

November 25, 2003

Request for Proposals

for

An Inducible Mouse Model of Spinal Muscular Atrophy



**In support of:
The National Institute of Neurological Disorders and Stroke (NINDS)
Collaborative Program to Accelerate Therapeutics Development for
Spinal Muscular Atrophy**

**RFP No: JL-32903-001
SAIC Prime Contract No.: N01-NS-3-2356**

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



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1. Introduction

The [National Institute for Neurological Disorders and Stroke](http://www.ninds.nih.gov) (NINDS) launched the Collaborative Program to Accelerate Therapeutics Development for Spinal Muscular Atrophy (SMA) in September 2003. This program will fund research aimed at identifying a treatment for SMA, a paralyzing neurodegenerative disease of childhood and implement a plan for rapid SMA therapeutics development through the strategic support of research projects. For more information about the program, visit the SMA Project website at <http://www.smaproject.org>.

1.1 Spinal Muscular Atrophy

SMA, the most common hereditary cause of infant death, is caused by the loss of function of a single gene, *SMN1*, which results in the death of motor neurons. This defined target suggests tractable strategies for therapeutics development. SMA is a progressive disease with varying severity ranging from infantile paralysis and death to more limited motor neuron loss and normal life expectancy. All SMA patients carry a mutation in the *SMN1* gene. A second gene, *SMN2*, produces low levels of functional SMN protein and is present in varying copy number. The severity of the disease correlates to a large extent with the number of copies of *SMN2*, indicating that increasing levels of *SMN* can result in an improved clinical outcome.

This solicitation for proposals to develop and characterize a temporally regulatable mouse model of SMA is aimed at determining when *SMN* function is necessary for proper motor neuron function and survival. This information will be critical to the success of a therapeutic approach based on restoring or bypassing *SMN* function.

1.2 Current Animal Models of SMA

A number of mouse models of SMA currently exist. Unlike humans, normal mice carry only a single *SMN* gene, and a knockout mutation in this gene is lethal in early embryogenesis. *SMN* knockout mice that carry the human *SMN2* transgene exhibit a phenotype resembling human SMA, with postnatal loss of motor neurons and premature death. Furthermore, varying the *SMN2* copy number results in variable phenotypic severity. However, the available transgenic genotypes result in quite severe phenotypes and early death. For example, mice with a phenotype resembling the infantile form of SMA die at 6-8 days. This research demonstrates that the phenotype depends on the level of *SMN* in motor neurons and suggests that the mouse can provide a useful model for testing therapeutic strategies based on increasing *SMN*.

Recent data from zebrafish suggest, however, that high-level *SMN* function is required in embryogenesis for mature motor neuron survival since knockdown of *SMN* function during embryogenesis results in defects in axonal morphology and pathfinding. It is not yet known whether similar developmental errors affect motor neurons in the mouse SMA model or in human SMA, but the zebrafish observations raise the possibility that a developmental requirement for *SMN* function results in postnatal motor neuron dysfunction and death. This has important implications for the design of a treatment for SMA.

This solicitation is aimed at determining when *SMN* function is necessary for proper motor neuron function and survival. It is hoped that such a mouse may also display a phenotype that is amenable to therapeutic testing in the mature animal.

Selected References:

- Monani et al. 2001. *Human Molecular Genetics* 9(16):2451-2457.
McWhorter et al. 2003. *Journal of Cell Biology* 162(5):919-931.

2. Solicitation Focus and Time Line

2.1 Focus of This Solicitation

Pre-Proposals are requested for the development and characterization of a mouse model of SMA that can be used to determine (1) the window of requirement for *SMN* function in the animal and (2) the stage when increasing *SMN* function can alter disease progression. In addition, we are soliciting an inducible mouse model of SMA that will be amenable to testing candidate therapies for SMA. These goals may be achieved with the development of a mouse that can be induced to express *SMN* through a continuously regulatable promoter. Alternatively, a useful model may be produced using a stage-specific and irreversible method for turning *SMN* on or off, such as a Cre/loxP recombination strategy. Characterization of an existing temporally regulatable mouse model of SMA can also be supported under this solicitation.

Models are sought that can be used to:

- Determine the stage at which high-level *SMN* is required for normal motor neuron survival and function.
- Determine the stage at which restoring *SMN* can alter disease progression.
- Test candidate therapies in postweaning animals.
- Test candidate therapies that target the human *SMN2* gene.

