Standards Reporting Requirements for Essential Assays in Clinical Trials**” to be used for BIQSFP applications – Dr. Jim Jacobson
- Cooperative Groups will be encouraged to use document for integral markers in trials even if not accompanied by a BIQSFP application

Anticipated Funding Timeline for 2009

- Open submission cycle throughout year
- Scientific Steering Committees will review concepts with BIQSFP correlative components
- CTROC* will recommend & prioritize BIQSFP proposals at regular meetings throughout the year
- CTAC will make final recommendations to NCI Director twice a year

*NCI Clinical Trials and Translational Research Operations Committee

Anticipated Funding Timeline

Concept approval date*	CTAC Meeting Presentation	Funding Consideration by NCI
June 1, 2009	Nov 4, 2009	Nov 30, 2009
Nov 1, 2009	March 10, 2010	March 31, 2010
June 1, 2010	Nov 17, 2010	Nov 30, 2010
Nov 1, 2010	March 2011 (date pending)	Mar 31, 2011

*Concepts approved by this date