

CLINICAL AND TRANSLATIONAL INFORMATION EXCHANGE ENVIRONMENT 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, sharing, and use of information of all types.

This Request for Proposals focuses on three targeted areas; specifically 1) the publication of defined linked open data on the web about scientists, their work, biomedical resources, core facilities, tools, and research data; 2) development of tools that utilize linked open data to facilitate scientific discovery, collaboration, or communication; 3) collaborations of patient and researcher communities to extend the CTSA national recruitment registry, ResearchMatch.org, for their disease focus.

PROJECT DETAILS

The CTSA program encourages institutions to implement policies, practices, and tools that facilitate collaboration and access to data to enhance research capability. Broader adoption by institutions, organizations, and individuals of tools and policies that facilitate electronic exchange and use of information would be valuable. The supporting infrastructure needs to be flexible to respond to new data types, scalable to accommodate increases in the amount and sources of data, and accommodate multiple uses of information. Appropriate privacy and confidentiality protections must be incorporated but not impede sharing when permitted.

Work Area 1

Many academic institutions, including those with CTSA's, make information about their faculty, staff, facilities, and resources available on their websites (research and institution profiles). Recently, institutions have adopted tools (VIVO, Harvard Profiles, Stanford CAPs, Iowa Loki, Collexis Expert Profiles, eagle-i, and others) that facilitate this process through electronic ingest from internal and public databases and manual annotation. This data is currently largely available on each institution site as web pages with limited sharing of the data itself. Ontology and format agreements would increase the quality and utility of data. There has been increasing recognition of the value of making this public data available such that other applications can utilize the data for multiple purposes.

Sharing of scientific data as open data is routine in some fields, however, it is limited in biomedical area. Some individuals, institutions, and labs are leading the way. Additionally, the US government is committed to making multiple types of government data available as linked data (see Data.gov).

Projects in Work Area 1 will make publically available data sets that include information about scientists, their work, biomedical resources, core facilities, tools, as well as research data sets. A range of informatics projects can be proposed; however, relevant aspects could include, but are not limited to:

- Availability of linked data from multiple CTSA institutions, organizations, and others
- Incorporate compatibility with a diversity of information sources and platforms
- Incorporate data annotations and exchange formats that allow interoperability of data.
- Include adoption of common policies for quality and currency.
- Incorporate independent evaluation of availability and utility of data.

Work Area 2

The availability of this information as linked open data provides opportunities to reduce burden on investigators who currently must provide their data redundantly, allows linkages to other data including the scientific output and contributions of those scientists, and enables visualizations of the multiple professional and intellectual connections that drive science. The linking and visualization of public data from various sources is proving to be a powerful discovery mechanism.

Projects in Work Area 2 will make available tools that utilize linked open data to facilitate scientific discovery, collaboration, or communication. A range of informatics projects can be proposed; however, relevant aspects could include, but are not limited to:

- Promote the use of linked open data to reduce burden on investigators for provision of the data for multiple purposes
- Promote the integration of junior investigators and students into the scientific community
- Facilitate multi-disciplinary scientific collaborations
- Allow discovery of new knowledge about effective collaborations and team science
- Demonstrate the value of linking scientist and resource information with other information

Work Area 3

The sharing of personal information between potential volunteers for clinical studies and researchers requires appropriate privacy and confidentiality protections. The CTSA consortium developed and implemented ResearchMatch (<https://www.researchmatch.org/>), a disease and institution neutral national recruitment registry for making connections between willing volunteers and researchers with approved studies in a secure setting. In less than a year, over 12,000 volunteers have registered and since March, over 27,000 volunteers have been contacted anonymously by researchers with over 5,600 volunteers responding that they wish to be contacted by the researcher. Although the potential for this national recruitment registry is

still unknown, many patient communities are excited as are researchers about a national exchange to promote patient volunteer connection with researchers studying specific diseases.

This solicitation will support collaborations between patient and research communities to utilize Research Match to facilitate connections to generate new knowledge that contributes to the development of novel approaches to diagnosis, prevent, and treat a disease or disorder. A range of informatics projects that encourage adoption of policies, practices, and extensions of Research Match by patient and researcher communities can be proposed. However, relevant aspects could include, but are not limited to:

- Options for sharing of relevant disease specific and study specific information between volunteer and researchers to increase collaboration in generation of knowledge of natural history of disease, disease sub-sets, and effectiveness of current and new diagnostics, preventive strategies, treatments, and management practices.
- Encourage provision of information about scientific and research advances to potential volunteers tailored to their disease interests
- Define a model for inclusion of other disease focus areas in future
- Incorporate independent evaluation of the implemented project by users of tool or data.
- Provide clear evidence of wide adoption or acceptability of policy, practice, and/or tool.
- Include agreement and commitment from relevant patient advocacy organizations and researchers, including those outside of CTSA consortium, to adoption and use.