Models should have the following characteristics:

- Motor neuron disease phenotype produced by uniformly low levels of full-length *SMN1* in motor neurons, similar to the human condition.
- Temporally controlled removal and/or restoration of *SMN* function, pre- and post-natally.
- Potential to achieve levels of pre- and postnatal *SMN* function likely to produce a normal mouse.
- Ability to track expression of transgenes via a reporter such as luciferase.

Information derived from these models will be critical for the success of a therapeutic approach based on restoring *SMN* function. Of note, models produced under this program will be made freely available to the scientific community and will be used in further research supported by the program to identify a treatment for SMA.

2.2 Time Line for This Solicitation

Key dates related to this RFP are as follows:

- | | |
|---|---------------------------------|
| • 2-page Pre-Proposals Due | December 23, 2003 |
| • Invitation to Submit Full Proposal | ~January 6, 2004 |
| • Full 10-page Proposals Due | ~February 3, 2004 ¹ |
| • Supporting Documentation for Subcontracts Due | ~February 10, 2004 ² |
| • Peer Review of Full Proposals | ~ February 12-13, 2004 |
| • Notification of Award Status | ~ February 17, 2004 |
| • Anticipated Start Date | ~ March 15, 2004 |

¹ Exact date to be provided in invitation letter.

² Proposals will NOT be considered further if supporting documentation has not been received by this date.

3. Proposal Preparation Procedures

NOTE: Before preparing a pre-proposal, offerors should read over this entire document and visit the SMA Project website (<http://www.smaproject.org>) to learn more about the program and the nature of subcontracts and task orders. Offerors should also review the Subcontract Agreement and the Representations and Certifications document when they are posted on the SMA Project website (expected in mid-December 2003).

3.1 Overview

The proposal preparation procedure has been designed to accelerate the time from solicitation to award. There are three submission deadlines for offerors that correspond to the submission of pre-proposals, full proposals, and supporting documentation for subcontracts.

- Pre-Proposals: Approximately 4 weeks after the release of an RFP, offerors are requested to submit 2-page pre-proposals that respond to the aims of the solicitation (see sections 2.1 and 3.2). Pre-proposals will be reviewed to determine which submissions best meet the intent of the solicitation.
- Full Proposals: Offerors whose pre-proposals are deemed most responsive to the solicitation will be invited to submit full 10-page proposals (see section 3.3); offerors will have approximately 4 weeks to prepare this technical proposal.
- Supporting Documentation: Additional supporting documentation for subcontracts will be due 1 week after full proposals are due (see section 3.4). However, the offeror may elect to submit the supporting documentation at the deadline for the full proposal.

Do NOT submit a full proposal or supporting documentation unless you receive a letter of invitation.

3.2 Pre-Proposals

3.2.1 Preparation of Pre-Proposals

The pre-proposal consists of a Pre-Proposal Submission Form (available on the SMA Project website) and an electronic file containing (1) the 2-page body of the pre-proposal, (2) up to 1 page of references, and (3) up to 3 biographical sketches. Please follow the instructions provided on the Pre-Proposal Submission Form.

3.2.2 Submission of Pre-Proposals

To submit a pre-proposal, the Contracting Officer (the individual at the offering institution who is authorized to conduct subcontract negotiations and contractually bind the offer) must send an **e-mail** to Jonathan Logan at jonathan.h.logan@saic.com by **5:00 p.m. Eastern Time (ET) on December 23, 2003** with the following electronic files attached:

- A copy of the Pre-Proposal Submission Form.
- A file containing (1) the 2-page body of the pre-proposal, (2) up to 1 page of references, and (3) up to 3 biographical sketches (see Pre-Proposal Submission Form for details).

In addition, offerors must print the completed Pre-Proposal Submission Form, have the Principal Investigator (PI) and Contracting Officer sign it in the appropriate places, and **fax the signed form to Jonathan Logan at 301-698-6188** by the deadline stated above. Offerors experiencing difficulty with the electronic submission procedure should contact Adam Book at 301-228-3114 or send an e-mail to smaproject-fd@saic.com.

3.3 Full Proposals

Full proposals should only be submitted if the offeror receives an invitation. Offerors must complete sections 3.3.1 – 3.3.9 and section 3.4.

3.3.1 Proposal Face Page

The Face Page must include items 1-9 from the Pre-Proposal Submission Form. In addition, please notate the following in a header on the Face Page:

- Response to JL-32903-001.
- Log number of your pre-proposal (this number can be found in your e-mail invitation to submit a full proposal).

3.3.2 Proposal Abstract and Body

There is a **10-page limit** inclusive of the Proposal abstract and any figures, tables, and graphs.

Proposal Abstract

Provide a brief summary of the proposal. Proprietary information should not be included in abstracts since abstracts for funded proposals will be posted on the SMA Project website.

