



Issue Date: April 22, 2021

Contracting Office: 4041 Powder Mill Road
Beltsville, MD 20705

PSC: D317— Automated News Services/Data Services

NAICS: 511120 – Periodical Publishers

Submission Date: Interested parties shall e-mail Todd Johnston, Todd.Johnston@fda.hhs.gov no later than April 29, 2021, 4:00 p.m. EST.

Description of Services:

The Center for Drug Evaluation and Research (CDER) Data Standards Program established in 2010 is a comprehensive program within CDER to identify and prioritize data standards needs and to implement good practices for standards development. Where current standard specifications are not available or not adequate, CDER engages the appropriate Standards Development Organizations (SDOs), as well as industry and other stakeholders, to take full advantage of the capabilities offered by the formal SDO processes. The Government intends to solicit a sole source requirement to the Clinical Data Interchange Standards Consortium for the CDISC Membership.

Quantity and options: A Platinum Membership to CDER for One Year

Estimated duration of contract period: August 1, 2021 to July 31, 2022

The proposed simplified acquisition action is for supplies and services for which the Government intends to solicit and negotiate with only one source in accordance with FAR 13.106-1(b). Interested parties may identify their interests and capabilities to respond to the requirement prior to the response date of this notice. A determination by the Government not to compete this proposed simplified acquisition based upon responses to this notice is solely within the discretion of the Government. Information received will normally be considered solely for the purpose of determining whether to conduct a competitive requirement. No further solicitation is available.

FDA will consider all responses received prior to the closing date of this notice and will use responses in determining whether it is necessary to use full and open competition for this requirement. Responses to the RFI should not exceed 10 pages in length. A complete response to the RFI should include all of the information below. Responses should demonstrate capability, not merely affirm the respondent's capability (e.g.: The response must go beyond the statement that, "XYZ company can provide training support.").