

March 26, 2007



## Request for Quote

# In Vitro Profiling Services for Pharmacologic, ADME, and Toxicologic Activities of Small Molecules

RFQ No: LD-032607

In support of:

The National Institute of Neurological Disorders and Stroke (NINDS)  
The SMA Project: A Collaborative Program to Accelerate Therapeutics  
Development for Spinal Muscular Atrophy (SMA)



*An SAIC-managed program to support the NINDS, National Institutes of Health,  
Department of Health and Human Services*

SAIC Prime Contract No.: N01-NS-3-2356



March 26, 2007

**TO ALL POTENTIAL OFFERORS**

**Subject: Request for Quotes for In Vitro Profiling Services for Pharmacologic, ADME and Toxicologic Activities of Small Molecules**

**Ref: Request for Quotes (RFQ) No: 032607**

To Whom It May Concern:

Science Applications International Corporation (SAIC) hereby solicits your firm's written offer, subject to the terms and conditions of the RFQ, to provide in vitro small molecule activity profiling services in accordance with the requirements set forth herein. (See Attachment 1 for specific Services Requested/Statement of Work, Attachment 2 for Pricing Form, and Attachment 3 for General Provisions of the RFQ.) Any subcontract resulting from this solicitation shall resemble the Subcontract Agreement (Attachments 4–12<sup>1</sup>), with the exception of appropriate modifications made at the time of award, including all applicable provisions required for flow-down by the prime contract and any provisions required by law on the date of execution of the Subcontract. The terms and conditions set forth or referenced herein shall apply and SAIC objects to and shall not be bound by any additional alternate terms and conditions proposed by the Offeror. The Offeror agrees, if an offer is accepted, to furnish any or all services for which the offer has submitted at the price(s) proposed and upon the terms and conditions contained in this RFQ, and the proposal shall be inclusive of all costs associated with performing the work or delivery the product, including profit.

**PROPOSAL DUE DATE:** Please submit your proposal, subject to the terms and conditions of this RFQ by 3:00 P.M. Eastern Time on **Thursday, April 5, 2007**.

**I. GENERAL INSTRUCTIONS AND INFORMATION**

1. Anticipated Type of Subcontract: Firm Fixed-Price Subcontract.
2. Anticipated Period of Performance: It is anticipated that the initial services will be performed and all data delivered between May 1, 2007 and September 25, 2007. In addition, two 1-year options to continue work beyond September 25, 2007 will also be included in the subcontract.
3. Technical Proposal: Offeror shall provide a technical proposal that outlines overall capabilities and details on each assay offered.
  - The description of overall capabilities should include standard compound handling practices, short-term compound storage capacity, analytic method development, data analyses and handling, GLP versus non-GLP capacity, and other information that is relevant to all assays.
  - For each assay proposed, the following should be provided: a general description of the assay, amount of compound required, assay conditions (including number of replicates and serial dilutions if appropriate), data analysis, frequency assay has been run over past year; capacity in number of compounds per run; schedule from request through data delivery. Assays may be offered independently or as part of a panel of assays. See Attachment 1 for an exemplary, non-inclusive list of assays.

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<sup>1</sup> Attachments 1 – 3 are included with the body of the RFQ; Attachments 4–12 are available on the SMA Project Solicitations page at <http://www.smaproject.org/solicitations.html> .

- In addition to the list of SMA Project assays listed in Attachment 1, Offerors may also propose additional optional assay services. Offerors may list any additional assays they provide; however, cost and full descriptions are not required for optional assays.

While there are no page limits on the technical proposal, Offerors are encouraged to be as concise as possible in their descriptions.

