Opportunity for CTSU Support for Collaborative Multi-Center Phase 2

Trials Led by NCI Designated Cancer Centers, CCR and SPORES

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Announcement expiration date: November 30, 2013 (unless re-issued)

Purpose:

This announcement highlights an opportunity for Cooperative Group, NCI Designated Cancer Center, NCI's Center for Cancer Research Center (CCR) and Specialized Programs of Research Excellence (SPORE) investigators to develop clinical trial collaborations through discussions in NCI's Scientific Steering Committees. Collaboration is an important underpinning of NCI's efforts to harmonize review guidelines across these three grant mechanisms and with CCR. For clinical trial collaborations requiring multi-center coordinating support that is not otherwise available through existing networks, NCI will prioritize requests for in-kind coordination support through its Cancer Trials Support Unit (CTSU). While most Cooperative Group study PIs are familiar with NCI's Scientific Steering Committees and CTSU capability, this announcement provides important details for how study PIs at NCI Designated Cancer Centers, CCR and SPOREs can interact with Scientific Steering Committees and request access to CTSU services for highly meritorious clinical trials. It is anticipated that CTSU support will be provided for up to two multi-center phase 2 trials per year under this announcement.

General Background:

The NCI is in the process of implementing a recommendation of its Clinical Trials and Translational Research Advisory Committee (CTAC) to harmonize review guidelines for Cooperative Group, NCI Designated Cancer Center and SPORE grant applications with respect to clinical research. The purpose is to align review criteria for each of these mechanisms such that scientific and patient accrual collaborations and translational research handoffs between these awardees are enhanced and recognized as part of the peer review process. As forums comprised of multiple stakeholders engaged in discussion around multi-center clinical trials, NCI's Scientific Steering Committees are uniquely positioned to foster collaborations and handoffs encouraged in these harmonized guidelines. The steering committees were established to evaluate clinical trial ideas (concepts) and facilitate collaborations among the Clinical Trials Cooperative Groups, Cancer Centers, CCR and SPOREs for late phase treatment trials. Representatives from each of these research mechanisms serve as steering committee members. More information about NCI's Scientific Steering Committees can be found at: http://restructuringtrials.cancer.gov/steering/overview

The Clinical Trials Cooperative Groups form the foundation of NCI's late phase clinical trial enterprise and for many clinical trials individual Cooperative Groups are able to develop and successfully accrue to these trials through their own network of clinical sites. However, collaborations that accelerate trial completion and potentially hasten the development of new standards of care are encouraged. For trials in some disease areas, such as uncommon diseases or common diseases with trial eligibility limited to unusual subtypes, collaborations may be essential. In addition, SPOREs, CCR and NCI Designated Cancer Centers bring important translational and early phase clinical trial expertise and ideas to Scientific Steering Committee discussions and clinical trial collaborations.

How SPORE, CCR and NCI Designated Cancer Center Study PIs can participate in Scientific Steering Committee discussions and seek CTSU coordination support for phase 2 multi-center clinical trials:

CTSU Support for Collaborative Multi-Center Phase 2 Trials Led by

NCI Designated Cancer Centers, CCR and SPORES

Because access to CTSU resources under this announcement may be very competitive, study PIs considering a request for CTSU support are strongly encouraged to first seek collaborations with investigators with access to multi-center clinical trial coordination (e.g. Clinical Trials Cooperative Group investigators). Study PIs at SPORE, CCR and NCI Designated Cancer Center institutions interested in seeking CTSU coordination support for their clinical trial concept through this announcement should contact Dr. Raymond Petryshyn in the Coordinating Center for Clinical Trials at NCI (contact information below) to ensure that their concept is officially submitted under this announcement. In addition, Dr. Petryshyn will provide investigators with contact information for the Cancer Therapy Evaluation Program (CTEP) and Coordinating Center for Clinical Trials (CCCT) representatives on each Scientific Steering Committee who are available to answer questions about their steering committees. Only highly meritorious treatment trial concepts recommended by Scientific Steering Committees will be considered for CTSU coordination funding by NCI's executive committee for clinical trials, the Clinical and Translational Research Operations Committee (CTROC). A clinical trial concept approved by CTROC should be developed into a full protocol by the study PI. Approval of the protocol and monitoring of trial conduct will be conducted by CTEP staff in accordance with policy for Clinical Trial Cooperative Group protocols.

