

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

Clinical Trials and Translational Research Advisory Committee 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

OEWG - Enhanced Biomarker Funding

- CTWG Recommendation:** Enhance funding and capabilities for use of biomarkers in NCI-funded clinical trials
- OEWG Goal:** Facilitate rapid activation of trials involving critical biomarker studies
- Implementation Element:** Change the role of the Clinical Trials and Translational Research Committee (CTAC), which currently reviews each individual BQSF award, to one of strategic oversight and advice

Current BIQSFP Approval Process

- Proposals come to CTAC after evaluation & recommendation by:
 1. SSC or CTEP/DCP review with expert external input
 2. appropriate NCI Division
 3. CTROC
- Three steps are completed by the time the BIQSFP proposal arrives at CTAC

Logistical Challenges...

- BQSFP applications are received, reviewed, & recommended for funding on a rolling cycle...no deadline for application
- CTAC meets 3 x / year (March-July-Nov)
- Potential for up to 4-month delay awaiting CTAC recommendation

Selected Activities for Strategic Oversight and Advice

- Identify types of studies that should be eligible for funds
- Advise on priorities for particular types of studies (i.e.; prevention, chemotherapy, imaging, HRQOL)
- Advise on prioritization criteria (i.e.; Phase 2 vs. Phase 3 concepts)
- Annual review of program implementation

For CTAC Consideration

Change the role of the Clinical Trials and Translational Research Committee (CTAC), which currently reviews individual BQSF award, to one of strategic oversight and advice.

Timeline For Implementation of Changes

- 2008 BIQSFP Announcement expires 12/14/09
- Publish revised Announcement in December 2009

Questions



CTROC-Recommended Biomarker Study

- CALGB 30801... *A Randomized Phase III Double-Blind Trial Evaluating Selective COX-2 Inhibition in COX-2 Expressing Advanced Non-Small Cell Lung Cancer*
- Integral & integrated biomarkers