

CLINICAL AND TRANSLATIONAL INFORMATION EXCHANGE ENVIRONMENT PILOT PROJECT REQUEST FOR PROPOSALS

Booz Allen Hamilton, Inc. (Booz Allen), in collaboration with the National Center for Research Resources (NCRR) and the National Institutes of Health (NIH) Roadmap, invites currently funded Clinical and Translational Science Award (CTSA) institutions to submit proposals for components of a Clinical and Translational Information Exchange Environment. The Clinical and Translational Science Awards are institutional awards with a focus on transforming institutional and national approaches to the disciplines of clinical and translational science including training the workforce and providing novel infrastructure and policies to enhance basic research translation into clinical application. The transformation of clinical and translational science requires a visionary approach to management and sharing of information which can only be accomplished with ubiquitous access to tools and processes by investigators to enhance the quality, availability, security, collection, and analysis of data. It is recognized that the informatics needs identified today for clinical and translational research will be rapidly augmented by new demands. Therefore, the supporting infrastructure needs to be flexible to respond to new challenges as they arise and scalable to accommodate increases in demand and the amount of data.

This Request for Proposals focuses on one component of a Clinical and Translational Information Exchange Environment; specifically the implementation, adaptation, development, and application of tools for clinical investigators and their research team to facilitate the performance of small and medium sized research studies, specifically related to the collection, management, and security of human subjects study data.

PROJECT DETAILS

One of the major problems in the translation of basic research findings into clinical application is lack of tools and robust processes for implementation of single or multi-site small and medium size clinical research studies at academic medical centers and their partners. The data management requirements of clinical and translational research are complex and unique. Clinical investigators frequently must separately interact with multiple institutional boards and committees prior to the implementation of their research studies. In many cases they must reformat and/or restructure their written materials to conform to separate requirements of each committee.

Data on approved studies must be gathered and archived using procedures that maintain the confidentiality of the human subjects, but investigators and the research team lack access to resources that adequately and reliably ensure their and their institution's ability to maintain the confidentiality of the human subjects' data collected in these studies. Investigators or research team members frequently must manually copy data from multiple electronic databases including hospital, clinic, and laboratory systems to spreadsheets or databases that are in many cases not routinely secured or backed up. The error rate for manual transfer is significantly higher

than for system to system transfer. Study spreadsheets or databases are often not protected by the level of security required for institutional email.

While significant resources do exist for some types of data transfer or sharing, the ability to integrate the various sources of clinical, laboratory, and genetic data is a significant problem for many individual or small research teams. Collaboration with investigators at other sites is also problematic for investigators who are not part of a large network or for studies that are small or investigator initiated.

The CTSA consortium offers a unique opportunity for a collaboration of informaticists, computer scientists, clinician researchers, coordinators, and laboratory scientists to develop, adapt, adopt, or implement flexible solutions that could have a significant impact on the ability of clinical and translational researchers to contribute knowledge to advance treatments. Adoption of standards, best practices, technology, and a commitment to interoperability in focused areas could have a major impact.

The goal of this solicitation is to provide informatics tools to clinical investigators and clinical research teams at and across CTSA institutions to enhance the collection and management of data in small and medium sized single and multi-site studies while ensuring the accuracy, quality, confidentiality, and security of the data. Facilitating sharing of the tools and the research data (as appropriate) are overall goals of the CTSA program.

A range of informatics based pilot projects that would benefit clinical researchers can be proposed. However, preference will be shown for projects that:

- Support multiple clinical and/or population research end-users irrespective of specialty or type of study.
- Clearly address barriers to adoption, as well as barriers to long term growth of the products and end-user communities.
- Facilitate informed sharing of investigator study data sets with the scientific community through institutional data sharing policies and tools.
- Incorporate technologies that support rules based handling and processing of information.
- Clearly demonstrate a collaborative activity between end users, informaticists, and institutional information technology support services.
- Provide clear evidence of wide adoption or acceptability.
- Incorporate standard interfaces and national data and metadata standards into the design.
- Plan for the active engagement of clinical scientists and the research team throughout the project.
- Incorporate independent evaluation of the implemented project by end users.
- Provide inter-institutional and intra-institutional electronic transfer of clinical and laboratory data to obviate human data entry errors and reduce investigator burden.