Clinical trial concept submission format: Clinical trial concepts should be submitted on a template that can be found at http://ctep.cancer.gov/protocolDevelopment/default.htm#lois_concepts and by clicking on Concept Submission Form.

CTSU resources: Available services may include regulatory support, website document hosting, protocol coordination, patient registration, study coordination, clinical database development, data management, data processing, information technology, and site accrual support. Investigational New Drug (IND) application and statistical support, data safety monitoring, and auditing services are not available through the CTSU.

Eligibility for CTROC consideration of CTSU coordination support under this announcement:

- Phase 2 randomized multi-center treatment trial with ≥ 100 and < 200 total patients led by a SPORE, NCI Designated Cancer Center investigator, or CCR investigator. Under special circumstances when there is a unique opportunity for important improvement to clinical outcomes, concepts of less than 100 patients and/or single arm or non-randomized concepts will be allowed.
- Collaboration with either another SPORE or NCI Designated Cancer Center or a Cooperative Group (i.e., mechanisms with harmonized guidelines) or the CCR. Clinical trial concepts approved by a Scientific Steering Committee. (For disease areas in which a relevant Scientific Steering Committee does not exist, CTEP will conduct the evaluation.)
- A trial proposed by a network with access to CTSU or other multi-center trial coordination support is ineligible.
- At least four accrual sites planned; although it is anticipated most clinical trial concepts will propose more than four accrual sites.
- An appropriate institutional official at the lead organization must ensure responsibility for compliance with the usual NIH policies.
- Agree to adhere to CTEP, NCI, and NIH policies for trial conduct.

Estimated timeframe for Scientific Steering Committee evaluation of clinical trial concepts seeking CTSU coordination: Many Scientific Steering Committees have Task Forces that focus on a particular organ site (e.g., the Prostate Cancer Task Force of the Genitourinary Steering Committee). When a relevant task

force exists, clinical trial concepts must be discussed in a Task Force prior to Scientific Steering Committee evaluation. Task Forces and Scientific Steering Committees generally meet monthly. Investigators should confirm with Dr. Petryshyn or other CCCT staff the deadlines for including discussion of their clinical trial concept on the next call of individual Task Forces and Scientific Steering Committees. Most Scientific Steering Committees require receipt of clinical trial concepts at least three weeks prior to their next scheduled meeting. Task Forces generally require one to two weeks' notice.

It is the intent of this announcement to be consistent with current NCI clinical trial protocol development timelines and procedures. Therefore, disapproved clinical trial concepts may not be resubmitted to the relevant Specific Steering Committee or CTROC for re-consideration. In addition, clinical trial concepts initially deemed by a Steering Committee as "pending with recommendations" may only be resubmitted once to the Specific Steering Committee. Study PIs for clinical trial concepts approved by CTROC must meet specific NCI timeline milestones, including protocol development and trial activation. More information can be found at (http://ctep.cancer.gov/SpotlightOn/OEWG.htm) or obtained from CCCT or CTEP staff.

Steering Committee Evaluation Criteria: While scientific quality is a key criterion, the Scientific Steering Committee will also consider novelty, lack of duplication, strength of proposed clinical outcomes, trial design attractiveness to patients and treating physicians, strength of correlative science, cost/benefit and disease-specific strategic priorities in the evaluation of concepts.

The above evaluation criteria do not apply to informal Scientific Steering Committee discussion of clinical trial ideas presented by NCI Designated Cancer Center, CCR and SPORE investigators when CTSU support is not being sought as described in this announcement. Such informal discussions by Scientific Steering Committees are encouraged as a way to enhance collaborations between NCI sponsored investigators.

Contact information: Please contact Dr. Petryshyn for questions regarding this announcement and to formally submit a clinical trial concept for consideration for CTSU coordination support:

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Under this announcement NCI intends to support CTSU multi-center clinical trial coordination for up to two phase 2 treatment trials per year led by NCI Designated Cancer Center or SPORE investigators. Study PIs should contact Dr. Petryshyn early in the preparation process to ascertain the current status of this opportunity.