SMALL BUSINESS SOURCES SOUGHT NOTICE

Notice Number: HHS-NIH-NCI-SBSS-TSB-17007-04

Title: "Support for Strategic Planning and Activities for NCI's Center for Strategic Scientific Initiatives (CSSI)"

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.

This National Cancer Institute (NCI), National Institutes of Health (NIH) project is for the renewal of contract HHSN261201000085I, N02-CO-07035 with CCS Associates, Inc. (CCSA) that was awarded on a sole source basis for a one year period. Freedom of Information Act (FOIA) requests regarding the current contract with CCS Associates, Inc. should be directed to Suzy Milliard at milliars@mail.nih.gov. This Small Business Sources Sought Notice (SBSS) 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).

A determination by the Government not to compete this requirement as a set-aside based upon responses to this Notice is solely within the discretion of the Government.

Interested parties are expected to review this Notice, the draft Technical Evaluation Criteria and the draft Statement of Work to familiarize themselves with the requirements of this project; failure to do so will be at your firm's own risk.

Background:

The National Cancer Institute (NCI) Center for Strategic Scientific Initiatives (CSSI) Office of the Director (CSSI-OD or the Office) has as its mission the task of planning, developing, executing, and implementing rapid strategic scientific and technology initiatives that keep the Institute ahead of the scientific curve with respect to potential new highly productive areas and discoveries. This may involve the development and application of advanced technologies, synergy of large scale and individual initiated research, and/or forging novel partnerships that emphasize innovation, trans-disciplinary teams and convergence of scientific disciplines to enable the translation of discoveries into new interventions, both domestically and in the international arena, to detect, prevent and treat cancer more effectively.

Under the leadership of the NCI CSSI-OD, several efforts are supported both within NCI and outside of NCI to carry-out its function of supporting timely execution and implementation of activities that have trans-NCI benefit. The Office is responsible for coordinating trans-NIH efforts through implementation of interagency and public private collaborations to enable progress against cancer. For example, the NCI-FDA Interagency Oncology Task Force (IOTF) focuses on the identification of scientific and process gaps in the regulatory pathways for cancer interventions and development of joint science-based approaches to addressing these barriers. Also, the Cancer Steering Committee of the Foundation for NIH (FNIH) Biomarkers Consortium is a public private partnership including NCI, FDA, Centers for Medicare and Medicaid Services (CMS), academia, the pharmaceutical and biotechnology industries, and advocates which plans and implements projects to develop and qualify biomarkers for use in accelerating oncology drug development and improving cancer patient management.

Within the Center, CSSI-OD oversees several Offices which together aims to accelerate our understanding of cancer and best practices in research and treatment via cutting edge technologies that take advantage of collaborative efforts to transfer knowledge and insights available from a spectrum of basic and applied research through programs and offices that include: (1) The Cancer Genome Atlas (TCGA) Program Office; (2) Office of Cancer Nanotechnology Research; (3) Office of Cancer Clinical Proteomics Research; (4) Office of Physical Sciences-Oncology; (5) Office of Biorepositories and Biospecimen Research; (6) Office of Cancer Genomics; (7) Knowledge Management and Special Projects Branch; (8) Center for Global Cancer Health Research. These offices support extramural research programs and lead standards and policy development initiatives with the goal of accelerating advances in biomedical technology and furthering the vision of personalized medicine.

The increasing success and development of these strategic scientific initiatives has created a requirement for a wide and changing spectrum of expertise that can be applied to support the efforts of CSSI, including activities in such areas as drug and device development, biomarker development and validation for use in drug development, U.S. regulatory requirements for investigational new drugs and investigational new devices, standard operating procedures for clinical laboratory research, clinical considerations in imaging probe development, clinical trial design in the development of biomarkers and imaging modalities as biomarkers that can be used in drug development, treatment, and monitoring of therapeutic responses.

Effort anticipated under this requirement could include, but not be limited to, continuation of assistance for CSSI-OD and CSSI Offices by providing scientific and project planning support for activities which require expertise in oncology, drug development, advanced technologies applied to drug and device development, biomarker science, and imaging technologies, regulatory affairs, research project management, clinical trial management, business plan development, scientific writing, meeting implementation, and general business documentation.

Purpose and Objectives:

The purpose of this Small Business Sources Sought Notice is to identify qualified small business concerns including 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 that are interested in and capable of performing the work described herein. The NCI does not intend to award a contract on the basis of responses received nor otherwise pay for the preparation of any information submitted.