Proposal Body

The body of the proposal should contain the following elements:

- Background information.
- Objectives/goals of the project.
- Relevance: Describe how the proposed work relates to the aims of this solicitation (as detailed in section 2.1).
- Research strategy: Provide details about the experimental study design and methodology (include information on reagents, cell lines, and animals to be used in the study).
- Milestones: Identify performance milestones to be used in the evaluation process and describe how they will be achieved. Milestones should be descriptions of outcomes not just completion of tasks (e.g., generating embryonic stem cell lines is not a milestone, but determining that the generated embryonic stem cell lines have the desired genotype is a milestone). **The feasibility and appropriateness of the milestones will be subject to peer review as the timely meeting of milestones will be the basis for continued funding during the period of performance of the subcontract.** For more information on performance milestones, see <http://www.smaproject.org/about/milestone.htm>.
- Facilities/resources: Specify the facilities (laboratory, clinical, etc.) to be used for the conduct of the proposed research. If there are multiple performance sites, then resources available at each site should be described.

General Format Specifications

The following format instructions must be followed when preparing the abstract and body of the proposal **or the application may be returned without review**. Prepare the documents single-sided. The proposal should not be stapled or otherwise bound. The documents must be clear, readily legible, and conform to the following requirements:

- Type font: Must be 10 point or larger (suggested font = 11-point Arial).
- Type density: Must not be more than 15 characters per inch (cpi) including spaces. For proportional spacing, the average for any representative section of text must not be more than 15 cpi or 114 characters per line.
- Spacing: Single-spaced; must not be more than 6 lines of type within a vertical inch.
- Margins: Must be a minimum of ½ inch in all directions.

Charts, tables, figures, figure legends, and footnotes may be smaller in size but must be readily legible. Do not use photo reduction. Prepare all graphs, tables, diagrams, and charts in black ink. The application must contain only material that reproduces well when photocopied or printed in black and white since some reviewers may only receive a printed version. Do not use Internet website addresses to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that directly accessing an Internet site could compromise their anonymity.

3.3.3 References

One-page limit. List relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of article, publication, volume, chapter, page numbers, and publisher, as appropriate).

3.3.4 Project Time Line

One-page limit. Present a detailed time line for the length of the subcontract with specific performance milestones. Time lines should be as efficient/short as possible. For a sample time line, see the SMA Project website.

3.3.5 Proposed Budget/Pricing Information

No page limit. Offerors should provide pricing information using the forms provided on the SMA Project website. The Summary of Labor and Direct Costs form must be submitted with the full proposal; this form will be forwarded to peer review. The Summary of Annual Costs must be submitted with the Supporting Documentation (see section 3.4); this form will not be forwarded to peer review. To access these forms, see the SMA Project website.

Offerors may be requested to provide additional information as necessary to make a proper determination of price in accordance with FAR Part 15.404 (<http://www.arnet.gov>). Failure to provide the additional information upon request may deem an offeror to be nonresponsive.

3.3.6 Biographical Sketches

Four-page limit for each biosketch; unlimited number of biosketches allowed. Include a biosketch for key personnel, including the PI. The National Institutes of Health's biosketch form (<http://grants1.nih.gov/grants/funding/phs398/biosketch.pdf>) can be used. Required elements of a biographical sketch are presented in Item 12 on the Pre-Proposal Submission Form.

3.3.7 Publication and/or Patent Information

Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent application abstract should provide a nonproprietary description of the patent application.

3.3.8 Letters of Support

No page limit. Provide letters of support from any collaborating individuals. Include letters of support documenting availability and quality control for all critical reagents.

3.3.9 Submission of Proposals

Six identical copies of the full proposal, complying with the requirements described in this RFP, must be submitted via **mail** or **overnight carrier** and received by **5:00 p.m. ET** on or about **February 3, 2004** (exact date to be provided in offeror's invitation letter):

Science Applications International Corporation (SAIC)
Attn: Jonathan Logan
5340 Spectrum Drive, Suite N
Frederick, MD 21703-7357
Phone: 301-228-3149

3.4 Supporting Documentation

3.4.1 Preparation of Supporting Documentation

Offerors invited to submit full proposals must also send in the following supporting documentation:

- **Subcontract Agreement** – to be available on the SMA Project website in mid-December. When completing this document, pay particular attention to the Contract Clauses in Schedule B, Part II. This section contains numerous items pertinent to laboratory research (e.g., Animal Welfare Assurance, Continued Ban on Funding of Human Embryo Research, Recombinant DNA and Human Gene Transfer Research, and Research Misconduct).
- **Representations and Certifications** – to be available on the SMA Project website in mid-December.

