Request for Information on Proposed NCI Policy Ensuring Public Availability of Results from NCI-Supported Clinical Trials

Notice Number: NOT-CA-13-019

Update: The following update relating to this announcement has been issued:

- November 4, 2013 - See Notice NOT-CA-14-005. The purpose of this Notice is to announce two amendments.

Key Dates

Release Date: September 30, 2013
Response Date: November 20, 2013

Related Announcements

NOT-OD-10-007
NOT-OD-09-147
NOT-OD-09-030
NOT-OD-08-023
NOT-OD-08-014

Issued by

National Cancer Institute (NCI)

Purpose

With this Notice, the National Cancer Institute (NCI) announces and seeks public input on NCI's plan to promote and ensure public availability of results from all commenced, NCI-supported clinical trials.

Background

NCI, a component of the National Institutes of Health (NIH), is dedicated to improving the health of Americans by conducting and funding biomedical research through an extensive portfolio of clinical trials and clinical trials-related research. A fundamental premise of all NIH-funded research is that the results of such work must be shared in order to contribute to the general body of science and ultimately, to the public health. Grantee institutions are expected to make the results and accomplishments of their activities available to the research community and to the public at large.
NIH funding recipients ensure the timely disclosure of their scientists' research findings through publications, presentations at scientific meetings as well as by sharing research tools, depositing information into databases and materials into repositories and through other means. NIH has many policies in place to educate funding recipients about their responsibility to share the results of NIH-funded work, and to facilitate such sharing. For example, the NIH Data Sharing Policy (http://www.grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm), the NIH Public Access Policy (http://publicaccess.nih.gov/), the NIH Research Tools Policy (http://www.ott.nih.gov/policy/research_tool.html), and the NIH Genome Wide Association Policy (http://gwas.nih.gov/03policy2.html) are all important examples of critical information and materials sharing policies that ensure that NIH research funding is used productively and to the best advantage of science and the public health. Such sharing is fundamental to biomedical research program performance.

NCI is aware that public dissemination of the results of NCI-supported clinical trials is particularly important to cancer patients since the results of such research, more so than with most preclinical research, could directly impact their care. Unfortunately, the results and findings of a sizeable number of NCI-supported trials are not published. This occurs most frequently when a trial has negative results or is not completed. Reasons for incomplete trials can include unanticipated toxicity, poor accrual or lack of drug availability. Trials that have negative results or are incomplete are harder to publish. Understandably, medical journals often seek to attract the attention of readers and positive trials do this more readily than incomplete trials or trials with negative results. This can lead to discouragement on the part of clinical investigators who may try to publish negative results or incomplete trials but often cease their efforts to publish after repeated rejections. This selective

publication of certain trials and not others is the source of publication bias which can lead to inappropriate conclusions about particular therapies. See, e.g., Nissen S, Biomarkers in Cardiovascular Medicine, The Shame of Publication Bias, JAMA Intern Med 2013 March 25; doi:10.001/jamainternmed.2013.4074; Dwan K et al., Systematic review of the empirical evidence of study publication bias and outcome reporting bias, PLoS One 2008 Aug 28;3(8):e3081. doi: 10.1371/journal.pone.0003081; Begg C, Berlin J, Publication bias and dissemination of clinical research, J Natl Cancer Inst 1989, Jan 18;81(2):107-15.

NCI believes that it is critically important for scientific information from all NCI-supported clinical trials, whether or not completed or positive, to be widely available to all health care providers, as well as to the many millions of Americans who seek credible information on clinical trials supported by NCI. Public access to such data drives scientific progress, advances patient safety, promotes health and assures optimal return on the nation's investment in cancer trials. Indeed, according to a recent commentary in JAMA on evidence-based medicine, "science advances only when the totality of available information is shared widely within the academic community," and clinical decision making is correspondingly hampered by the absence of findings from all available studies. See Nissen S, Biomarkers in Cardiovascular Medicine, The Shame of Publication Bias, JAMA Intern Med 2013 March 25; doi:10.001/jamainternmed.2013.4074.

While studies with positive results often have the most immediate impact on clinical practice, it is nonetheless true that negative results and incomplete studies can also be informative. For example, information about side effects can help guide other studies; unexpected negative interactions between agents or between radiation and drugs can prove useful to the development of newer approaches; and understanding the reasons for incomplete trials can reduce unnecessary duplication. The current situation, where many NCI-supported clinical trials fail to be adequately communicated to the scientific community and the public, wastes precious, limited resources (including human resources, time and money) and undermines the ability of NCI to fulfill its mission to provide evidence-based approaches to cancer therapy.

For these reasons, NCI expects funded grantees, contractors and supported principal investigators conducting interventional clinical trials to find other ways to make their results publicly available when the traditional route – peer-reviewed publication – is not available.

Although certainly not the only way, one way to achieve this is through a publicly available registry or database. In its April, 2010 Consensus Report, "A National Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program" (the IOM Report), the Institute of Medicine identified the need for and promoted the use of such a registry to list and maintain comprehensive information about clinical trials for drugs, biologics, and other therapeutic modalities. Such a registry, the IOM Report states, "could improve both physician and patient awareness of the available trials" and facilitate and improve subject involvement. NCI believes that publicly available databases could likewise be a useful and important means of communicating the results of clinical trial research to the public; particularly in cases where no peer-reviewed publication resulted from the trial. Accordingly, as more fully described below, appropriate reporting of results of an NCI-supported clinical trial in a publicly available registry will be considered satisfactory compliance with the new policy.

Request for Information on the Proposed Policy

NCI seeks comments and input concerning its draft policy through which results from NCI's investment in clinical research will be communicated and made available to scientists and the public as outlined in this Notice. Interested parties may wish to react to the draft policy as a whole or to on one or more specific issues. Your comments to NCI can include but are not limited to the following areas:

- The extent and effectiveness of the draft policy to address an important gap in reporting results of NCI clinical trials.
- Discussion of particular benefits or drawbacks with respect to the short-term and long-term effects of the draft policy.
- Suggestions for other options for making clinical trial results publicly available other than via publication in journals and registration with public registries such as ClinicalTrials.gov.

Submitting a Response

Persons, groups and organizations interested in providing input on NCI's results reporting policy should direct their comments to the following email address: NCIPublicationPolicy@mail.nih.gov. Comments must be received on or before November 20, 2013.

This request is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of the Federal Government. The NIH does not intend to make any awards based on responses to this RFI or to otherwise pay for the preparation of any information submitted or for the Government's use of such information.

The NIH will use the information submitted in response to this RFI at its discretion and will not provide comments to any responder's submission. However, responses to the RFI may be reflected in future funding opportunity announcements. The information provided will be analyzed and may appear at http://publicaccess.nih.gov. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential, or sensitive information should be included in your response.

Inquiries

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