Request for Information (RFI): Immune Response Modifiers Pathway Translational Research Opportunities

Notice Number: NOT-CA-09-031

Key Dates

Release Date: July 20, 2009
Response Date: Responses must be received by August 24, 2009

Issued by

National Cancer Institute (NCI), (http://www.cancer.gov)

This is a Request for Information (RFI). It is to obtain knowledge and information for project planning purposes only and should not be construed as a solicitation for grants, contracts, etc.

Purpose and Objectives

This RFI is to gather information from the scientific community regarding opportunities in cancer immunotherapy and immunoprevention that would benefit from accelerated development through focused funding and coordinated management. This request is part of the NCI's new Process to Accelerate Translational Science as recommended by the Translational Research Working Group (TRWG). At the discretion of the NCI, the information gathered in response to this RFI may be used in a variety of ways by the NCI, including but not limited to: 1) assist NCI in the development of Requests for Proposals (RFP), Requests for Applications (RFA), Program Announcements (PA), Cooperative Research and Development Agreements (CRADA), Cooperative Agreements and/or other mechanisms/agreements; 2) assist in developing formulations, production and implementation of products/devices/processes using existing internal NCI mechanisms, to include but not limited to in-house staff, contracts, grants, cooperative agreements, etc.; or 3) no action taken.

Background

The TRWG was an NCI-sponsored working group charged with evaluating the status of the NCI's investment in translational research and envisioning its future in an inclusive, representative, and transparent manner. In 2007, the NCI accepted the 15 TRWG recommendations to accelerate translational cancer research as outlined in the report entitled *"Transforming Translation: Harnessing Discovery for Patient and Public Benefit,"* (http://www.cancer.gov/trwg).

One of the TRWG recommendations was the establishment of a yearly process to identify a small number of opportunities for specific cancer treatment, prevention or assessment modalities that are "ripe" for further development, and then to provide the funding or resources as well as the project management required to advance these opportunities as rapidly as possible to early stage clinical trials. This recommendation is being implemented and includes a prioritization process to identify and rank individual translational research opportunities, the provision of dedicated project management resources for the resulting prioritized projects, and the development of project specific funding approaches for these new, prioritized Special Translational Research Acceleration Projects (STRAPs).

The Process to Accelerate Translational Science was initiated with the first NCI Translational Science Meeting, held November 7-9, 2008 (http://ncitranslates.nci.nih.gov). This meeting educated the translational cancer research community about the TRWG Pathways to Clinical Goals (Clinical Cancer Research 14: 5663-5714, 2008, http://clincancerres.aacrjournals.org/content/vol14/issue18/#CCR_SPECIAL_FOCUS) and demonstrated that there are compelling translational research opportunities that warrant acceleration. The Pathways to Clinical Goals describe the steps required to create a treatment, prevention or assessment modality based on advances in scientific knowledge, and develop that modality to the point of early phase clinical trials. The term "Translational Research Opportunity" refers to a developmental project that follows one of these six TRWG Pathways (Agent, Immune Response Modifier, Interventive Device, or Lifestyle Alteration intervention, or Biospecimen-Based or Imaging-Based Assessment tool), and identifies the population/cancer type in which it is to be tested.

Information Requested

This RFI invites input from the scientific community on Translational Research Opportunities that follow the Immune Response Modifiers Pathway to testing in Phase I/II clinical trials (Clinical Cancer Research 14: 5692-5699, 2008, http://clincancerres.aacrjournals.org/cgi/reprint/14/18/5692.pdf). Information is sought from members of the scientific community at large, academic and non-academic translational cancer researchers, clinical oncologists, and investigators from the pharmaceutical/biotechnology

industry. The opportunities can relate to a range of specific therapeutic regimens and target populations. Any information that can be shared regarding the immunogenicity and therapeutic function of an antigen, the scientific validity and feasibility of the formulation for that antigen, and/or the scientific validity and feasibility of combinations with immune modifier agents is requested. In addition, information on assays of immune response, assays for patient selection, and the availability of patients for clinical trials, is requested. The Translational Research Opportunity Template (see below) provides the preferred submission format. Use of this format is requested; however, respondents are not required to use this format for their submission.

This RFI is for planning purposes and should not be construed as a solicitation for applications or as an obligation on the part of the Government to provide support for any opportunities identified in response to it. Please note that the United States Government will not pay for the preparation of any information submitted or for its use of that information.

Information Submission Instructions

1. Respondents are encouraged to utilize the Translational Research Opportunity Template to organize their responses. The template can be found at http://patsinitiative.nci.nih.gov.
2. Responses should be limited to twenty (20) pages in length. Brief and/or bullet information are encouraged wherever applicable in order to minimize overall response length and aid in the data processing.
3. It is preferred that responses be submitted in MS Word or PDF format via e-mail to NCI-RFI-IRMPathway@mail.nih.gov marked with the above RFI identifier (Notice Number) noted in the subject line. Respondents will receive an email confirmation acknowledging receipt of their response, but will not receive individualized feedback.
4. Responses will only be accepted through August 24, 2009.

Confidentiality

Responses to this RFI are voluntary and may be anonymous. Any identifiers (e.g. names, institutions, e-mail addresses, etc.) will be removed when responses are compiled. Anonymized results may be shared with scientific advisors convened by the NCI under confidentiality and conflict of interest agreements. No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s). As previously indicated, NCI can use the information gathered to develop grant, contract, or other funding initiatives.

Inquiries

Inquiries regarding this Notice may be directed to:

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