Sources Sought Notice No.: SS-ETSB-01008-03

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 a 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.

The NAICS code for this project is 541990.
The small business size standard is $7,000,000 per annum.

Background:
In 1979, the Cancer Therapy Evaluation Program (CTEP) initiated site visit auditing and monitoring of phase1 clinical trials when it established the Clinical Trials Monitoring Service (CTMS) contract. The first contractor for the CTMS contract was Besselar Associates; the contract included only phase 1 data collection and audits. The CTMS contract was expanded in 1983 to include not only the phase 1 data collection and the phase 1 audit program, but also the Cooperative Group co-site visits and the Cancer Center and single institution audits. Since 1983 Theradex, Inc. has been the contractor.

Purpose and Objectives:
The purpose of this project is to assist the Cancer Therapy Evaluation Program (CTEP), NCI in fulfilling its responsibilities to meet the regulations set forth by the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) as an Independent New Drug (IND) sponsor and funding agency by monitoring NCI sponsored clinical trials.

Project Requirements:
Major tasks required of the Contractor include the following:

1) Provide a protocol central patient registration, protocol patient data capture resource, and patient data quality control reviews for the Division of Cancer Treatment and Diagnosis (DCTD), NCI for clinical investigators conducting phase 0 (exploratory IND), phase 1 and selected phase 2 clinical trials.

2) Provide an on-site auditing resource for the DCTD to assure that contractors, grantees and other clinical investigators conducting phase 0, phase 1 and selected phase 2 clinical trials are in compliance with federal regulations, Good Clinical Practices (GCP), and NCI policies and procedures in order to verify submitted protocol patient data, assure the

quality of submitted data, assure protocol compliance, and assure patient safety through proper reporting.

3) Assure the DCTD that the quality assurance programs of the Cooperative Groups, Community Clinical Oncology Program (CCOP) Research Bases, the Clinical Trials Support Unit (CTSU), and other selected multi-institutional consortiums are actively monitoring their NCI sponsored clinical studies in compliance with the "Guidelines for Monitoring of Clinical Trials for Cooperative Groups, CCOP Research Bases, and the Cancer Trials Support Unit." This shall be accomplished by attending as co-site visitors scheduled audits conducted by Cooperative Groups, Cancer Center CCOP Research Bases, and the CTSU or selected consortiums.

4) Assure the DCTD that all cancer centers, single institutions, multi-institutional consortiums and networks conducting clinical trials using DCTD sponsored trials are in compliance with Federal regulations, Good Clinical Practices (GCP), and NCI policies and procedures. This oversight shall be accomplished by on site auditing at these institutions at least once every three years.

5) Assure the DCTD that international groups/institutions who are collaborators in DCTD sponsored clinical trials are conducting these trials in accordance with Good Clinical Practices (GCP) and International Conference on Harmonization (ICH) standards. This shall be accomplished through training and administrative support for quality assurance programs to ensure that GCP clinical trial and regulatory standards are met, particularly the protection of human subjects.

6) There are two options associated with the requirement:

A: Integration of NCI purchased Clinical Data Management System (CDMS) into Clinical Trials Monitoring Service processes, workflow and IT infrastructure.

B: Expand capability for conducting on-site audits to encompass the expanded scope of trials conducted under the auspices of the Cancer Trials Support Unit (CTSU). This expansion may also include clinical trials sponsored by other NCI Programs (SPORES, RAID and imaging).

Anticipated Period of Performance:
The anticipated period of performance is May 1, 2010 – April 30, 2011 with six (6), one (1) year award term option periods from May 1, 2011 – April 30, 2017.

Capability Statement/Information Sought:
Interested qualified small business organizations should submit a tailored capability statement for this requirement, not to exceed 10 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 Erin Bain, Contract Specialist at: bainerin@mail.nih.gov in MS Word, WordPerfect or Adobe Portable Document Format (PDF) by **Thursday, May 14, 2009, 3:00 PM EST.** All responses must be received by the specified due date and time in order to be considered. ANY RESPONSES RECEIVED AFTER THAT DATE AND TIME WILL NOT 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 the 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).