As a result of this SBSS Notice, the NCI may issue a Request for Proposal (RFP). THERE IS NO SOLICITATION AVAILABLE AT THIS TIME. However, should such a requirement materialize, no basis for claims against NCI shall arise as a result of a response to this Small Business Sources Sought Notice or the NCI's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

The National Cancer Institute (NCI) is an institute within the National Institutes of Health (NIH), one of eight agencies that compose the Public Health Service (PHS), Department of Health and Human Services (DHHS). The mission of the NCI is to plan, conduct, and coordinate the National Cancer Program and involves (a) research on the causes, detection, diagnosis, prevention, treatment, and palliative care of cancers and on rehabilitation of the cancer patient and (b) demonstration of the effectiveness of cancer control methods and techniques.

Project Requirements:

1. Develop and plan senior scientific strategy that supports activities in multi-center, multi-agency committees and initiatives such as NCI-FDA Interagency Oncology Task Force (IOTF) and the Cancer Steering Committee of the FNIH Biomarkers Consortium.

2. Design approaches and provide operational/documentation support to management of intellectual property and data sharing for multidisciplinary, multi-institutional projects carried out under the auspices of the Director and Deputy Director of CSSI.

3. Develop and maintain processes for multidisciplinary, multi-institutional projects.

4. Develop science-based regulatory strategy and provide regulatory affairs support for studies sponsored by the Office of the Director of CSSI and its collaborators. Develop, submit and maintain regulatory documentation (*e.g.*, investigational device exemption (IDE) applications, 510(k) applications, investigational new drug (IND) applications and Master INDs, imaging charters, briefing documents, biomarker qualification packages). Manage safety data and reporting and Data and Safety Monitoring Board (DSMB) activities.

5. Manage operations for sponsored studies. For example, qualify sites for carrying out the studies; ensure manufacturing, tracking, and delivery of study materials to appropriate locations; assist in development of data management/bioinformatics systems; monitor study progress; and carry out quality assurance audits of study data and processes.

6. Prepare draft manuscripts, critical reviews, news releases, PowerPoint presentations and other graphics, *etc.*, as requested for publication of research results and plans. Assist in publication *via* a dedicated website, (government, if available, contractor, if not) as well as by preparing draft presentations for relevant scientific and trade association meetings, articles in the scientific and trade association literature, and news releases directly to the public or *via* other interested parties. Ensure that the required Government clearances/approvals are obtained prior to starting work and/or releasing/publishing these items.

7. Perform administrative coordination activities. Maintain contact information for working groups, committees, project teams, *etc.*; assist in planning business meetings and teleconferences; prepare agendas and minutes for same; maintain files of correspondence and other documentation as directed.

8. Facilities, staff, equipment and processes in place at start of contract. Including a relevant data management system that is caBIG capatible, and supports regulatory submissions, including preclinical and clinical data management, safety data, regulatory document tracking and background materials for IND/IDE maintenance.

9. The Contractor shall be readily available to attend meetings in person in Bethesda with one hour advance notice and respond to requests after normal business hours and on weekends.

10. Conduct literature/media research and prepare written summaries for specific CSSI initiative(s) steering committees in support of high-priority initiatives.

11. Provide scientific literature research and review (including written summaries and databases) for selection of biomarkers, laboratory technologies and imaging modalities along with clinical settings providing the best possible opportunities for development of biomarkers, nano-based moieties and technologies, and proteomics-based technologies useful in oncologic drug development and improving the care of cancer patients; include information to address both scientific and economic criteria for qualifying candidate biomarkers.

12. Develop priority ranking of research efforts within CSSI initiative(s) by drafting criteria for determining their utility for developing new oncology therapies or new uses of approved therapies or other intended uses.

13. Prepare and maintain documentation for justifying CSSI initiatives and assisting with implementation with all stakeholders (e.g. academia, patient advocates, FDA, industry).

14. Prepare and maintain overall research and business plans for the Office of the Director of CSSI on CSSI initiative(s) projects.

15. Prepare draft manuscripts, news releases, PowerPoint presentations, *etc.* Assist in publication *via* a dedicated website, (Government, if available, contractor, if not) as well as by preparing draft presentations for relevant scientific and trade association meetings, articles in the scientific and trade association literature, and news releases directly to the public or *via* other interested parties. Ensure that the required Government clearances/approvals are obtained prior to starting work and/or releasing/publishing these items.

16. Perform literature/media research and prepare written summaries to keep CSSI and the individual initiatives abreast of complementary research initiatives, both in the U.S. and worldwide.

17. Perform administrative coordination activities for grantees and the individual initiatives. Maintain contact information for members; assist in planning business meetings and teleconferences; prepare agendas and minutes for same; maintain files of correspondence and other documentation as directed by CSSI.

Anticipated Period of Performance:

The period of performance for this requirement is five (5) years, consisting of a one-year base period plus four (4) one-year options. The anticipated start date is September 30, 2011.

