Request for Information (RFI): Input on a Potential Change in National Cancer Institute (NCI) Policy Regarding the Submission of Grant Applications that Request Support for Phase III Clinical Trials/Therapeutic Interventions

Notice Number: NOT-CA-12-013

Key Dates

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Response Date: September 14, 2012

Issued by

National Cancer Institute (NCI)

Purpose

The purpose of this Request for Information (RFI) is to obtain feedback and comments from the extramural research community as well as from persons representing other relevant segments of scientific communities and the American public on a potential change in National Cancer Institute (NCI) policy regarding the submission of grant applications that request support for Phase III clinical trials/therapeutic interventions.

Background

Cancer clinical trials (http://www.nlm.nih.gov/services/ctclintrial.html) range from small, first-in-human studies (Phase 0/I) to larger trials of activity (Phase II) or efficacy (Phase III) (http://www.nlm.nih.gov/services/ctphases.html). These trials may be related to cancer prevention, treatment, screening, symptom control, and cancer-relevant behavior modification. Multi-modality approaches are frequently involved (i.e., surgery, radiation, systemic treatments, and/or imaging). NCI has traditionally provided support for all phases of trials and interventions via grants and cooperative agreements (R03, R21, R01, P01, U01, UM1, and U10). Historically, the majority of early phase cancer clinical trials have been conducted under R03, R21, R01, P01, U01, and UM1 grant and cooperative agreement mechanisms. Most Phase III clinical trials have been conducted under the U10 cooperative agreement mechanism, with a limited number of phase III trials performed under R01, P01, and U01 mechanisms. However, cancer-focused Phase III clinical trials using therapeutic interventions (drugs, surgery, radiotherapy) taking longer than 5 years have primarily been supported through the use of U10 cooperative agreement applications and awards by the NCI's Clinical Cooperative Groups Program, now the National Clinical Trials Network (NCTN).

Due to the complex nature of cancer chemoprevention, symptom control, and treatment-related Phase III clinical trials, NCI is trying to optimize the ways to support such efforts. In particular, it seems important to determine whether or these clinical trials should continue to be supported under the R01 and P01 investigator-initiated grant mechanisms in the future. Most Phase III clinical trials testing these therapeutic interventions cannot be completed from protocol development to enrollment, follow-up, and final analysis within the 5-year funding cycle associated with R01 and P01 grant mechanisms. As the renewal of such R01 and P01 awards cannot be guaranteed, commitments to Phase III clinical trials that will take longer than 5 years are impractical under R01 and P01 grant mechanisms. Some Phase III clinical trials that do not involve medical interventions and that could be completed within 5 years might still be appropriate for funding under the R01 or P01 grant mechanisms. For example, some behavior modification studies (i.e., smoking prevention, weight loss) might still best be performed using R01 or P01 mechanisms.

Information Requested

The NCI seeks feedback and information relevant to the optimization of the NCI support for cancer clinical trials, in particular with regard to the question of whether applications proposing Phase III clinical trials should be allowed for under R01 and/or P01 funding mechanisms. Any information that may assist NCI in making this determination, including but not limited to, anticipated needs, possible and optimal approaches, benefits and limitations, is welcome.

Responses

Responses will be accepted through September 14, 2012. Please email your response to the above inquiries to: NCICTEPPhase3GrantsP@mail.nih.gov.

***In your response,* include the Notice number NOT-CA-12-013 in the subject line** and, if you are willing to do so, please also provide the following:

- Name of the organization/site
- Full contact information for the point of contact

Note: Do not include any proprietary or confidential information.

This RFI is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of NIH. NIH does not intend to award a grant or contract to pay for the preparation of any information submitted or for use of such information. Acknowledgment of receipt of responses may not be made, nor will respondents be notified of evaluation of the information received. No basis for claims against NIH shall arise as a result of a response to this request for information or use of such information as either part of our evaluation process or in developing specifications for any subsequent announcement.

All individual responses will remain confidential. Any identifiers (e.g., names, institutions, e-mail addresses, etc.) will be removed when responses are compiled. Only the processed, anonymized results will be shared internally with NIH staff members and members of scientific working groups convened by the NCI, as appropriate.

Inquiries

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