All pilot projects must incorporate institutional database support for clinical research data for small and medium size studies that is flexible, secure, backed up, and easily accessible on demand (if allowed by study design) to the clinical investigators and research team. Pilot

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projects that do not utilize fully maintained secure databases are not responsive to this solicitation.

At least three CTSAAs must work together on the proposed project and implement the resource at their institutions within the time frame of the project.

Offerors must not propose pilot projects that duplicate efforts already underway. When possible, offerors should adopt or adapt resources of ongoing NIH supported efforts in informatics as well as other national efforts. Examples of major NIH supported efforts include the caBIG™ program (<http://cabig.cancer.gov/index.asp>), the many resources supported by the National Library of Medicine such as the Unified Medical Language System (UMLS) (<http://umlsinfo.nlm.nih.gov>), the National Centers for Biomedical Computing (<http://www.bisti.nih.gov/ncbc/>), and the Biomedical Informatics Research Network (<http://www.nbirn.net>).

FUNDS AVAILABLE

It is anticipated that a total of \$4 million will be available to support approximately 3 awards for a maximum of two years.

DATA AND SOFTWARE SHARING REQUIREMENTS

A software dissemination plan, with appropriate timelines, must be included in the description of any project that includes software. There is no prescribed single license for software produced under this project. However, NIH does have goals for software dissemination, and reviewers will be instructed to evaluate the dissemination plan relative to the following goals:

1. The software should be freely available to biomedical researchers, educators, and institutions in the non-profit sector, such as institutions of education, research institutions, and government laboratories.
2. The terms of software availability should permit the commercialization of enhanced or customized versions of the software, or incorporation of the software or components of it into other software packages.
3. The terms of software availability should include the ability of research institutions outside the Offeror and affiliated organizations to modify the source code and to share modifications with other colleagues.

Offerors can propose to build their software on top of commonly available commercial infrastructure (an Oracle database, for example). However, offerors must clearly describe the **exact** infrastructure that will be necessary to run the software. The description must be sufficiently detailed to allow a new user to obtain/purchase the required infrastructure using the description in the proposal.

PROPOSAL INSTRUCTIONS

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1.0 PROPOSAL PURPOSE

The proposal must provide a detailed description of the proposed project, the specific tasks and their timelines, alternative approaches if problems are encountered, and how the Offeror intends to oversee, manage, and staff the project.

2.0 ELIGIBILITY AND PARTNERING

Partnership of at least three (3) CTSA awardees is required for any proposal. An institution that holds a currently funded CTSA grant must be the prime respondent to the RFP and the partnering organizations must be designated as subcontractors. Additional partners outside of the minimal number of CTSA partners may be included in the proposal as subcontractors. Organizational qualifications of all subcontractors should be detailed in the Technical Proposal, including relevant resumes.

All contractual interactions including contract negotiations, deliverable submission, invoicing, payment, etc. will be between the identified lead institution and Booz Allen. Booz Allen will only issue a single subcontract agreement to the identified lead institution for each successful bid. The lead institution is responsible for ensuring their proposed subcontractors deliverables.

3.0 LETTER OF INTENT

All Offerors are requested to submit a letter of intent to bid by 5:00 pm ET, February 25, 2008. Submit your Letter of Intent to CTSA_Solicitations@bah.com. Qualified individuals from organizations that do not submit a Letter of Intent may be called upon to participate as a reviewer in the proposal evaluation.

4.0 QUESTIONS AND INQUIRIES

Questions and inquiries will be accepted from all eligible Offerors. Written questions should be submitted to CTSA_Solicitations@bah.com. All questions must be received by 5:00 pm ET, February 25, 2008.

Answers to these questions will be delivered to all eligible offerors no later than 5:00 pm ET, March 10, 2008 to allow adequate time to incorporate this information into the proposal.

5.0 DUE DATE AND FORMAT OF SUBMISSION

Your complete proposal is due no later than 5:00 pm ET, April 14, 2008. Submit **one** electronic file in Microsoft Word or Adobe PDF format to CTSA_Solicitations@bah.com. Confirmation of receipt of your proposal will be provided. No responses will be accepted after this date.