4. Pricing Requirements (Attachment 2): All pricing shall be firm fixed price. Offeror may either (1) complete the pricing schedule provided in this request as Attachment 2 or (2) use their own format and provide all information requested in Attachment 2. Offerors must provide complete pricing for the services requested. Services requested are summarized in Attachment 1. Offerors are not required to provide pricing on all optional services.
5. RFQ/P General Provisions (Attachment 3): General provisions contains additional information to assist offerors in the preparation of their offers.
6. Subcontract Agreement (Attachments 4–7): These documents must be read and completed as necessary. Signatures are required on the final page of Schedule A. In addition, if negotiations are initiated with an Offeror, additional documents will need to be submitted to support Schedule B.
7. Annual Master Certification (AMC)/Part E, Section I (Attachment 8): The AMC, also known as Representations and Certifications, are to be completed by the Offeror as required by the Federal Acquisition Regulations. These certifications and representations must be completed prior to any award decision. Failure of the Offeror to provide completed representations and certifications may deem the Offeror non-responsive to this RFQ.
8. Vendor Questionnaire (Attachment 9): The Offeror must complete the attached vendor questionnaire to demonstrate financial viability and satisfactory performance as it relates to the requested product.
9. Vendor Master Data Template (Attachments 10 and 11): The Offeror must complete this form to allow SAIC to enter their company information into our national vendor database. Award cannot be made unless this form is completed. If you are currently doing business with SAIC, you do not have to complete this form unless your business information has changed.
10. U.S. Government Property Questionnaire (Attachment 12). Please complete form as part of your proposal.
11. Points of Contact:  
 Technical: Dr. Catherine Kappel Hall 301-698-5991  
 Contractual: Lynne Darby 301-698-7459
12. *You are requested to submit 1 electronic copy of your written offer, complying with the requirements set forth herein.*

The offer should include a cover or a letter with signatures of both the Project Manager/Principal Investigator and Business Representative.

Offers should be submitted via e-mail or on disk to:

Science Applications International Corporation  
 Attn: Lynne Darby  
 5340 Spectrum Drive, Suite N  
 Frederick, MD 21703-7357  
 Tel: 301-698-7459  
 Fax: 301-698-7437  
 darbylm@saic.com

Signatures on the cover page/letter and Schedule A can be submitted electronically or via fax to Lynne Darby at 301-698-6188 by the deadline stated above.

Offerors may submit a paper copy of the proposal via overnight carrier, to the address listed above. This duplicate will only be used to confirm quality of the print version of the proposal submitted on time via e-mail.

## **II. SPECIAL INSTRUCTIONS AND INFORMATION**

1. SAIC reserves the right under all circumstances to select and award to the Offeror, in whole or in part, any portion of this project, which is in the best interest of SAIC.
2. The Offeror is encouraged to contact the SAIC Contract Representative with any questions regarding this RFQ:
  - The Offeror is to furnish to SAIC all information required by this RFQ.
  - The individual authorized to submit the offer must initial erasures or changes to a proposal.
  - The individual submitting the offer must have the authority to contractually bind the Offeror.
3. Qualifications of Prospective Offer: The Offeror must have a site within the continental United States, have adequate resources to perform any resulting subcontract in accordance with the terms and conditions of this RFQ, and upon request furnish proof of the same. The SAIC Contract Representative may request verification of the Offeror's financial status, cost data related to the bid, verification of insurance, anticipated project scheduling, and/or any other pertinent data needed to establish the responsibility of the Offeror.
4. Evaluation of Offerors: Award of any subcontract resulting from this RFQ will be based upon the following factors: (1) an SAIC evaluation of the responsiveness of the Offeror to the requirements of this RFQ, (2) the price reasonableness of the Offeror's proposal, (3) the ability of the Offeror to provide the required services (4) the Offeror's experience and record of past performance with these services, (5) the Offeror's financial viability, and (6) what is determined to be in the best interest of the SMA Project.
5. Offer, Acceptance, and Award:
  - SAIC may accept any offer regardless of whether there are negotiations conducted subsequent to its receipt. Any such negotiations shall not constitute a rejection or counteroffer on the part of SAIC.
  - SAIC reserves the right to reject the offer, to waive minor informalities in offers, and/or to conduct further negotiations with Offeror.
  - SAIC assumes no responsibility for any promise or representation, either oral or written, that a subcontract award will be made, unless done so by the SAIC Contract Representative and only when an SAIC Pro-Forma Subcontract of the type incorporated in this RFQ is executed with the Offeror.
6. Inconsistencies: In the event of an inconsistency between the terms and conditions of the RFQ, the inconsistency shall be resolved by giving precedence in the following order: (1) RFQ General Instructions and Information, (2) RFQ Special Instructions and Information, (3) SAIC RFQ General Provisions (attached), (4) SAIC Pro-Forma Subcontract Schedule A (attached), and (5) any Prime Contract flow-down clauses, if applicable. The technical terms and conditions associated with this RFQ shall be governed by the attached specifications.
7. Preparation and Submission Costs: Please be advised that this RFQ does not commit SAIC to pay any costs associated with the Offeror's preparation and submission of its proposal and that the SAIC

Contract Representative referenced earlier is the only individual legally authorized to contractually bind SAIC for this solicitation. This is not an authorization to proceed with the work referenced herein.

