Sources Sought Notice

Sources Sought Notice No.: HHS-NIH-NCI-SBSS-PCPSB-5014-29

Title: Phase I and II Clinical Trials of Cancer Chemopreventive Agents

Description:
This is a Small Business Sources Sought notice. This is **NOT** a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) the type of small businesses, e.g., HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses, etc.; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice. This Sources Sought notice is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Cancer Institute (NCI).

The NAICS code for this project is 541712.

The small business size standard is 500 employees (or less).

Background:
The National Cancer Institute (NCI), Division of Cancer Prevention (DCP) seeks to fund early phase clinical trials poised to efficiently evaluate the biologic effect of NCI, DCP-sponsored cancer preventive agents on their molecular targets and determine clinically-relevant correlates.

Purpose and Objectives:
The purpose of this project is to conduct early phase cancer prevention clinical trials for the NCI DCP. Conducting these clinical trials requires:

- Scientific, technical and operational capacities for conducting clinical trials
- Experience with cancer prevention drug development
- Expertise in standard and innovative laboratory methodologies
- Availability of sufficient participants for clinical trials
- Access to sufficient hospital and laboratory facilities and services

Project Requirements:

<u>Scientific, Technical and Operational Capacities for Conducting Trials</u>
Possess sufficient scientific, technical and operational capacities for conducting early phase clinical cancer prevention trials. This includes demonstrating the ability to conduct clinical trials by assembling multi-institutional consortia consisting of clinicians, statisticians, data managers, and research nurses with expertise in performance of early phase clinical trials with investigational agents and cancer preventive agent development.

Experience with Cancer Prevention Drug Development
Demonstrate expertise in cancer prevention drug development, including knowledge of cancer prevention strategies in one or more target organ sites; phase 0, I and II cancer prevention clinical trials; biomarker analysis; pharmacology and pharmacodynamics.

Expertise in Laboratory Methodologies
Provide evidence of expertise, or access to expertise, in diagnostic and functional imaging, interventional radiology, pathology, and other potentially relevant laboratory methodologies.

Availability of Sufficient Participants for Clinical Trials
Demonstrate the availability of sufficient numbers of participants to simultaneously conduct 1 to 3 clinical trials per year using NCI-directed cancer preventive agents.

Access to Sufficient Hospital and Laboratory Facilities and Services
Provide evidence of access to accredited hospitals with outpatient and, if need be, inpatient services, as well as access to CLIA-certified laboratories.

Anticipated Period of Performance:
The anticipated period of performance is for 5 base years starting in the spring of 2011. This contract is expected to also include two (2) one year option periods.

Capability Statement/Information Sought:
Small businesses that believe that they have the ability to satisfy all of the above stated Project Requirements, and who meet the stated size standard, are encouraged to submit a capability statement. The capability statements will be evaluated based on the information provided in relation to the Project Requirements and the current capacity to perform the work including: (a) technical capabilities and ability to conduct chemoprevention clinical trials; (b) qualifications and availability of appropriate personnel; (c) prior completed projects of a similar nature; (d) organizational experience and management capabilities; and (e) availability of facilities and equipment sufficient for clinical trials. On the first page of the capability statement, clearly state the small business concern's size status and type(s), name, address, point of contact, and DUNS number. The remainder of the capability statement should be tailored to the project requirements stated above and must demonstrate that similar work has been performed in the past, including the dollar value of that work.

Information Submission Instructions:
All capability statements sent in response to this SMALL BUSINESS SOURCES SOUGHT notice must be submitted electronically (via e-mail) to Virginia DeSeau, Contract Specialist, at vd9t@nih.gov, in either MS Word, WordPerfect or Adobe Portable Document Format (PDF), by **3:00pm Eastern time on March 12, 2010**. All responses must be received by the specified due date and time in order to be considered. ANY RESPONSES RECEIVED AFTER THE SPECIFIED DATA AND TIME WILL NOT BE CONSIDERED. Capability statements should not exceed fifteen (15), single-sided pages (including all attachments, resumes, charts, etc.), presented in single-spaced, 12-point font size minimum. All proprietary information should be marked as such.

Disclaimer:
This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. 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. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality:
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).