Notice Number: HHS-NIH-NCI-RDSS-ETSB-01018-83

Title: Early Therapeutics Development with Phase II Emphasis

"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) whether they are small businesses; 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; 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"

Background

CTEP, NCI holds INDs for new anticancer agents from a variety of sources including those developed through NCI's Developmental Therapeutics Program (DTP), numerous agents developed and supplied by the pharmaceutical and biotechnology industries, and agents developed by academic investigators. NCI has collaborative agreements with 65 industry partners for 160 investigational agents. CTEP has filed approximately 8-10 IND applications annually in recent years and expects to file 10 this year. All but two of NCI's current INDs are for early clinical trials.

A number of interrelated initiatives have recently been developed or implemented to create a cohesive and integrated NCI program in drug discovery and clinical development focused on molecularly targeted new agents. The contracts for Early Therapeutics Development with Phase 2 Emphasis will provide the major resource for rapid, efficient, systematic implementation of drug development plans for evaluation of NCI's portfolio of investigational agents in specific tumors

CTEP requires a total resource that will provide for 1400 to 1700 patients accrued to 15-25 trials per year. CTEP intends to make multiple contract awards. Each Contractor shall be able to initiate one or more clinical trials per year using NCI-held IND anticancer agents. The size of each trial may vary depending upon whether it will involve the evaluation of an investigational agent administered alone, utilizing a 2-stage design of up to 35 or 40 patients, or whether the investigational agent will be added to another therapy, which will require randomization to two or more arms, with each arm numbering 50-75 patients

These contracts will require single institutions or multi-institutional consortia of clinicians, pathologists, imagers, statisticians, data managers, research nurses and others with early phase clinical trial expertise with investigational agents in cancer, as well as demonstrate the capability of carrying molecular and functional imaging and of acquiring, in sequential fashion, high quality patient samples.

Reflecting the need to incorporate novel imaging endpoints in the development of investigational agents, the re-competed Phase 2 N01 Program will include the integration of molecular imaging with investigational drug development Over the next 1-2 years, the DCTD Cancer Imaging program will be qualifying NCI designated Cancer Centers for their ability to carry out advanced molecular and functional imaging Participation in this Phase 2 N01 Program will require that each offeror have at least 1-2 sites which have undergone such qualification and have identified committed personnel with appropriate imaging expertise i e. nuclear medicine physicians and radiologists, who will be an integral part of the drug development team

Rapid translation of promising discoveries in the fields of molecular and functional imaging probes and methodologies requires timely and substantial support. We propose to support, in selective Phase II treatment trials, the evaluation of molecular and functional imaging agents, in a standardized, prospective fashion. This would enable the evaluation of the core issues of preliminary efficacy as well as technical performance issues which is often lacking in current trials (for e g. reproducibility, quantitative vs. semi-quantitative analysis). The imaging agents and methods which prove successful in these early clinical trials can then be validated in larger studies through clinical trials in Cancer Centers and/or Co-operative Groups

Purpose and Objectives

The objectives of these contracts are to conduct Phase 2 and early clinical trials of NCI-sponsored agents, to evaluate biologic effects of these agents on their molecular targets, to evaluate other relevant biologic effects and to determine clinically relevant outcomes/correlates. Major emphasis shall be on Phase 2 studies, pilot protocols that explore promising combination therapies, and high priority studies that are pivotal for drug development and require rapid initiation, completion, and data reporting.

Project Requirements

This project requires the contractor to perform clinical trials for NCI-IND therapeutic agents against and imaging agents for cancer. The Contractor shall

a rapidly conduct clinical trials necessary to assess the anti-tumor activity and carry out the development plans for NCI sponsored agents of varying classes;

b. obtain, process, and ship (as required) blood, normal and tumor tissue and carry-out imaging evaluations such as (advanced PET, SPECT and MR) in qualified scanners using standardized methodology;

c. study relevant pharmacology and biologic effects of new agents;

e. determine the antitumor activity of select combinations of antitumor agents;

f. determine the safety and efficacy of these agents; and,

g. to characterize the effects of new agents on their targets through biopsies and suitable assays, functional imaging, and other appropriate technologies and to correlate those effects with clinically relevant endpoints;

The NCI-IND agents to be studied shall include the following:

a. Agents developed by the pharmaceutical industry and provided to the NCI for collaborative development; and agents developed by academic investigators and/or the Chemical Biology Consortium, DCTD, NCI;

b Agents which have completed some or all Phase 1 testing, and;

c. Combinations of agents for which the individual toxicities are known.

d Imaging IND agents (for PET, SPECT or MR). The PET and SPECT IND agents evaluated under the NCI IND, will be distributed regionally by commercial radiopharmacies, whose SOPs for manufacturing have been filed in the NCI IND(s)

Because of the complex nature of the project requirements, a draft Statement of Work is attached.

Anticipated Period of Performance

The anticipated period of performance for this requirement is 5 years, with option for additional quantities.

Capability Statement/Information Sought.

Interested qualified small business organizations should submit a tailored capability statement for this requirement, not to exceed 20 single-sided pages (including all attachments, resumes, charts, etc.) presented in single-space and using a 12-point font size minimum, that clearly details the ability to perform the aspects of the notice described above. Statements should also include an indication of current certified small business status; this indication should be clearly marked on the first page of your capability statement, as well as the eligible small business concern's name, point of contact, address and DUNS number

Information Submission Instructions

All capability Statements sent in response to this SOURCES SOUGHT notice must be submitted electronically (via email) to Michael Marino, Contract Specialist, at marinomic@mail.nih.gov in MS Word, WordPerfect or Adobe Portable Document Format (PDF), by February 15, 2010 3:00PM, EST. All responses must be received by the specified due date and time in order to be considered

Disclaimer and Important Notes

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. Respondents will be added to the prospective offerors list for any subsequent solicitation. 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 information in any resultant solicitation(s).

Richard L. Hartmann
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