

JUSTIFICATION FOR AN EXCEPTION TO FAIR OPPORTUNITY

1. **Contracting Activity:** Department of Veterans Affairs (VA)
Office of Acquisition Operations
Technology Acquisition Center
1701 Directors Blvd., Suite 600
Austin, TX 78744

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).

3. **Description of the Supplies or Services:** VA, Office of Information and Technology, Cooperative Studies Program, Clinical Research Pharmacy Coordinating Center (CRPCC), requires access to a subscription website of U.S. Food & Drug Administration (FDA), Adverse Event Reporting System (FAERS) data, to include training and technical support. The total estimated price of this proposed action is [REDACTED] including a base year and four 12-month option periods.

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:** More than one awardee is capable of providing the supplies or services required, but fair opportunity is limited by restriction to a brand name Advera Health Evidex. No other brand software offers a similar solution with the ability to import ad-hoc or historic data as needed. Only Advera Evidex is available as both a stand-alone, locally installed application or as a cloud based system that integrates with the FDA's reporting systems to gather and scrub datasets for use by Research Organizations to support Human Subject Clinical Trials.

6. **Efforts to Obtain Competition:** Market research was conducted, details of which are in section 8 of this justification. This effort did not yield any additional sources that can meet the Government's requirements. However, it was determined that limited competition is viable among resellers for these brand name items. In accordance with FAR 5.301 and 16.505(b)(2), this action will be synopsisized at award on the Federal Business Opportunities Page (FBO) and the justification will be made publicly available.

7. **Actions to Increase Competition:** The Government will continue to conduct market research to learn if there are changes in the marketplace that would enable future actions to be competed.

Evidex Drug Safety Evidence Collection and Generation Tool

8. Market Research: Government subject matter experts (SMEs) conducted market research in September of 2017 by reviewing the technical specifications of Advera Evidex and found that there are no other products or solutions that provide an on-demand FDA, AERS compatible data retrieval and scrubbing solution. In addition, the contract specialist (CS) reviewed the FDA website at <https://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm> to determine other vendors with similar reporting tools. The FDA website outlined the Sentinel Initiative as a possible tool. The CS reviewed the Sentinel System website at <https://www.sentinelinitiative.org/>. However, the Sentinel System is an active surveillance system that uses routine querying tools and pre-existing electronic healthcare data from multiple sources to monitor the safety of regulated medical products. In addition, the SMEs reviewed the Sentinel Systems market research documents and determined that the data is different from the data Evidex is utilizing. Based on this market research, the Advera Evidex Drug Safety Evidence Collection and Generation Tool software subscription is the only one that meets the requirement.

The Contract Specialist (CS) conducted market research in August 2017 by using the NASA SEWP V GWAC RFI tools and Vendor Information Pages to determine what vendors are capable of meeting the requirement. Based on this market research, the CS found service-disabled Veteran-owned small businesses (SDVOSB) interested and capable of meeting the full requirement.

9. Other Facts: None.