Draft Statement of Work:

A copy of the draft Statement of Work (SOW) and draft technical evaluation criteria, which is subject to revisions, are attached to this sources sought announcement.

NAICS Code and Size Standard:

In the event an RFP is issued, North American Industry Classification System (NAICS) code 541990 with a size standard of 6.5 million dollars is being considered.

Capability Statement/Information Sought:

Tailored Capability Statements shall demonstrate a clear understanding of all tasks specified in the draft Statement of Work (SOW). Tailored Capability Statements for this requirement shall address the following areas:

In support of Task Area 1:

1. Develop and plan senior scientific strategy that supports activities in multi-center, multi-agency committees and initiatives such as NCI-FDA Interagency Oncology Task Force (IOTF) and the Cancer Steering Committee of the FNIH Biomarkers Consortium. Activities include:

    a. Design and perform background research, participate in planning, develop relational databases and prepare draft white papers on topics relevant to the research and business needs of the initiatives and collaborations of the Director and Deputy Director of CSSI.

    b. Identify, qualify, and convene key participants for scientific workshops and conferences relevant to these initiatives; draft meeting agendas; participate in the meetings; draft meeting reports for internal use in project planning and for publication. Parties involved may include NCI, other NIH entities, FDA, academia, and industry.

    c. Design and perform literature/media research and prepare written summaries to keep the Director and Deputy Director of CSSI abreast of complementary research initiatives, both in the U.S. and worldwide.

    d. Develop and maintain research and business plans for projects undertaken by the Director and Deputy Director of CSSI. These plans shall emphasize the use of best practices and shall include:

        i. Definition of what will be measured and calculated;
        ii. Gap analysis to identify data needed to successfully complete a project;
        iii. Instruments or reagents to be used;
        iv. Standardized acquisition parameters for imaging, bioassay and tissue data;
        v. Drugs selected for use in protocols;
        vi. Clinical studies performed to validate biomarker assays and new technologies (including development and analyses of retrospective databases) and to evaluate the biomarker as a correlate of clinical status;
        vii. Sites and investigators who will carry out the clinical studies;
        viii. Governance plan for the project;

ix. Further data and analyses required to bring the biomarker, clinical trial process, *etc.* to routine use in drug development and/or other clinical settings, and publication of methods and results (including guidance from the FDA);

x. Business plans will include project timelines, projected resources and budget, and decision points for continuing or abandoning specific components of the plan or the entire plan.

e. Develop and review research protocols and analysis plans for projects carried out under the auspices of the Director and Deputy Director of CSSI. It is anticipated that many of the protocols will have novel and complex designs (*e.g.*, adaptive randomization, multiple investigational agents and/or devices) aimed at advancing the sciences of oncology drug development and management of cancer patients.

2. Design approaches and provide operational/documentation support to management of intellectual property and data sharing for multidisciplinary, multi-institutional projects carried out under the auspices of the Director and Deputy Director of CSSI.

3. Develop and maintain processes for multidisciplinary, multi-institutional projects:

   a. Track project working groups, and define roles and responsibilities of individuals and working groups in carrying out projects.
   b. Design and develop processes and systems for communicating and sharing information among project participants.

4. Develop science-based regulatory strategy and provide regulatory affairs support for studies sponsored by the Office of the Director of CSSI and its collaborators. Develop, submit and maintain regulatory documentation (*e.g.*, investigational device exemption (IDE) applications, 510(k) applications, investigational new drug (IND) applications and Master INDs, imaging charters, briefing documents, biomarker qualification packages). Manage safety data and reporting and Data and Safety Monitoring Board (DSMB) activities.

5. Manage operations for sponsored studies. For example, qualify sites for carrying out the studies; ensure manufacturing, tracking, and delivery of study materials to appropriate locations; assist in development of data management/bioinformatics systems; monitor study progress; and carry out quality assurance audits of study data and processes.

6. Prepare draft manuscripts, critical reviews, news releases, PowerPoint presentations and other graphics, *etc.*, as requested for publication of research results and plans. Assist in publication *via* a dedicated website, (government, if available, contractor, if not) as well as by preparing draft presentations for relevant scientific and trade association meetings, articles in the scientific and trade association literature, and news releases directly to the public or *via* other interested parties. Ensure that the required Government clearances/approvals are obtained prior to starting work and/or releasing/publishing these items.

7. Perform administrative coordination activities. Maintain contact information for working groups, committees, project teams, *etc.*; assist in planning business meetings and teleconferences; prepare agendas and minutes for same; maintain files of correspondence and other documentation as directed.

8. Facilities, staff, equipment and processes in place at start of contract. Including a relevant data management system that is caBIG capatible, and supports regulatory submissions, including preclinical and clinical data management, safety data, regulatory document tracking and background materials for IND/IDE maintenance.