6.0 AGREEMENT TYPE

A firm fixed price subcontract will be awarded. In a firm fixed price subcontract, the subcontractor agrees to deliver the proposed deliverables on the proposed date for the agreed-

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upon price, inclusive of labor, travel and equipment expenses.

This solicitation and any resulting subcontract are governed by appropriate provisions of the Federal Acquisition Regulation (FAR).

7.0 PERIOD OF PERFORMANCE

For pricing purposes, assume a period of performance no longer than 2 years from date of award. Awards will be funded incrementally.

Booz Allen reserves the right to make multiple awards against this solicitation, or to make no award, if such is deemed to be in the best interests of Booz Allen and the US Government.

8.0 PROPOSAL CONTENT

The information required to be submitted in response to this RFP has been determined to be essential in the bid evaluation and contract award process. The following components must be submitted, using the forms provided. Components of the proposal are:

- Technical Proposal, including resumes/biographical sketches of key personnel. Key Personnel are defined as those personnel who:
 - Are essential to the delivery of the project
 - Will be materially involved in the execution of the project
 - Are committed to working on the project and will be produced upon award.
- Budget Proposal, including detailed travel justification.
- Deliverable Payment Schedule.

8.1 Technical Proposal

The technical proposal should demonstrate your organization's capability and approach for addressing the goals and requirements described in the solicitation. Please include:

- Title page with contact person, responsible entity, address, phone, fax and email address.
- Description of the project, the specific tasks and their timelines, alternative approaches if problems are encountered.
- Specific plan for oversight and management of the project, including staffing.
- Specific objectives and deliverables with timelines.
- Details of the impact on the completed project on clinical investigators and their teams.
- Resumes/biographical sketches for all key personnel assigned to work on this project.
- Identification of the CTSA's involved in the project and their role.

There is no required length for the technical proposal, but it should not exceed thirty (30) pages (exclusive of resumes/biographical sketches). It should be long enough to concisely define the work to be done on the project. Please see the Technical Proposal template located at www.bahcontractmanagement.com.

8.2 Budget Proposal

The budget proposal provides detailed, itemized pricing for the proposed effort. The proposal must be inclusive of all personnel, travel, equipment, supplies, and Facilities & Administration (F&A)/indirect costs needed to complete the project. The budget proposal must provide the name and/or title of the personnel assigned to each deliverable and the number of hours required by these personnel to complete the deliverable. All proposed subcontracts budgets must be itemized, and the total dollar value for each budget category must be detailed (including travel and other expenses). The total dollar value of the budget proposal must match the total dollar value on the Deliverable Payment Schedule (Section 8.3).

All travel estimates must conform to the current Federal Travel Regulations (FTRs). Food, travel and lodging payments are based on the official government per diem rates found at http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentId=17943&contentType=GSA_BASIC. A detailed justification of the travel budget must be provided and should include the purpose of each trip, the city of origin and the destination, the mode of transportation, and the total cost of the trip.

Your budget proposal must also clearly show your organization’s proposed F&A or indirect rate(s), which must be consistent with and supported by a copy of your organization’s US Government-approved F&A or indirect rate cost agreement.

The budget proposal need only be as long as necessary to describe all proposed costs. There is no page limit for the budget proposal. Please use the following table to detail travel costs.

Purpose of Travel	From	To	R/T or O/W*	# Persons	Mode of Transportation	Cost (\$)
Total						→

*R/T = roundtrip O/W = one way

Booz Allen reserves the right to request supporting documentation for any proposed labor or other direct costs.

8.3 Deliverable/Payment Schedule

The Deliverable/Payment Schedule outlines the cost and timing for completion of each deliverable and thereby clarifies expectations. Payment for contract work will be based on the receipt and approval of each deliverable (artifact) listed and justified in the Technical Proposal. Please use the table below to itemize your proposed deliverables, the schedule for delivery, the proposed invoice amount for each deliverable, and the total proposed cost.

