Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
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NCI-Sponsored Cooperative Group Clinical Trials Program Policy for International Clinical Trials on the Cancer Trials Support Unit (CTSU) Web Site
July, 2013

Background

The primary scope of clinical trials under the current NCI-sponsored Cooperative Group Clinical Trials Program on the CTSU web site open to cross-organizational partcipation consists of Phase 3 trials and selected Phase 2 trials led by the NCI-supported Cooperative Groups located in the United States and Canada (listed below). Scientific collaborations on clinical trials may also exist between the National Cancer Institute (NCI) and international cancer research organizations and between the Cooperative Groups and international cancer research organizations.

- American College of Surgeons – Oncology Group (ACOSOG)
- Children's Oncology Group (COG) for selected trials in the adolescent and young adult populations
- Cancer and Leukemia Group B (CALGB)
- Eastern Cooperative Oncology Group (ECOG)
- Gynecologic Oncology Group – (GOG)
- NCIC – Clinical Trials Group (NCIC-CTG)
- National Surgical Adjuvant Breast and Bowel Project (NSABP)
- North Central Cancer Treatment Group (NCCTG)
- SWOG (formerly the Southwestern Oncology Group)
- Radiation Therapy Oncology Group (RTOG)

Any international collaboration on a clinical trial under the NCI-sponsored Cooperative Group Clinical Trials Program or future NCI National Clinical Trials Program (NCTN) must be approved by the NCI. Further consideration of these trials for cross-organizational partcipation on the CTSU web site will be balanced by the primary mission of supporting trials led by the NCI-supported adult Cooperative Groups and must be approved by the NCI.

Criteria

International clinical trials will be considered for cross-organizational partcipation on the CTSU web site when the following criteria have been met.

1) The international group receives funding directly from the NCI under the NCI-sponsored Cooperative Group Clinical Trials Program and the trial is approved by the NCI for conduct under the Program and for inclusion on the CTSU web site OR the international Group has a contractual arrangement with one of the Cooperative Groups that has been reviewed and approved by the NCI and the trial is approved by the NCI under the Program and for inclusion on the CTSU menu.

2) Conduct of the study within the CTSU system presents no unusual logistical challenges, such as
   - Special materials submissions,
   - Complicated enrollment procedures,
   - Site training over and above what is provided with other CTSU trials, or
   - Extension of operating hours to cover differences in time zones.

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3) Conduct of the study will not require regulatory procedures over and above those generally required for Phase 3 trials on the CTSU web site, such as
   - Collection of special qualifications forms,
   - Unusual investigator qualifications,
   - Unusual site or facility qualifications, or
   - Site audits by international regulatory authorities.

4) Drug distribution arrangements for sites in the United States and Canada will be the responsibility of the Lead organization.
   - The CTSU may assist in this by identifying qualified organizations for drug distribution.

5) The Lead organization will be responsible for all regulatory contact and coordination with international regulatory authorities.
   - The CTSU will work with Health Canada through an arrangement with NCIC-CTG.

6) The Lead organization will agree 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.
   - Clinical investigators and institutions will be identified for regulatory approval and patient enrollment using codes established in the NCI CTEP enterprise database.
   - The NCI AdEERs system will be used to report serious adverse events and will be responsible for medical review of all adverse events.
   - Any arrangements for "per case" management funding associated with patient enrollments must be discussed, reviewed, and approved by the NCI, along with the mechanism of payment.
   - Any contractual arrangements needed with the CTSU must be reviewed and approved by the CTSU and the NCI CTSU Project Officer at in the Cancer Therapy Evaluation Program (CTEP).

Procedure

1) Those interested in having internationally led trials placed on the CTSU web site must first have the study evaluated for scientific merit and prioritization through the processes specified under the NCI-sponsored Cooperative Group Clinical Trials Program or future NCTN Program and the trial must be approved for conduct under the Program by NCI. The request for inclusion of the study on the CTSU menu should be referenced in the materials sent to the NCI for evaluation of the trial proposal. A letter of request should be sent to the CTSU Operations Manager (Ms. Martha Hering) after approval of the study by NCI for conduct under the Program. The letter should explain the benefits of having the trial on the CTSU web site and demonstrate how the criteria provided above will be met. The letter should also identify any contractual agreements with pharmaceutical companies, or other sponsors of the therapeutic agents, that pertain to conduct of the trial in the CTSU system.

2) The CTSU Project Officer, in consultation with NCI and CTSU management staff, will assess the impact of the trial on available and future resources.

3) The requesting party will be notified of the decision by NCI regarding the request for inclusion of the trial on the CTSU web site in writing by the CTSU Project Officer. The acceptance will be considered conditional upon confirmation that all the criteria have been met.

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4) If the trial is accepted for the CTSU, the CTSU Operations Manager will initiate contacts with the requesting organization to review the criteria and make all effort to prepare for activation of the trial in the CTSU.

5) Upon confirmation that all criteria have been met and that all logistical and contractual arrangement in order, final approval will be given to include the trial on the CTSU web site.

6) The trial will be activated once all of the logistical arrangement have been made and agreed upon by the CTSU and the lead organization.

7) The trial will be removed from the CTSU web site if the trial is closed by the Lead organization or if it has been determined by NCI that continued inclusion within the CTSU is of no benefit to the trial.

Contacts

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