9. The Contractor shall be readily available to attend meetings in person in Bethesda with one hour advance notice and respond to requests after normal business hours and on weekends.

In support of Task Area 2

Senior scientific strategy development and support for research business planning specific to CSSI initiatives. Tasks shall include:

1. Conduct literature/media research and prepare written summaries for specific CSSI initiative(s) steering committees in support of high-priority initiatives.

2. Provide scientific literature research and review (including written summaries and databases) for selection of biomarkers, laboratory technologies and imaging modalities along with clinical settings providing the best possible opportunities for development of biomarkers, nano-based moieties and technologies, and proteomics-based technologies useful in oncologic drug development and improving the care of cancer patients; include information to address both scientific and economic criteria for qualifying candidate biomarkers.

3. Develop priority ranking of research efforts within CSSI initiative(s) by drafting criteria for determining their utility for developing new oncology therapies or new uses of approved therapies or other intended uses.

4. Prepare and maintain documentation for justifying CSSI initiatives and assisting with implementation with all stakeholders (e.g. academia, patient advocates, FDA, industry).

5. Prepare and maintain overall research and business plans for the Office of the Director of CSSI on CSSI initiative(s) projects, including elements listed above under Task Area 1, Task 1.d.

6. Under the direction of CSSI staff, develop, plan support, and oversee physical, chemical and biological assays required to support CSSI-sponsored studies.

B. Support grantees and other stakeholders in the initiatives of CSSI. It is anticipated that this support shall include tasks such as:

1. Assist in implementation of research plans. Activities include:

    a. Prepare draft documentation of the definitions and standards for review by CSSI and individual initiative committees, including review and assurance of standards adequate for data sharing among protocols.
    b. Draft clinical protocols and provide project management tools (*e.g.*, *via* Microsoft Project) for clinical protocols.
    c. Provide regulatory affairs support (see Task Area 1, Task 4).
    d. Provide quality assurance support (see Task Area 1, Task 5).
    e. Provide scientific and technical assistance for data analyses and documentation on clinical trials.
    f. Prepare draft manuscripts, PowerPoint presentations, news releases, *etc*. to assist in publication of the results of studies and research plans.
    g. Compiling and analyzing study data for use in drafting regulatory guidance and to support approval applications.

    Examples of specific tasks include preparation of a clinical development plan for a nano-based drug or drug delivery system; development and maintenance of specific clinical protocols and regulatory documentation (*e.g.*, IND, IDE, 510(k)) for the nano-based product in support of the clinical development plan or for proteomics assay; and assisting in preparation of briefing documents and data packages for FDA validation and qualification of proteomics assays.

2. Prepare draft manuscripts, news releases, PowerPoint presentations, *etc.* Assist in publication *via* a dedicated website, (Government, if available, contractor, if not) as well as by preparing draft presentations for relevant scientific and trade association meetings, articles in the scientific and trade association literature, and news releases directly to the public or *via* other interested parties. Ensure that the required Government clearances/approvals are obtained prior to starting work and/or releasing/publishing these items.

3. Perform literature/media research and prepare written summaries to keep CSSI and the individual initiatives abreast of complementary research initiatives, both in the U.S. and worldwide.

4. Perform administrative coordination activities for grantees and the individual initiatives. Maintain contact information for members; assist in planning business meetings and teleconferences; prepare agendas and minutes for same; maintain files of correspondence and other documentation as directed by CSSI.

Information Submission Instructions:

1. Page Limitations:

Interested qualified small business organizations should submit a tailored capability statement for this requirement not to exceed twenty (20) single sided pages including all attachments, resumes, charts, etc. (single spaced, 12 point font minimum) that clearly details the firm's ability to perform the aspects of the notice described above and in the draft SOW. Tailored capability 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 (preferably placed under the eligible small business concern's name and address) as well as the eligible small business concern's name, point of contact, address and DUNS number.

2. Number of Copies:

All capability Statements sent in response to this SMALL BUSINESS SOURCES SOUGHT notice must be submitted electronically (via e-mail) to C. Timothy Crilley, Contracting Officer, at tcrilley@mail.nih.gov or Contract Specialist, Kimberly Goetz, at goetzkm@mail.nih.gov in MS Word, WordPerfect or Adobe Portable Document Format (PDF). The e-mail subject line must specify HHS-NIH-NCI-SBSS-TSB-17007-04. Facsimile responses will not be accepted.

3. **Common Cut-off Date:**

Electronically submitted tailored capability statements are due no later than 2:00 PM (Eastern Prevailing Time) on February 28, 2011. ***CAPABILITY STATEMENTS RECEIVED AFTER THIS 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 this 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).