



United States Department of the Interior
Office of the Secretary



SOURCES SOUGHT

The Department of the Interior, Acquisition Services Directorate, on behalf of the National Cancer Institute, is issuing this sources sought as a means of conducting market research to identify parties having an interest in and the resources to support this requirement for Research Electronic Data Capture and Management Systems. The result of this market research will contribute to determining the method of procurement. The applicable North American Industry Classification System (NAICS) code assigned to this procurement is 541712.

THERE IS NO SOLICITATION AT THIS TIME. This request for capability information does not constitute a request for proposals; submission of any information in response to this market survey is purely voluntary; the government assumes no financial responsibility for any costs incurred.

If your organization has the potential capacity to perform these contract services, please provide the following information: 1) Organization name, address, email address, Web site address, telephone number, and size and type of ownership for the organization; and 2) Tailored capability statements addressing the particulars of this effort, with appropriate documentation supporting claims of organizational and staff capability. If significant subcontracting or teaming is anticipated in order to deliver technical capability, organizations should address the administrative and management structure of such arrangements.

The government will evaluate market information to ascertain potential market capacity to 1) provide services consistent in scope and scale with those described in this notice and otherwise anticipated; 2) secure and apply the full range of corporate financial, human capital, and technical resources required to successfully perform similar requirements; and 3) implement a successful project management plan that includes: compliance with tight program schedules; cost containment; meeting and tracking performance; hiring and retention of key personnel and risk mitigation;

BASED ON THE RESPONSES TO THIS SOURCES SOUGHT NOTICE/MARKET RESEARCH, THIS REQUIREMENT MAY BE SET-ASIDE FOR SMALL BUSINESSES and multiple awards MAY be made. Telephone inquiries will not be accepted or acknowledged, and no feedback or evaluations will be provided to companies regarding their submissions.

Submission Instructions: Interested parties who consider themselves qualified to perform the above-listed services are invited to submit a response to this Sources Sought Notice by 2:00 PM, Eastern Time, December 4, 2014. All responses under this Sources Sought Notice must be emailed to Jenny Taylor (jenny_taylor@ibc.doi.gov).

APPENDIX 1: Purpose and Objectives

I. Instructions

The National Cancer Institute (NCI) Center for Biomedical Informatics and Information Technology (CBIIT) is requesting information from developers and purveyors of clinical trials and related human-subjects research data management software. This is a Request for Information only. Do not submit a proposal or quote. Interested parties are invited to review the information below and to make comments or suggestions. Nothing in this document should be considered binding nor does it obligate NCI CBIIT to conduct any future activities (including procurements). Although NCI CBIIT has identified questions of particular relevance, we welcome comments on any part of this document.

II. Background and Goals

NCI, a major biomedical research institute within the National Institutes of Health (NIH), coordinates the nation's research program on cancer prevention, detection, diagnosis, treatment, rehabilitation, survivorship and control. As a result of the 1971 National Cancer Act legislation, the NCI has built a research community that includes regional and community cancer centers, physicians who are cancer specialists, cooperative groups of clinical researchers, and volunteer and community outreach groups. NCI also has initiated cancer control programs to hasten the application of knowledge gained through cancer research.

NCI has developed research programs supported by an infrastructure for discovery composed of support mechanisms, organizations, and networks linking scientists, facilities, and information. This infrastructure is the underpinning for activities that encompass all aspects of cancer prevention, detection, diagnosis, treatment, rehabilitation, survivorship and control. In addition, the infrastructure supports basic, translational, and clinical cancer research, which culminates in a significant contribution of scientific advances in all areas of cancer research based on the efforts of thousands of scientists supported by NCI.

NCI invests several hundred million dollars annually to sponsor and conduct clinical trials in the areas of cancer therapy, prevention, diagnosis, and epidemiology. Studies are conducted both at the NCI and at NCI-funded organizations nationwide. These organizations include the NCI-designated Cancer Centers; the NCI Clinical Trials Cooperative Groups; the Specialized Programs for Research Excellence (SPOREs) along with several smaller trial consortia. The major NCI Centers and Divisions sponsoring clinical trials include: NCI Center for Cancer Research (CCR, Division of Cancer Prevention (DCP), Division of Cancer Epidemiology and Genetics (DCEG), Division of Cancer Control and Population Sciences (DCCPS), and Division of Cancer Treatment and Diagnosis (DCTD). These research activities, the institutions where these activities are performed, and the personnel conducting these activities, are collectively referred to as the NCI Clinical Research Enterprise.

The NCI has made significant investments in electronic data capture (EDC) systems for the Research Enterprise. In order to respond to ever evolving requirements and provide greater flexibility for a broad range of programs, the NCI is exploring currently available

data management systems for basic, translational, clinical and related human-subjects research via this request for information. The government is seeking information on both open source and commercial off-the-shelf (COTS) products from locally deployed lightweight systems to federated robust FDA Title 21 CFR Part 11 compliant systems.

III. Information Requested

NCI CBIIT is interested in learning about available solutions that can be leveraged by the NCI Research Enterprise for a broad range of applications. The goal of this RFI is to identify solutions for research EDC systems. These solutions must currently be in production and verifiable by an independent client.

Organizations with such a product should submit a response of no more than 10 pages in length (single spaced, 12 point font minimum) that addresses the topics described above.

In response to the RFI, interested parties shall submit the following information no later than December 4, 2014, 2:00 PM Eastern Time to Jenny Taylor (jenny_taylor@ibc.doi.gov).

Please provide the following information in the response to the RFI.

Organizational Information

Name of Organization

Type of Organization: (For-profit Company, Non-profit Entity, College or University, Government Agency)

Business Classification: (Large, small, disadvantaged, 8(a), etc.)

Organization Point of Contact: (Name, Address, Phone, E-Mail)

Contracts Held by Organization: (GSA Schedule 70, Alliant, CIO-SP3, 8(a) STARS II). If none, please indicate.

Experience: Describe the direct experience your organization has with EDC systems used for scientific research including basic, translational and clinical research. Please be specific about the role of your organization in the initiative(s) and the initiative(s) current status.

General Information

We welcome all feedback from entities experienced in the specific solution described above. The following requirements are of particular interest to NCI CBIIT. Responses must meet the minimum requirements described below.

Minimum Requirements

1. The solution is currently in production and verifiable by an independent 3rd party client.
2. The solution must have a built-in designer component for allowing staff to design Electronic Case Report Forms (eCRFs) or patient surveys for their specific studies.

3. The solution must have data import/export functionality to enable data exchange and analysis.
4. The solution must support role-based security, allowing users to be assigned to roles and specific studies.
5. The solution must encrypt and secure data leveraging government and industry standards.

Optional Requirements

1. For the majority of applications the solution must have the capability to leverage standard data elements.
2. The solution provides edit checking support to facilitate data entry.
3. The solution provides conditional branching capabilities.
4. The solution provides eCRF/survey versioning and deployment capabilities.
5. The solution supports data discrepancy management and query tracking.
6. The solution has application programming interfaces to facilitate external integration and data exchange.
7. The solution supports electronic signatures and audit trail.

IV. Disclaimer and Important Notes

This notice does not obligate the Government to issue a solicitation, award a contract, or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities, or on other GWAC websites. However, response to this notice will not be considered an adequate response to a solicitation.

V. Confidentiality

No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).