

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, NJ 07724

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

3. Description of the Supplies or Services: The Department of Veterans Affairs, Office of Research and Development (ORD), Massachusetts Veterans Epidemiology Research and Information Center has a requirement for maintenance and support for three existing sets of Datalabs software in support of Cooperative Studies Program (CSP) clinical trials. One set is for 200 licenses, another set is for 60 sites, and the other is for 65 sites. The CSP presently owns 200 individual Datalabs licenses in support of CSP clinical trial 578 and 125 site licenses in support of CSP Trials 590 and 595. In 2004, Datalabs software maintenance and support was procured per individual license. Subsequently to 2015, Parexel evolved its licensing model and the newer licenses were procured by site. In September 2015, VA procured 60 sites in support of CSP trial 594 and, in September 2016, VA procured 65 sites 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. Datalabs is a software package that provides a web based data capture tool utilized for managing clinical trial studies and data within the CSP. Support consists of bug fixes, patching, security fixes, and 12X12X5 telephone support. This action will cover maintenance and support for the 200 individual Datalabs licenses and the 125 Datalabs Term Software site Licenses. The period of performance is July 1, 2017 through June 30, 2018. [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. 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. If VA chooses another vendor, it would require VA to completely develop, test, and implement a new system and not utilize the already existing Datalabs infrastructure. It is estimated that to replace the Datalabs infrastructure would cost an estimated \$700,000.00 to \$1,000,000.00. 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 shutdown 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 synopsised on the Federal Business Opportunities (FBO) page in accordance with (IAW) FAR 5.201. Any proposals that are received shall be evaluated. Additionally, IAW 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 shall be implemented at the CSP. The estimated timeframe to replace the system based on life-cycle is 2020.

8. Market Research: In November 2016, market research was performed by the Government's technical experts via web research and discussions with the original equipment manufacturer (OEM), Parexel. It was confirmed by the OEM that only the OEM can provide Datalabs software maintenance. Other vendors that provide similar services such as 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 OEM also confirmed that they have no authorized resellers of the licensing or maintenance/support. Based on this market research, no competition is anticipated.

9. Other Facts: None.