Sources Sought Notice

Sources Sought Notice No.: HHS-NIH-NCI-SBSS-PCPSB-5027-29

Title: From Concept to Reality: the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)

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 541720.

The small business size standard is $7 million.

Background:
The NCI's PRO-CTCAE system provides a web-based platform to collect patient reports of symptoms they are experiencing while undergoing treatment for the purposes of enhancing adverse event (AE) reporting (http://outcomes.cancer.gov/tools/pro-ctcae.html). The accurate reporting of AEs that occur to patients on clinical trials is a federal requirement that facilitates evaluation of new therapies.

To date, 77 symptoms of the CTCAE (version 4) have been identified to be amendable to patient-reporting. These symptoms have been converted to patient terms (e.g., CTCAE term "myalgia" converted to "aching muscles"). For symptoms like fatigue and pain, the PRO-CTCAE system will ask patients information about symptom frequency, severity, and interference with usual activities. For other symptoms like rash, questions will focus on the presence on the body. These items have undergone extensive qualitative review among experts and patients. The PRO-CTCAE electronic system will provide an interface for patients, investigators, and clinicians in a secure web-based platform. The system is currently undergoing usability testing and a validation study is soon underway.

Purpose and Objectives:
The purpose of this project is to expand the capabilities of the current PRO-CTCAE system and to build a body of knowledge and evidence to support the implementation of the PRO-CTCAE system in multi-site clinical research studies supported by the NCI. The three primary objectives of the contract are to: 1) increase accessibility of the PRO-CTCAE system for cancer patients and researchers; 2) conduct a feasibility study in NCI clinical trial networks; and 3) evaluate shared (patient-clinician) and stand-alone (patient only) models for symptom AE reporting.

Project Requirements:

Enhance Accessibility of PRO-CTCAE System for Cancer Patients and Researchers
1) Translate the PRO-CTCAE items and instructions from English to Spanish (American dialect) and test for equivalence. 2) Enable home-based (non-clinic) assessment of the PRO-CTCAE system via secure electronic web-based platform. 3) Develop an interactive voice response system to allow patients to report their symptoms by phone. 4) Enhance the PRO-CTCAE system to upload and administer additional quality of life questionnaires.

Conduct Feasibility Study in NCI Clinical Trial Networks
Conduct feasibility study of the PRO-CTCAE system within NCI's clinical trial networks with the goals to: 1) evaluate barriers to implementation and acceptance of the PRO-CTCAE at the individual site level (technical; logistical/workflow-related; training; cultural; financial), as well as any difficulties with sustained use of the system over time in trials; 2) estimate initial and ongoing costs associated with adopting PRO-CTCAE in a trial; 3) document clinicians' responses to patient-reported adverse symptoms; and 4) assess patient and clinician satisfaction and valuation of the system and its output.

Evaluate Shared (Patient-Clinician) and Stand-alone (patient only) Models for Symptom AE Reporting
Conduct a study comparing independent clinician and patient ratings with shared reporting to identify adverse symptoms that should be reported only by patients and symptoms that should be reported by both patients as well as clinician input. In particular, the study will need to evaluate the impact of these different means of reporting upon CTCAE severity grading, alteration of treatment regimen and compliance with full course of therapy.

Anticipated Period of Performance:
The anticipated period of performance is a multi-year contract for 5 years starting around September 30, 2010.

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) method and approach; b) staff availability, experience, and training; c) prior completed projects of a similar nature; and d) corporate experience and management capabilities. 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, Contracting Officer, at vd9t@nih.gov, in either MS Word, WordPerfect or Adobe Portable Document Format (PDF), by **3:00pm Eastern time on February 16, 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.

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).