Amendments to NOT-CA-13-019 "Request for Information on Proposed NCI Policy Ensuring Public Availability of Results from NCI-Supported Clinical Trials"

Notice Number: NOT-CA-14-005

Key Dates
Release Date: November 4, 2013

Related Announcements
NOT-CA-13-019

Issued by
National Cancer Institute (NCI)

Purpose

The purpose of this Notice is to announce two amendments to NOT-CA-13-019 "Request for Information on Proposed NCI Policy Ensuring Public Availability of Results from NCI-Supported Clinical Trials", which was published on September 30, 2013.

With this Notice, the following two amendments are being announced:
(1) Comments must be received on or before December 5, 2013 (instead of on or before November 20, 2013, as previously announced in NOT-CA-13-019); and,

(2) The information provided in NOT-CA-13-019 is hereby augmented by the full text of the draft NCI Clinical Trial Access Policy (below).

NCI Clinical Trial Access Policy - Draft

I. Principles
Consistent with the mission of the National Cancer Institute ("NCI") to provide evidence-based approaches to cancer therapy, NCI believes that the full value of NCI-Supported Interventional Clinical Trials can be realized only if Final Trial Results are published as rapidly as possible. Rapid and broad access to Final Trial Results by investigators, clinicians and patients is particularly important for cancer research studies because the results of such research, more so than with most preclinical research, has the potential to directly impact patient care.

II. Terms
Covered Trials. "Covered Trials" means all initiated or commenced NCI-supported Interventional Clinical Trials whether extramural or intramural. Extramural trials include research grants, cooperative agreements, and contracts to conduct Interventional Clinical Trials in all phases and disciplines (e.g., treatment, prevention, supportive care, diagnosis). "Covered Trials" excludes Observational Studies and any NCI-Supported Interventional Clinical Trial in which no subjects are enrolled, but includes any NCI-Supported Interventional Clinical Trial in which at least one subject is enrolled even if the trial is not completed.

Final Trial Results. "Final Trial Results" means summary data and information about the Covered Trial including, at a minimum, data and information that characterize the study design including allocation, drop-outs, and population included in the analysis; the baseline characteristics of the population studied; pre-specified primary and secondary endpoints; adverse events; and other relevant information, including study limitations.

Interventional Clinical Trials. "Interventional Clinical Trials" means studies involving human beings (or subjects) in which the investigator assigns study subjects (randomly or not randomly) to receive a specific intervention based on the applicable protocol. Such subjects may receive diagnostic, therapeutic, behavioral, or another type of intervention and the intervention may, but need not, be investigational or involve an investigational agent (e.g., clinical trials involving surgery, radiation or screening tests). The subjects are then followed and biomedical and/or health outcomes are assessed. The term "Interventional Clinical Trials"

encompasses all types of trials in all phases including pilot trials, phase zero trials, and normal (or healthy) volunteer trials.

NCI-Supported. “NCI-Supported” means all trials financially supported – whether in whole or in part – by NCI. In the case of NCI-designated Cancer Centers, the Policy does not apply to the subset of trials which, although they may benefit from core support from a Center grant, are funded privately and in which the data from the trial belong to the private funder. However, all trials at NCI-designated Cancer Centers that are funded in whole or in part with NCI funds and for which the data resides with the academic investigator are considered “NCI-Supported” and subject to this Policy.

Observational Studies. “Observational Studies” means those studies in which investigators observe and analyze the outcomes of patients receiving care in a routine setting.

Primary Completion Date. “Primary Completion Date” means the date that the final subject was examined or received an intervention for the purpose of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.

Publish. To “Publish” means to report in a publicly accessible manner.

III. Applicability

The NCI Clinical Trial Access Policy (the “Policy”) applies to all Covered Trials and, with respect to NCI-funded grants and cooperative agreements that support a Covered Trial, will be incorporated as a term and condition of the grant award.

With respect to research contracts involving a Covered Trial, submission of this information will be incorporated as a contract deliverable and failure to comply with this Policy will be cause for penalty or contract termination.

IV. Results Reporting Expectation

For every Covered Trial, Final Trial Results are expected to be Published within twelve (12) months of the Trial’s Primary Completion Date. Primary Completion Date, as defined in Section II of this Policy, refers to the date that the final subject was examined or received an intervention for the purpose of final collection of data for the primary outcome, whether the Covered Trial concluded according to the pre-specified protocol or was terminated. Accordingly, under the Policy, data from incomplete trials are expected to be reported within twelve (12) months of the date that the last subject had data collected or was examined even if the Trial does not achieve its primary aim.

To comply with the Policy, Final Trial Results are expected to be Published (i.e., reported in a publicly accessibly manner). This expectation may be satisfied in several ways including, but not limited to, by publishing trial results in a peer-reviewed scientific journal (whether published in print or on line), or through on-line registration and reporting with a publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov. Recently, some journals have indicated renewed willingness to publish small, incomplete or negative trials using an abbreviated format. This would be an acceptable option under the Policy even if the peer review process for these abbreviated publications is itself less rigorous than the full length articles in the respective journals. NCI will not mandate use of a single mechanism but any mechanism used is expected to enable ready access to the Final Trial Results not only by researchers and providers but by patients as well. Public access to the results generally, and patient access specifically, are important goals of the Policy. Accordingly, if publication in a journal is the mechanism selected to satisfy the Policy, the institution must comply with the NIH Public Access Policy (http://publicaccess.nih.gov) under which "investigators funded by the NIH must submit or have submitted for them, to the National Library of Medicine's PubMed Central, an electronic version of their final peer-reviewed manuscripts upon acceptance for publication, to be made publically available no later than 12 months after the official date of publication."

V. Responsible Institutions

With respect to each Covered Trial, the grantee or contract recipient, as applicable, is responsible for ensuring reporting of Final Trial Results in accordance with this Policy. For Covered Trials involving multiple grantees, the lead institution is responsible for ensuring compliance with the Policy and for any NCI-designated Cancer Center participating in a multi-center Interventional Clinical Trial that is NCI-Supported, the lead Center is responsible for ensuring Policy compliance.

All other aspects of NOT-CA-13-019 remain the same.

Inquiries

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