ALL WORK AREAS

At least three CTSA's must collaborate on any proposed project and implement the policies, practices, and tools at their institutions within the time frame of the project. Inclusion, outreach, and consultation with non CTSA partners are encouraged.

Offerors must not propose projects that duplicate efforts already underway.

FUNDS AVAILABLE

It is anticipated that a total of \$4 million will be available to support approximately 4-5 awards for a maximum of 18 months.

DATA AND SOFTWARE SHARING REQUIREMENTS

A data and software dissemination plan, with appropriate timelines, must be included in the description of any project that includes data or software. There is no prescribed single license for software produced under this project. However, NIH does have goals for data and 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.
4. Offerors can propose to build their software on top of commonly available commercial infrastructure. 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.
5. Data in WORK AREA 1 and 2 must be publically available for use without restriction.
6. Data in ResearchMatch is private and protected and volunteers control access to their personally identifiable information. De-identified data is available to researchers for purpose of contacting volunteers anonymously about IRB approved studies for which they may qualify.

The offeror may propose alternative mechanisms for data and/or software sharing. However, this requires strong justification.

PROPOSAL INSTRUCTIONS

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 designated as the lead institution and 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. These are not required to be at CTSA institutions. Organizational qualifications of the lead institution and 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 with the identified lead institution/prime respondent. Booz Allen will only issue a single subcontract agreement to the identified lead institution/prime respondent for each

successful proposal. The lead institution is responsible for ensuring their proposed subcontractors deliverables.

3.0 LETTER OF INTENT

All Offerors are required to submit a letter of intent to bid by 5:00 pm ET, January 18, 2011 that briefly describes the proposed project, approach, and key collaborators. 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, January 21, 2011.

Answers to these questions will be delivered to all eligible offerors no later than 5:00 pm ET, February 1, 2011 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, February 25, 2011. Submit **one e-mail with two files attached: 1) Technical proposal in Microsoft Word or Adobe PDF format, 2) Budget proposal in the Microsoft Excel format using the template provided.** Submit email 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-upon price, inclusive of labor, travel, equipment, and other direct costs.

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 18 months from date of award. Awards may 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 subcontract 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 supporting documentation and justification for all categories.
- Deliverable Description and 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 title of project, the WORK AREA addressed, 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 how the impact on the completed project on environment for clinical and translational research will be evaluated.
- Resumes/biographical sketches for all key personnel assigned to work on this project.
- Identification of the CTSA's and other organizations 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 <http://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, equipment, supplies, travel, and F&A/indirect costs needed to complete the project. The budget proposal must provide the name and/or title of the personnel assigned to project and the number of hours required by these personnel. 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/category/21287>. 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 Facilities & Administration (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.

Booz Allen reserves the right to request supporting documentation for any proposed labor, equipment, travel, 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. The total proposed cost of deliverables must match the total proposed budget.

| Deliverable | Delivery Schedule | Invoice Amount |
|--|------------------------------------|-----------------------|
| <i>Examples:</i> | | |
| <i>- Data elements for scientist profile</i> | <i>6 months from date of award</i> | <i>\$10,000.00</i> |
| <i>- Prototype delivery of tool</i> | <i>6 months from date of award</i> | <i>\$10,000.00</i> |
| <i>- Data elements for ResearchMatch disease volunteer profile</i> | <i>6 months from data of award</i> | <i>\$10,000.00</i> |
| | TOTAL COST | \$30,000.00 |

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 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. All awardees will be required to submit a “Lessons Learned” document for public posting at the completion of the project.

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 CTSAAs 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 12, Eligibility and Partnering.
- 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 detailed deliverable payment schedule with appropriate timeline. 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 | Proposed measures of impact of the project on public availability of data about scientists, their work, biomedical resources, core facilities, tools, and research data for WORK AREA 1. Proposed measures of the impact of tool on investigator burden, scientific collaboration, communication, and/or new knowledge discovery for WORK AREA 2. Proposed measures of the impact of project on participation by patient volunteers and researchers in ResearchMatch.org and number of completed studies for WORK AREA 3. | 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, including informatics, non-informatics domain knowledge, and policy qualifications and experience. | 20% |

| | Criteria | Importance/Definition | Evaluation Weight |
|---|---|---|--------------------------|
| 4 | Staffing Plan | Demonstration of appropriate allocation of personnel that are specifically qualified to achieve goals described in the proposal. | 20% |
| 5 | Commitment to Data and Software Sharing | Commitment of Offeror and affiliated organizations to wide distribution and sharing of the data/tools based on the terms and conditions outlined in the solicitation. | 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.**