Deliverable	Delivery Schedule	Invoice Amount
<i>Examples:</i>		
<i>Communications Plan</i>	<i>2 weeks from date of award</i>	<i>\$9999.99</i>
<i>Monthly Report</i>	<i>5th working days of each month</i>	<i>\$9999.99</i>
<i>Working prototype</i>	<i>9 months from date of award</i>	<i>\$9999.99</i>
	TOTAL COST	\$29999.97

The Invoice Amount is the dollar amount the Prime CTSA will receive upon successful delivery and acceptance of the deliverable. The Invoice Amount must include all costs (including travel and other expenses) associated with the deliverable. All reports and deliverables will be inspected by Booz Allen and final approval is subject to review and acceptance by the NIH.

9.0 PROPOSAL EVALUATION

Proposals will be evaluated by an Evaluation Committee, which will be composed of NIH and Booz Allen personnel and independent outside experts. Only proposals that are compliant with the RFP requirements will be evaluated. A compliant submission will:

- Identify three or more CTSA's that will work together on the proposed project.
- Identify the prime CTSA and a single corresponding point of contact that is solely, and contractually responsible for the execution of the project and coordination with the other listed partners on the project. See Section 2, Eligibility and Partnering.
- Identify a fully maintained secure database of clinical research data as part of the proposed project.
- Provide a technical approach and schedule as to how the project will be accomplished. See Section 8.1, Technical Proposal.
- Provide a description of the management and oversight mechanisms to be utilized on the project.
- Identify key personnel.
- Provide a detailed budget which details by deliverable the personnel, travel, equipment, and supplies needed to complete the project. See Section 8.2, Budget Proposal.
- Provide a completed deliverable payment schedule. See Section 8.3, Deliverable/Payment Schedule.

Technical Evaluation Criteria

Evaluation criteria have been established that will enable the evaluation committee to systematically compare responses to this Request for Proposal, in the interest of conducting fair and open competition for the award of this work. The successful Offeror(s) will need to demonstrate a significant impact, a solid technical approach, extensive domain knowledge and experience, an appropriate staffing plan, and an adequate data and software sharing plan.

The technical evaluation criteria, as well as their weighted importance to the Evaluation Committee, have been included in the table below:

	Criteria	Importance/Definition	Evaluation Weight
1	Impact of Project	The impact of the proposed project on clinical and translational research investigators; plan to engage and support the end user community throughout the project, including initial adoption as well as ongoing enhancement and integration work.	30%
2	Technical Approach	Well thought out and solid technical plan for applying informatics and information technology to proposed project; extent to which Offeror demonstrates that the project can be implemented within the time/schedule constraints defined in the solicitation and their proposal.	20%
3	Domain Knowledge and Experience	Qualifications of the Offeror (including stated subcontractors and collaborators) that directly relate to performance and informatics support of clinical and translational research and researchers.	20%
4	Staffing Plan	Demonstration of appropriate allocation of personnel that are specifically qualified to achieve goals described in the proposal.	20%
5	Data and Software Sharing	Commitment of Offeror and affiliated organizations to wide distribution and sharing of the tools/results of the pilot project based on the terms and conditions outlined in the solicitation. This includes consideration of the following questions: If required, is the description of any commercial infrastructure clear? Would a new user be able to obtain/purchase the necessary commercial infrastructure using the description provided?	10%

10.0 BUDGET EVALUATION

While lowest cost is not a determining factor in selection, it is important to demonstrate that the cost proposed is in line with the projected real value that the CTSA community as a whole will realize as a result of this work.

11.0 PROPOSAL SELECTION

After Proposal Evaluation by the Evaluation Committee, Booz Allen and the NIH will meet to select the winning proposal(s) or to identify proposals in the competitive range. Booz Allen reserves the right to request Best and Final Offers (BAFO) from those Offerors determined to be in the competitive range if it is determined that additional information is necessary in order to make a final decision. In this case, all Offerors whose proposals are in the competitive range will be given 10 business days in which to revise and return their proposals. Booz Allen reserves the right to engage members of the evaluation committee in secondary review of the Best and Final Offers, but is not required to do so. **Note that Booz Allen reserves the right to issue multiple or no awards against this Request for Proposals.**