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NCI-Sponsored Cooperative Group Clinical Trials Program / NCI National Clinical Trials Network (NCTN) Policy for Phase 2 Clinical Trials on the Cancer Trials Support Unit (CTSU) Web Site July, 2013

Background

The primary scope of clinical trials under the NCI-sponsored Cooperative Group Clinical Trials Program on the CTSU web site open to cross-organizational participation has been to provide support for Phase 3 treatment trials. During the transition to the NCI Clinical Trials Network (NCTN), the Cancer Therapy Evaluation Program (CTEP) will support the addition of select phase 2 studies to the CTSU web site for cross-organizational participation. One of the primary criteria NCI uses for selecting which phase 2 trials go on the CTSU web site is the need for wide cross-organizational participation to complete the study objectives in a timely manner.

The purpose of this document is to establish the policies and procedures of the addition of Phase 2 trials to the CTSU web site that are open to cross-organizational participation.

Criteria

Phase 2 cancer treatment clinical trials under consideration for cross-organizational participation on the CTSU web site must meet the criteria below.

- 1) The lead organization agrees to the following general requirements for working within the CTSU system:
 - The lead organization will be responsible for reporting accrual through the NCI Clinical Data Update System (CDUS).
 - Clinical investigators and institutions will be identified for regulatory approval and patient enrollment using codes established in the CTEP enterprise database.
 - The NCI Adverse Events Expedited Reporting Systems (AdEERs) will be used to report serious adverse events where applicable and the lead organization will be responsible for medical review.
 - Reimbursements for patient enrollments will be made as with Phase 3 studies (including the new provision that a site may credit accrual to any Group of which it is a member as of 8/1/2013, although until the start of the new NCTN in March 2014, a site must credit the Lead Group/organization for the trial if the site is a member of that Group).
 - The study must use the Oncology Patient Enrollment Network (OPEN) to support enrollment.
 - Newly activated trials must have the study database housed in iMedidata Rave.
- 2) Lead organization enrollment is not expected to be sufficient to meet the accrual goals of the trial.
 - Expectation of insufficient accrual must be demonstrated after a reasonable period of conduct or by a determination by NCI that the patient population needed for the trial is not available through the lead organization alone and/or will benefit from wide cross- organizational participation.



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3) Any consolidated Cooperative Groups (e.g. Alliance) requesting addition of a phase 2 study to the CTSU web site prior to the roll out of the new NCTN grants must follow the *Cooperative Group Consolidation, Interim Protocol Submission Policy and Endorsement Procedures*.

Procedure

- 1) Groups interested in placing a NCI Phase 2 clinical trial on the CTSU web site for cross-organizational participation should submit an e-mail request from the Group Administrator or Protocol Coordinator, to the CTSU Lead Protocol Coordinator. The correspondence should explain briefly why the CTSU will provide a benefit to the trial and demonstrate how the criteria provided above will be met. If available, the email should include Co-chair information for any Cooperative Groups collaborating with the Lead Group.
- 2) The Clinical Investigations Branch (CIB) Chief in the Cancer Therapy Evaluation Program (CTEP), or designee, in consultation with other NCI staff, will assess the scientific and clinical merit of the trial for cross-organizational participation on the CTSU web site.
- 3) The CIB Chief, or designee, in consultation with the CTSU management staff, will assess the impact of the trial on available and future resources.
- 4) The requesting party will be notified of the decision via e-mail from the CTSU Lead Protocol Coordinator of the NCI/CIB decision regarding placing the trial on the CTSU web site.
- 5) Once the trial is accepted for cross-organizational participation on the CTSU web site, the CTSU protocol coordinator will initiate contact with the Lead Group/organization and provide a study-specific logistical appendix in support of CTSU participation.
- 6) The trial will be removed from the CTSU if it is closed by the lead organization or if has been determined by the NCI/CIB that continued inclusion on the CTSU web site is of no benefit to the trial.

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