8. Right of Denial or Termination of Services: SAIC reserves the right to deny the services of an employee due to inadequate qualifications and/or to terminate an employee's efforts with SAIC due to poor work performance. SAIC will notify the Offeror of service denial or termination and will require an acceptable replacement within a reasonable period of time from the date of SAIC's notification.
9. Complete Offers: To form a complete offer, the Offeror is required to return completed Attachment 2 (Pricing Form), Technical Requirements, Representations and Certifications, Vendor Questionnaire, and the completed Vendor Master Data Template (if not previously submitted). **The Offeror's proposal must be valid for a minimum of 180 calendar days.**

Respectfully,

Lynne Darby  
Subcontract Administrator

ATTACHMENTS:<sup>2</sup>

1. Services Requested/Statement of Work (1 page)
2. Pricing Form (2 pages)
3. RFQ/P General Provisions (3 pages)
4. Subcontract Agreement – Schedule A, Firm Fixed Price (8 pages)
5. Subcontract Agreement – Schedule B Part I, U.S. Government Terms and Conditions/ FAR Clauses (5 pages)
6. Subcontract Agreement – Schedule B Part II, National Institutes of Health, Special Requirements/Contract Clauses – Prime Contract No. N01-NS-3-2356 (9 pages)
7. Subcontract Agreement – Schedule B Part III, National Institutes of Health, Reporting Requirements – Prime Contract No. N01-NS-3-2356 (3 pages)
8. Annual Master Certification (AMC)/Part E, Section I (12 pages)
9. Vendor Questionnaire (2 pages)
10. Vendor Master Data Template Instructions (1 page)
11. Vendor Master Data Template Form (1 page)
12. U.S. Government Property Questionnaire (2 pages)

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<sup>2</sup> Attachments 1 – 3 are included with the body of the RFQ; Attachments 4–12 are available on the SMA Project Solicitations page at <http://www.smaproject.org/solicitations.html>.

# ATTACHMENT 1

## SERVICES REQUESTED/STATEMENT OF WORK

### IN VITRO PROFILING SERVICES FOR PHARMACOLOGIC, ADME, AND TOXICOLOGIC ACTIVITIES OF SMALL MOLECULES

Seller shall provide all labor, tools, materials, and other resources necessary to provide in vitro bioactivity profiling services for the Spinal Muscular Atrophy Project. The services will support the preclinical development of small molecule chemical entities. For additional information on this development effort, see the SMA Project web site at <http://smaproject.org>.

The SMA Project requires broad profiles of the pharmacologic, ADME, and toxicologic activities of small molecules to inform the selection and characterization of candidate compounds for clinical testing. We seek services from commercial organizations that specialize in conducting inclusive panels of biological assays. Assay panels should encompass a sufficient range of assays to predict the span of known pharmacological and/or toxicological and/or ADME activities. Assay panels and assays proposed in response to this RFQ must be in routine use and currently operational at the Offeror's site.

- **Pharmacologic Profiling** is required to evaluate the activity of compounds against a broad array of cellular targets. Assays should include, but are not limited to, receptors, ion channels, transporters, enzymes, and second messengers.
- **ADME Profiling** is required to predict and evaluate the results of in vivo testing. Assays should include, but are not limited to, in vitro measures of permeability, solubility, intestinal and hepatic metabolism, and protein binding.
- **Toxicologic Profiling** is required to predict potential in vivo toxicities. Available assays should evaluate activities that include, but are not limited to, P450 (CYP) enzyme induction, metabolic activation, CYP inhibition, and the potential for cardiotoxicity, lipidosis, endocrine interactions, and other toxicities.