3.4.2 Submission of Supporting Documentation

Two identical copies of the supporting documentation outlined above are due 1 week after the full proposal submission deadline. This documentation is to be sent via **mail** or **overnight carrier** to SAIC at the address listed in section 3.3.9. **Note: Proposals will not be considered further if these documents are not received by this date.**

4. Review Procedures

4.1 General Information

Award of any subcontract resulting from this RFP will be based on evaluation of full proposals against the review criteria with assigned weights as outlined in section 4.3.2.

4.2 Pre-Proposals

Pre-proposals will be evaluated for appropriateness to this solicitation's aims (as described in section 2.1) by the SMA Program Steering Committee.

4.3 Full Proposals

4.3.1 Proposal Review Process

An independent peer review panel composed of scientists with appropriate expertise will evaluate the full proposals. Each proposal will be assigned a primary and secondary reviewer. Members of the SMA Steering Committee may serve in an advisory role during peer review but

will not be voting members of the peer review panel. Steering Committee members will use peer reviewers' evaluations when deciding which proposals to recommend to the NINDS and SAIC for funding. Offerors should be prepared to be available by telephone during the peer review meeting to answer questions pertaining to their proposal; details of this procedure will be provided to offerors after the pre-proposal submission deadline.

Upon completion of peer review, recommendations for awards will be forwarded to the NINDS for approval. Funding of subcontracts will be based on the approved annual appropriation of funds. Multiple-year contracts shall be incrementally funded based on the prime contractor's annual increment received under the contract.

4.3.2 Proposal Review Criteria

Peer reviewers will evaluate proposals against the review criteria listed below. The relative importance of these criteria is indicated by the assigned point weights. The maximum total score possible is **100 points**.

Understanding the Requirements of This Solicitation (75 points total):

- **Relevance (30 points)** – How relevant is the proposed research to the aims of this solicitation (as detailed in section 2.1)? Will the proposed animal model aid in determining when *SMN* function is needed for proper motor neuron function and survival and/or be amenable for testing candidate therapies for SMA? Overall, is the proposed research likely to yield a useful animal model of SMA?
- **Research Strategy (30 points)** – Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Is the research well conceived and scientifically sound? How feasible is the proposed technology/approach for controlling *SMN* expression?
- **Milestones/Timeline (15 points)** – Are the performance milestones well described? Are they descriptions of outcomes and not just descriptions of tasks? Do the milestones provide a defined measure of both positive and negative outcomes? Is the project time line reasonable for the research proposed and as efficient/short as possible?

Qualifications of Personnel and Environment (25 points total):

- **Qualifications of PI and Key Personnel (15 points)** – Do the investigators (including the PI) have a record of achievement in the development and/or characterization of animal models? Are appropriate personnel available to successfully complete the proposed research within the subcontract period? Have the PI and other key personnel committed a sufficient level of effort to ensure the success of this project? Are conflicts-of-interest and commercial interests adequately identified and justified (if applicable)?
- **Environment and Facilities (10 points)** – Is the scientific environment in which the work will be performed appropriate for the proposed research and does it contribute to the probability of success? Does the offeror have the necessary facilities/equipment for the conduct of the proposed research?

In addition to the review criteria listed above, peer reviewers will consider the appropriateness of the **budget/pricing information** supplied by the offeror. The estimated cost of a proposal must be reasonable for the work to be performed.

5. Additional Information for Offerors

5.1 General Information

The offeror is to furnish all information required by this RFP to SAIC. Any erasures or changes to a proposal must be initialed by an individual authorized to submit the offer, on behalf of the offeror. The individual submitting the offer must have the authority to contractually bind the offer.

This RFP does not commit SAIC to pay any costs associated with the offeror's preparation and submission of its proposal. The SAIC Subcontracts Representative 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.

5.2 Contact Information

For technical questions regarding this RFP, please contact Adam Book at 301-228-3114. For contractual questions related to this RFP, please contact Jonathan Logan at 301-228-3149. Alternatively, technical or contractual questions can be e-mailed to smaproject-fd@saic.com.

5.3 Progress Monitoring of Awards

Progress on each subcontract and task order will be monitored. Offerors who receive funding will be asked to submit monthly reports covering progress toward the completion of each performance milestone. Progress monitoring will be conducted by doctoral-level scientists, regulatory affairs specialists, and project control specialists deriving from SAIC's professional staff. As needed, SMA Project Steering Committee members will also review progress reports. Offerors should note that the timely meeting of milestones will be the basis for continued funding during the period of performance of the subcontract. For more information on reporting requirements, progress monitoring, and the differences between grants and subcontracts, please see <http://www.smaproject.org/about/aboutindex.htm> and review the reporting requirements outlined in the Subcontract Agreement.

