

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Technology Acquisition Center
23 Christopher Way
Eatontown, New Jersey 07724

2. Description of Action: The proposed sole source action is for a firm-fixed price effort for the renewal of brand name Datalabs software licenses and associated software maintenance and support with Parexel International Corporation (henceforth referred to as Parexel) 195 West Street Waltham, Massachusetts (MA), 02451-1111.

3. Description of Supplies or Services: The Department of Veterans Affairs, Office of Research and Development (ORD), Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) requires support and maintenance of 200 existing Datalabs perpetual licenses and renewal of existing Datalabs term licenses with associated support and maintenance at 125 sites, in support of the Cooperative Studies Program (CSP) clinical trials. Datalabs is a software package that provides a web based data capture tool utilized for managing clinical trial studies and data within the CSP. The CSP presently owns 200 individual Datalabs licenses in support of CSP clinical trial 578 and 125 term site licenses in support of CSP Trials 590 and 595. In 2004, Datalabs software maintenance and support was procured per individual license on a perpetual basis. Subsequent to 2015, Parexel evolved its licensing model and the newer licenses were term. In September 2015, VA procured 60 term licenses in support of CSP trial 594 and, in September 2016, VA procured 65 term licenses in support of CSP trial 590. The CSP is a VA-wide program that runs multiple, national clinical trials for the ORD and helps in the research of various healthcare issues that directly relate to Veterans. This program not only analyzes the medical aspects of the research but also the economic impact these possible clinical trials would have if implemented. Support consists of bug fixes, patching, security fixes, and 12X12X5 telephone support. The period of performance is July 1, 2018 through June 30, 2019 with one, 12-month option period. [REDACTED]

4. Statutory Authority: The statutory authority permitting other than full and open competition is 41 U.S.C.3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1 entitled, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements."

5. Rationale Supporting Use of Authority Cited Above: The proposed source is Parexel 195 West Street Waltham, MA, 02451-1111. Based on market research, as described in Section 8 of this document, the Government has determined that no competition is available for this action. The current CSP data infrastructure is based on existing Datalabs software and VA requires licenses and support compatible with the existing infrastructure protocols and functionality for continued operational availability. CPS has eight years of research data that can only be accessed using

Datalabs licenses. Datalabs is proprietary software. These licenses are required so that researchers can access current studies to review, update, edit, and analyze data. Without these Datalabs licenses users would not be able to access the system. There are no other vendors that sell licenses that support the use of this software.

Parexel owns all rights to the Datalabs software and does not allow resellers to provide the software or services. As this is proprietary software, no other vendor can provide the maintenance and support which includes: feature releases, security fixes, and bug fixes. Maintenance provides application support in the event there is a problem with the system. Datalabs has and continues to resolve application issues that if not resolved would have a significant impact on the CSP's ability to continue to collect data including instances where the entire system has been unavailable. Without this support, the CSP could experience extended downtime and in a worst case not being able to make the system available at all to researchers. If researchers are not able to retrieve and analyze the data, this would impact future clinical outcomes which could improve the wellbeing for Veterans. Without the maintenance, the Government would not have access to the software updates. Without access to the software updates, the CSP would not get new releases and fixes. Recently, Parexel provided a new release for the Datalabs software that resolved major internet security vulnerabilities. These vulnerabilities would have put VA at risk for the potential release of Veteran Personally Identifiable Information. In addition, without these fixes, Enterprise Operation would not issue an Authority to Operate. This would have the potential to shut down the entire CSP program.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Government's requirements. There is no competition anticipated for this acquisition. The proposed action will be synopsized on the Federal Business Opportunities (FBO) page in accordance with FAR 5.201. Any proposals that are received shall be evaluated. Additionally, in accordance with FAR 6.305(a) this Justification for Other Than Full and Open Competition will be made publicly available on FBO within 14 days after contract award.

7. Actions to Increase Competition: The Government is currently conducting market research to determine if new cloud base, competed electronic data capture systems can be implemented at the CSP. The estimated timeframe to replace the system based on life-cycle is 2025. The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed. The program office will continue to monitor the market for availability of other solutions that are compatible with VA's infrastructure, and will continually conduct test and evaluation of those tools when feasible for consideration during the next competitive procurement and or technology refresh.

8. Market Research: In April 2018, market research was performed by the Government's technical experts via web research. Other vendors that provide web based data capture such as Metadata, OpenClinica, and DataFax are not compatible with the existing data infrastructure. Additionally, the maintenance services provided by Metadata, OpenClinica, and DataFax cannot provide the updates, bug fixes, and related software support due to the proprietary nature of this software. In addition,

the original equipment manufacturer (OEM) also confirmed that they have no authorized resellers of the licensing or maintenance/support.

Additional market research was conducted by posting a Request for Information (RFI) on the National Aeronautics and Space Administration Solutions for Enterprise Wide Procurement V Government Wide Acquisition Contract website on April 2018 to ascertain if there were resellers of the Datalabs software. On April 19, 2018, zero responses were received. Furthermore, discussions with the OEM Parexel confirmed that the OEM is the only provider of Datalabs software and software maintenance. Based on this market research, no competition is anticipated, and the Request for Proposal will be solicited sole source to Parexel.

9. Other Facts: None