

## JUSTIFICATION FOR AN EXCEPTION TO FAIR OPPORTUNITY

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 action is for the issuance of a Firm-Fixed-Price Delivery Order (DO) under the National Aeronautics and Space Administration (NASA) Solutions for Enterprise-Wide Procurement (SEWP) V Governmentwide Acquisition Contract (GWAC) for brand name Clinical Studio Software csCoder license, end-user web-based training, installation, maintenance, and technical support.
  
3. Description of the Supplies or Services: VA, Office of Information and Technology , Cooperative Studies Program, Clinical Research Pharmacy Coordinating Center (CRPCC), has a requirement for one Clinical Studio Software csCoder license, software installation, product use training, on-going software maintenance, and end-user technical support. Clinical Studio csCoder is a computerized electronic software application system to perform medical coding per the Food and Drug Administration (FDA) required set of terminology for medical events using the Medical Dictionary for Regulatory Activities (MedDRA) and World Health Organization (WHO) dictionaries. These dictionaries are used in the process of coding and to research medical trends within clinical trials. The software maintenance shall include a maximum of four dictionary updates for the WHO Drug Dictionary as well as server-side application software, all client-side software or connectors, and any additional supporting application updates. The technical support shall include unlimited technical support requests via telephone, email, or web-based support for the period of performance specified, for 24 hours a day, 7days a week, 365 days a year. Installation shall include all server-side application software and client-side software and or connectors. In addition to application software, installation must also include all import of historical data from Galt's DSNavigator application, customization of new data sources to comply with local regulatory requirements and existing protocols in place at the CRPCC. The software is used to manage multiple, large adverse medical event databases and code those events efficiently, consistently, and accurately. Delivery is required within 30 days of delivery order award. The period of performance for support shall be 12 months from date of software delivery, plus four 12-month option periods for continued support.
  
4. Statutory Authority: The statutory authority permitting an exception to fair opportunity is 41 U.S.C. 4106(c)(2) as implemented by Federal Acquisition Regulation (FAR) 16.505(b)(2)(i)(B), entitled "Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized."
  
5. Rationale Supporting Use of Authority Cited Above: Based on market research, as described in section 8 of this document, it was determined that limited competition is available among resellers of the required Clinical Studio Software csCoder license, training, installation, maintenance, and technical support. VA requires an auto-encoding

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and dictionary management tool that integrates with MedDRA, the FDA-required set of terminology for medical events, and the WHO Drug Dictionary. The Clinical Studio Software csCoder software is used to manage multiple, large adverse medical events, and concomitant medication databases and code those events efficiently, consistently, and accurately. VA requires a stand-alone system that is Personal Identity Verification (PIV) compliant and is supported by the VA infrastructure. This is a VA functional requirement for security that must be met by the software. This system must also allow the import and export of data without additional software customization. This system must allow for multiple imports of the same data, and differentiate between old and new records. The system must allow for a 2-step data verification function and the addition of comments. This system must also be flexible to allow for differences in data collection methods for different studies. This system must have revision control and auditing of all changes, with the ability to build reports.

No other brand software offers a solution with the ability to import ad-hoc or historic data as needed. Only Clinical Studio Software is available as both a stand-alone, locally installed application or as a cloud based, auto-encoding and dictionary management tool that integrates with MedDRA, the FDA-required set of terminology for medical events, and the WHO Drug Dictionary.

In addition, no other source is capable of providing the required software maintenance and technical support as only Clinical Studio csCoder or its resellers have access to the proprietary source code necessary to provide the required technical support, ongoing training, and software updates. Since the software is proprietary, a legal restriction is placed on access to the software code that is required in order to develop updates to the software. Without this access it is impossible to modify the software code as necessary to provide the required updates. Access to this code is also required to ensure the services provided to the software are properly configured.

Failure to acquire brand name Clinical Studio csCoder software, software maintenance, and technical support would impact VA's ability to retrieve critical research data stored in the current storage infrastructure. Furthermore, failure to acquire Clinical Studio csCoder will result in a stoppage of a service essential to monitoring the safety of participant's involved in clinical trials sponsored by the Cooperative Studies Program.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in section eight of this document. The market research did not yield any other products that can meet the Government's technical requirements. Although the Government is limiting competition as a result of specifying Clinical Studio csCoder brand name software application system, there are multiple resellers of this product that hold current NASA SEWP V contracts. In accordance with FAR 5.301 and 16.505(b)(2)(ii)(D), the resulting notice of award will be synopsisized and this justification will be made publicly available on the Federal Business Opportunities website within 14 days of award. In addition, in accordance with FAR 16.505(a)(4)(iii)(A)(2), this justification will be posted with the solicitation on the NASA SEWP web site.

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7. Actions to Increase Competition: In order to remove or overcome barriers to competition in future acquisitions for the requirements described herein, the agency will continue to perform market research to ascertain if there are changes in the marketplace that would enable future actions to be competed. Additionally, VA's technical experts regularly review industry trade publications and white papers, consult with industry subject matter experts, and conduct internet research to ascertain if any other software is available in the marketplace that can meet the Government's requirements.

8. Market Research: Government subject matter experts (SMEs) conducted market research in April and May of 2017 by reviewing the technical specifications of MedDRA and WHO certified software solutions, to include those offered by ClinPlus, Oracle Health Sciences, MediCoder3/XCoding Technologies, DDi, and Medidata Rave Coder. The Government SMEs determined that while the aforementioned software solutions were capable of performing specific pieces of the overall requirements, none were capable of meeting the full spectrum of requirements. For instance, no other solution is PIV compliant and allows for a 2-step data verification function with individual electronic signing of submissions. Additionally, no other solution offers both locally installed application or as a cloud based, auto-encoding and dictionary management tool that integrates with MedDRA. Based on all of these market research efforts, the Government's SMEs determined that only Clinical Studio Software csCoder license, training, installation, maintenance, and technical support can meet the Government's requirements.

Additional market research was conducted in June 2017 by utilizing the NASA SEWP Provider Lookup tool to determine whether the brand name Clinical Studio csCoder is available from NASA SEWP V GWAC holders. It was determined that there are several resellers of the brand name Clinical Studio csCoder that hold current GWACs such that limited competition is anticipated.

9. Other Facts: None.