5.4 Data Sharing

As the title suggests, the SMA Program is intended as a **collaborative program**. Collaboration is deemed essential for being able to identify and rapidly complete preclinical development of the SMA therapeutics that are most likely to be safe, effective, and approved for clinical use by the U.S. Food and Drug Administration. To facilitate data sharing and the generation of new ideas, funded investigators will be required to participate in quarterly investigator teleconferences and meetings in which recent research results will be presented and discussed with other funded investigators and the scientific and regulatory affairs staff from the contractor organization (each quarter), as well as the SMA Program Steering Committee and NINDS officials (every other quarter). For more information on data sharing, please see <http://www.smaproject.org/about/aboutindex.htm>.

To ensure that intellectual property claims are adequately protected and/or appropriately pursued, program participants who are not employees of the federal government will be required to read and sign the program's Data Sharing Plan (see the Subcontract Agreement). Enforcement of the plan will be carried out by NINDS with assistance from SAIC.

The commercialization of models and other research tools developed under this program must not be restricted. Investigators should be aware of and are expected to follow along with, as

appropriate, the provisions of the *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999) and the *NIH Grants Policy Statement* concerning the availability of research results: publications, intellectual property rights, and sharing biomedical research resources.

The following section is intended primarily for the offeror's Business Office. Offerors should familiarize themselves with the information contained in this section and forward the material to their Business Office as soon as possible.

6. Information Related to Subcontracts

6.1 General Information

Cost Plus Fixed Fee/Time and Materials, Indefinite Delivery/Indefinite Quantity (ID/IQ) subcontracts will be issued for offers received in response to this RFP. Any subcontract resulting from this solicitation shall resemble the Subcontract Agreement posted on the SMA Project website, with the exception of appropriate modifications made at the time of award, including all applicable provisions required for flowdown by the prime contract to SAIC 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 is submitted at the price(s) proposed and upon the terms and conditions contained in this RFP, and the proposal shall be inclusive of all costs associated with performing the work, including profit/fee.

6.2 Proposal Validity

To be considered valid, your proposal must be addressed to Jonathan Logan and remain firm for 180 calendar days.

6.3 Qualifications of Prospective Offeror

The offeror must have adequate resources to perform any resulting subcontract, in accordance with the terms and conditions of this RFP, and upon request furnish proof of the same. The SAIC Subcontracts Representative may request verification of the offeror's financial status, cost data related to the proposal, verification of insurance, anticipated technical approach, preliminary project scheduling, and/or any other pertinent data needed to establish the responsibility of the offeror. Offers will not be accepted from any SAIC employee or business unit.

6.4 Procurement of Certain Equipment

Offerors will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the government contracting officer.

- 67 - Photographic Equipment
- 69 - Training Aids and Devices
- 70 - General Purpose ADP Equipment, Software, Supplies, and Support (Excluding 7045-ADP Supplies and Support Equipment)
- 71 - Furniture
- 72 - Household and Commercial Furnishings and Appliances

- 74 - Office Machines and Visible Record Equipment
- 77 - Musical Instruments, Phonographs, and Hometype Radios
- 78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the offeror and determined essential by the contracting officer, the government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

Additional unallowable items include accountable government property (defined as both real and personal property with an acquisition cost of \$1,000 or more and a life expectancy of more than 2 years) and “sensitive items” (defined and listed in the Contractor’s Guide for Control of Government Property (<http://knownet.hhs.gov/log/contractorsguide.htm>], 1990), regardless of acquisition value.

6.5 Late Offers

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

6.6 Offer Acceptance and Award

SAIC reserves the right under all circumstances to select and award to the offeror, in whole or in part, any portion of this project that is in the best interest of SAIC and its client.

Of note:

- 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 the 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 Subcontracts Representative and only when an SAIC Pro-Forma Subcontract of the type referenced in this RFP is executed with the offeror.

6.7 Right of Denial

SAIC reserves the right to deny the services of an offeror due to inadequate qualifications and/or failure to complete a contract or demonstrated poor performance on contracts similar in nature, or the offeror who, under investigation, shows is not in a position to perform the contract.

To form a complete offer, the offeror is required to provide a detailed cost proposal in accordance with this solicitation, a technical proposal that demonstrates the offeror’s understanding of the requirements, and other pertinent documents as outlined in section 3.4 of this RFP.