

## SOURCES SOUGHT NOTICE

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**Notice Number:** HHS-NIH-NCI-SBSS-TSB-67000-11

**Title:** "Preclinical Pharmacokinetic and Pharmacological Studies Being Developed for Cancer Patients."

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 HHSN261201100012C with SRI International, HHSN261201100013C with Southern Research Institute, HHSN261201100014C with Mayo Clinic, HHSN261201100015C with University of Pittsburgh, and HHSN261201100016C with University of California – San Francisco which were awarded on a competitive basis for a five year period. Freedom of Information Act (FOIA) requests regarding the current contract should be directed to Suzy Milliard at [milliards@mail.nih.gov](mailto:milliards@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 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 central mission of the National Cancer Institute (NCI) Experimental Therapeutics (NExT) Program is the discovery and development of agents with clinical anticancer activity. Pharmacokinetic and metabolism studies are an integral part of the drug development process from discovery to clinical trials. Characterization of the pharmacokinetics of new compounds provides critical information for the selection of optimal drug development candidates and design and interpretation of preclinical efficacy studies. Another essential relationship is the correlation between tumor pharmacodynamic modulation or preclinical toxicology data with drug exposures, e.g., plasma concentrations and/or area under the curve (AUC). Achievement of these goals

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depends heavily on the availability of sensitive methods for quantifying compounds in biological fluids and tissues/tumors and the careful integration of pharmacokinetic pharmacodynamics, and toxicology data. Developmental Therapeutic Program (DTP)/ Toxicology Pharmacology Branch (TPB) provide the expertise and resources needed to carry out pharmacokinetic evaluations of agents being investigated for efficacy in the NExT pipeline.

### **Purpose and Objectives:**

Independently and not as an agent of the Government, the Contractor will be asked to furnish all the necessary services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government, as needed to perform the draft Statement of Work available below, including the following Specific Tasks.

### **Project Requirements:**

#### Specific Tasks

1. Implement and validate appropriate analytical methodology that is sufficiently sensitive, specific, and reproducible for measurement and quantitation of assigned test agents (e.g., small molecule therapeutics and well-characterized biologicals) and metabolites in body fluids and/or tissues of animals and humans at therapeutic and/or toxic concentrations.
2. Conduct pharmacokinetic studies in animals (e.g., mice, rats, optionally larger animals) to support early lead and candidate drug characterization. Various routes of administration (e.g., intravenous, oral, intraperitoneal, subcutaneous, continuous infusion, etc.) may be utilized. Studies may include collection of multiple blood samples obtain plasma or serum and, in some studies, collection of urine, feces, and tissue and/or tumor samples.
3. Utilize analytical methods to determine concentrations of test agents in various matrices (cell extracts, media, plasma, urine, bile, saliva, tumors, and normal tissues) derived from:
  - (a) Pharmacokinetic studies conducted under item 2 above;
  - (b) Other Government-sponsored laboratories
4. Use state-of-the-art modeling software to fit concentration vs. time data (for plasma and possibly tissues) to suitable non-compartmental and/or compartmental pharmacokinetic models and calculate relevant pharmacokinetic parameters (e.g., half-life, volume of distribution, area under the curve, clearance, etc.) for a given agent and route of administration.
5. Calculate systemic bioavailability for various routes (e.g., oral, ip, sc) and determine if bioavailability is dose-dependent. Calculate mass-balance parameters if sufficient data is collected.

6. Determine the suitability of various formulations for the administration of test agents to animals by the desired route and at the desired dose level(s).
7. Conduct *in vitro* plasma protein binding and stability studies of test agents in biological fluids and tissues.
8. Conduct studies in tumor-bearing mice and collect plasma, tissue, and/or tumor samples for drug level determinations and analysis of specified pharmacodynamic endpoints.
9. Measure metabolites and/or degradation products of test agents present in blood, plasma, urine, and/or other fluids.
10. Characterize the plasma and tissue pharmacokinetics of major metabolites.
11. Store samples generated in-house or received from other laboratories under suitable conditions and ship samples to other laboratories upon request.

**Anticipated Period of Performance:**

The anticipated period of performance for this requirement is five years, consisting of a base period and optional quantities. The expected start date is July 1, 2016.

**Other Important Considerations:**

Draft Statement of Work:

A copy of the draft Statement of Work (SOW), which is subject to revisions, may be accessed on the NCI Office of Acquisitions Website at URL:

<http://ncioa.cancer.gov/oa-internet/>

Once there, click on Solicitations on the right hand side of the page. For your convenience the Draft Statement of Work is also attached.

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 15.0 million dollars is being considered.

**Capability Statement/Information Sought:**

1. A tailored Capability Statement is requested which demonstrates the ability of your organization to perform all tasks specified in the draft Statement of Work (SOW). Capability Statements must address all eleven (11) specific tasks referenced under Project Requirements : Implement and validate appropriate analytical methodology that is sufficiently sensitive, specific, and reproducible for measurement and quantitation of assigned test agents

2. Conduct pharmacokinetic studies in animals (e.g., mice, rats, optionally larger animals) to support early lead and candidate drug characterization.
3. Utilize analytical methods to determine concentrations of test agents in various matrices (cell extracts, media, plasma, urine, bile, saliva, tumors, and normal tissues) derived from:
  - (a) Pharmacokinetic studies conducted under item 2 above;
  - (b) Other Government-sponsored laboratories
4. Use state-of-the-art modeling software to fit concentration vs. time data (for plasma and possibly tissues) to suitable non-compartmental and/or compartmental pharmacokinetic models and calculate relevant pharmacokinetic parameters (e.g., half-life, volume of distribution, area under the curve, clearance, etc.) for a given agent and route of administration.
5. Calculate systemic bioavailability for various routes (e.g., oral, ip, sc) and determine if bioavailability is dose-dependent. Calculate mass-balance parameters if sufficient data is collected.
6. Determine the suitability of various formulations for the administration of test agents to animals by the desired route and at the desired dose level(s).
7. Conduct *in vitro* plasma protein binding and stability studies of test agents in biological fluids and tissues.
8. Conduce studies in tumor-bearing mice and collect plasma, tissue, and/or tumor samples for drug level determinations and analysis of specified pharmacodynamic endpoints.
9. Measure metabolites and/or degradation products of test agents present in blood, plasma, urine, and/or other fluids.
10. Characterize the plasma and tissue pharmacokinetics of major metabolites.
11. Store samples generated in-house or received from other laboratories under suitable conditions and ship samples to other laboratories upon request.

## **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

(preferable 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 Statement sent in response to this SOURCES SOUGHT notice must be submitted electronically (via e-mail) to Alexis Hudak, Contracting Officer, at [alexis.hudak@nih.gov](mailto:alexis.hudak@nih.gov) and Lynne Schneider, Contracting Officer, at [lynne.schneider@nih.gov](mailto:lynne.schneider@nih.gov) in MS Word, WordPerfect or Adobe Portable Document Format (PDF). The e-mail subject line must specify "HHS-NIH-NCI-SBSS-TSB-67000-11". Facsimile responses will not be accepted.

## 3. Common Cut-off Date:

Electronically submitted tailored capability statements are due no later than 2:00PM (Eastern Prevailing Time) October 16, 2015. ***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 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).