#### SMA Project Required Services

Offerors must be able to provide assay panels and individual assays to support profiling of pharmacologic and/or ADME and/or toxicologic activities. Offerors must also provide the necessary analytic method development to support these assays. Assays may be proposed as a single package/panel and as individual assays. Specific assays and measurements that the SMA Project might utilize include, but are not limited to:

- AMES test
- Blood brain barrier penetration
- Brush-border membrane vesicle uptake
- Caco-2 permeability
- Cell proliferation
- CYP induction and/or inhibition
- hERG interaction
- Ionizability (pKa)
- Lipophilicity
- Liver microsomes
- MDCK-MDR1
- Membrane integrity
- Micronucleus in CHO-K1
- Mitochondrial function
- Plasma protein binding
- Plasma stability
- S9 metabolism
- Solubility

#### Additional/Optional SMA Project Services

The above list of assays and measurements is not comprehensive. Offerors may list all additional assays with which they have experience and currently provide; however, they are not required to provide cost and full descriptions for assays beyond those that support broad profiling of pharmacologic and/or ADME and/or toxicologic activities.

## ATTACHMENT 2

### PRICING FORM

#### IN VITRO PROFILING SERVICES FOR PHARMACOLOGIC, ADME, AND TOXICOLOGIC ACTIVITIES OF SMALL MOLECULES

All Offerors must fill out the accompanying Price Chart or provide all information requested in a single table/form.

**All costs except analytic method development must be factored into the prices entered below. For example, any per-batch processing fees, labor costs, etc. must be included in the unit prices quoted.**

Analytic method development should be priced as follows:

1. If method development is performed independent of running an assay, a separate line item should be included as an “assay.”
2. Each assay should indicate if analytic method development is included in the cost.
3. In some instances, costs may be provided for the same assay with and without method development. For example, if methods were developed for human microsome assays and at a later date mouse microsomes were requested, LC/MS method development would be required for one but not both assays.

Offerors are not required to provide prices for all source species or for additional species.

#### Sample Pricing Chart (See next page for actual chart)

Assay Name or Panel Name (Assays should be clearly labeled to correspond with the technical proposal.)	Batch Size (e.g., 1-2 and 5-20)	Method Development Costs Included (Yes/No)	Cost (Indicate if cost is provided per batch or per compound in indicated batch size)	Comments (e.g., schedule, other discounts, and GLP vs. non-GLP)
Mini-Ames	1-3	Yes	\$X/cmpd	
	4-10	Yes	\$Y/cmpd	
	10-20	Yes	\$Z/cmpd	Each additional compound over 40 is \$x



**ATTACHMENT 3**  
**REQUEST FOR QUOTATION (RFQ)**  
**GENERAL PROVISIONS**

**1. PREPARATION OF OFFERS**

- a. All information shall be in ink or typewritten. Mistakes may be crossed out and corrections inserted before submission of your offer. The person signing the offer shall initial corrections in ink.
- b. An authorized officer of the offeror shall sign all offers.
- c. All offers shall include the request number shown.

**2. LATE OFFERS**

Formal offers, amendments, or requests for withdrawal of offers received after the date specified for submittal may not be considered.

**3. ALTERNATE PROPOSALS**

In addition to the offer solicited herein, the Offeror is invited to submit an alternate proposal, which may be advantageous to SAIC.

**4. COMPLETENESS**

All information required by RFQ must be supplied to constitute a responsive bid. Non-responsive offers may not be considered.

**5. BRAND NAMES**

- a. Brand names and numbers, when used, are for reference to indicate the performance or quality desired.
- b. Equal items will be considered provided that the Offeror describes the article. Offers for equal items shall state the brand and number, or level of quality. The determination of the Buyer as to what items are equal shall be final and conclusive.
- c. When brand, number, or level of quality is not stated by the Offeror, it is understood the offer is exactly as specified.

**6. NET PRICES**

Offered prices, unless otherwise specified, must be net, including transportation and handling charges, which shall be set forth as a separate line item on quotation/proposal and fully prepaid by the contractor to destination and subject only to cash discount for prompt payment of invoices.

**7. EVALUATION**

Science Applications International Corporation reserves the right: (1) to award on the basis of individual items, or groups of items, or on the entire list of items; (2) to reject any or all offers, or any part thereof; (3) to waive any informality in the offers; and (4) to accept the offer that is in the best interest of Science Applications International Corporation. The Buyer's decision shall be final.

**8. NO BID**

In the event you cannot submit an offer on our requirements, as set forth in the RFQ, provide an explanation as to why you are unable to bid on these requirements.

