

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 contract with Datalabs Inc. University Research Park Irvine, CA 92617 for additional Datalabs software licenses and corresponding software maintenance/support.

3. Description of the Supplies or Services: The Department of Veteran Affairs, Office of Research and Development (ORD), Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) has a requirement for Datalabs licenses at 60 sites throughout VA hospitals nationally in support of two new Cooperative Studies Program (CSP) clinical trials. The CSP runs multiple clinical trials for the ORD. Datalabs is a software package that provides a web based data capture tool utilized for managing clinical trial studies and data within the CSP. CSP is a VA-wide program that 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. The CSP presently owns 200 individual Datalabs licenses in support of CSP clinical trial 578. These licenses were procured as individual licenses. Datalabs has evolved its licensing model and the licenses are now procured for each site. Due to the increase of end users expected to utilize the system, VA requires software licenses for an additional 60 sites. Licenses will also include support which consists of bug fixes, patching, security fixes, and 12X12X5 telephone support. In addition, this action will provide for the support and maintenance of the current 200 Datalabs licenses currently housed in Webops in Martinsburg, VA. This will include patches, bug fixes, and technical support. The period of performance is 12 months with one, 12-month option period. Delivery of licenses is due within 30 days of award. [REDACTED]
[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: Based on market research, as described in section 8 of this document, the Government has determined that no competition is available for this action. VA has owned and properly maintained 200 individual, existing Datalabs licenses since 2004. By purchasing additional Datalabs licenses, the Government will be able to increase capacity to continue to provide a web based electronic data capture system in support of national and international clinical

trials with no disruption to on-going operations. The proposed source, Datalabs, owns all rights to the software and does not allow resellers to provide the software or services. Additional Datalabs licenses are the only licenses that will provide a web based electronic data capture system in support of national and international clinical trials with no disruption to on-going operations. No other vendor can provide the licenses required as this is a proprietary system. As this is proprietary software, no other vendor can provide the maintenance and support which includes: feature releases, security fixes, and bug fixes. 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. [REDACTED]

[REDACTED] The current infrastructure would also need to be maintained while this process is occurring.

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 (IAW) FAR 5.201. Additionally, IAW FAR 6.305(a) this Justification and Approval 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 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 2015, market research was performed via web research and discussions with the original equipment manufacturer (OEM). It was confirmed by the OEM that only the OEM can provide Datalabs software licenses. 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.