**9. TAXES**

SAIC may be exempt from the payment of any federal excise or any state sales tax. The price offered must be net, exclusive of taxes. However, when under established trade practice, any federal excise tax is

included in the list price, Offeror may quote the list price and shall show separately the amount of federal tax, either as a flat sum or as a percentage of the list price, which shall be deducted by SAIC.

#### **10. AWARD(S)**

The contract(s) will be awarded to the lowest responsible and responsive Offeror(s) complying with all the provisions of the RFQ, provided the offered price is reasonable and is in the best interest of SAIC. The Buyer reserves the right to reject the offer of an Offeror who has previously failed to perform properly, or complete on time, contracts of similar nature, or the offer of an Offeror who, under investigation shows is not in position to perform the contract.

#### **11. ACCEPTANCE**

A written award mailed (or otherwise furnished) to the successful Offeror shall be deemed to result in a binding contract without further action by either party.

#### **12. SERVICE LIFE**

When applicable, all Offerors will state their company policy regarding the return of defective and unserviceable items or products as well as the minimum service life of the offered item or product.

#### **13. COMPLIANCE**

When applicable, delivery must be made as ordered and in accordance with the offer or as directed by the Buyer when not in conflict with the offer. The decision of the Buyer as to reasonable compliance with delivery terms shall be final. The burden of proof of delay in receipt of goods by the Buyer shall rest with the Seller.

Any request for extension of time of delivery from that specified must be approved by the Buyer, such extension applying only to the particular item or shipment affected.

#### **14. DELIVERY**

When applicable, all shipments are to be made F.O.B. to a specific destination as specified, or prepaid. Collect shipments only can be accepted with proper advance notification and only with specific approval from the Buyer.

#### **15. PACKING SLIPS OR DELIVERY TICKETS**

When applicable, all shipments or deliveries shall be accompanied by Packing Slips or Delivery Tickets in triplicate and shall contain the following information for each item delivered:

- Purchase Order Number
- Item Number
- Description or Part Number
- Quantity Ordered
- Quantity Shipped
- Name of the Supplier

The above requirement is extremely important when accepting shipments. Offerors are cautioned that failure to comply with these conditions shall be considered sufficient reason for refusal to accept the goods.

#### **16. LIABILITY**

The Contractor shall hold Science Applications International Corporation, its officers, agents, servants, and employees, harmless from liability of any nature or kind because of use of any copyrighted or uncopied compositions, secret process or patented or unpatented invention; for articles or appliances furnished or used under this bid and agrees to defend, at his own expenses, any and all actions brought

against Science Applications International Corporation, or itself, because of the unauthorized use of such articles.

## 17. GENERAL

Any Purchase Order or Subcontract issued as a result of this RFQ is subject to SAIC Terms and Conditions regardless of Offeror's terms and conditions submitted with the proposal. Specific exceptions are to be noted as part of Offeror's proposal and if incorporated into Buyer's Purchase Order or subcontract will become binding on the parties.

## 18. TERMS and CONDITIONS

This prospective order is subject to the following attachments as checked:

- SAIC Purchase Order Standard Terms and Conditions
- SAIC Terms and Conditions for Commercial Items (Government)
- SAIC Schedule A Subcontract Specific Terms and Conditions
- SAIC Schedule B Part I U.S. Government Terms and Conditions
- SAIC Schedule B Part II, NIH/HHS (Agency)
- SAIC Schedule B Part III, NIH Reporting Requirements

If a U.S. Government Contract is indicated, you are required to follow the provisions of DPAS 15 CFR 700 and all other applicable regulations and orders of the U.S. Department of Commerce in obtaining products, materials, and services needed to fill this order. This order is certified for national defense under DPAS, if a rating is shown.

U.S. Government Contract:

No. N01-NS-3-2356

DPAS Rating: N/A

## 19. GRATUITIES

By acknowledgment of response to this RFQ, the Offeror hereby certifies that no gratuities were offered by the supplier or solicited by any SAIC employee either directly or indirectly. Any situation where a gratuity is solicited should be reported immediately to the Director, Corporate Procurement.

## 20. BID SECURITY

The following bid security (if any) is applicable as outlined below:

## 21. VALIDITY PERIOD

The Offeror's offer shall remain valid for a period of **180 calendar days** from the SAIC due date (or other period of time as mutually agreed upon in writing by the parties).