Solicitation

FDA Center for Drug Evaluation and Research (CDER)

Clinical Data Interchange Standards Consortium

CDISC Membership

RFQ-FDA-22-1255090

This is a RFQ for an FDA CDER membership to Clinical Data Interchange Standards Consortium (CDISC). The purpose of the CDISC membership is to ensure complete and easy access to all CDISC standards, work products and webinars for all FDA staff. The membership will include a 1-year base period and 4 option years. The following solicitation is an intent to Sole Source due to only one vendor being capable of issuing this specific membership.

This announcement constitutes the only solicitation; The FDA is not requesting competitive quotes due to this being anticipated as a sole-source requirement. Period of Performance August 1, 2022 Solicitation Number 1255090 is issued a a request for quotation (RFQ).

Solicitation Start Date: July 27, 2022

Solicitation Closing Date: July 30, 2022 12:00 PM ET

Statement of Work

FDA Center for Disease and CDISC Membership

RFQ-FDA-22-1255090

A. BACKGROUND INFORMATION

The 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.

Section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), requires that submissions under section 505(b), (i), or (j) of the FD&C Act and submissions under section 351(a) or (k) of the Public Health Service Act (PHS Act) be submitted in electronic format specified by the Food and Drug Administration (FDA or the Agency) beginning no earlier than 24 months after FDA issues a final guidance specifying an electronic submission format.

FDA has determined that study data contained in the electronic submissions described above must use the standards specified in the Data Standards Catalog (Catalog). The standards for study data (clinical and nonclinical) are Clinical Data Interchange Standards Consortium (CDISC) standards. In addition to the existing standards in use, the Prescription Drug User Fee Act (PDUFA VI)1 Performance Goals state that FDA is committed to supporting the enhancement of analysis data standards for product development and review in the human drug review program. The standards for analysis data, defined in the Catalog, are also CDISC standards.

Working with CDISC and CDISC standards is part of the day to day work carried out by the CDER/OSP Data Standards Team and many offices within CDER. The team is

[1] https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm

charged with supporting the implementation of data standards and developed guidance from FDA for industry on the use of CDISC data standards for the electronic submission of study data in applications.

CDISC standards consist of Foundational Standard, Therapeutic Area, Data Exchange, and Controlled Terminology.

- Foundational standards are the basis of the complete suite of standards, enhancing the quality, efficiency, and cost effectiveness of clinical research processes from beginning to end.
- Therapeutic Area standards extend the Foundational standards to represent data that pertains to specific disease areas.
- Data Exchange (XML) facilitate the sharing of structured data across different information systems. Data Exchange Standards are optimized to represent CDISC content, and flexible enough to be used by information systems that haven't implemented the Foundational Standards (e.g., legacy data, academic studies).
- Controlled Terminology the set of CDISC-developed or CDISC-adopted standard expressions (values) used with data items within CDISC-defined datasets.

This CDISC membership ensures complete and easy access to all CDISC standards, work products, and webinars for all FDA staff.

B. REQUIREMENTS

CDISC is a standards development organization that develops data standards to streamline clinical research and enable connections to healthcare, empowering the valuable information offered by patients participating in research studies around the world.

CDER requests to continue having membership access to support its work with CDISC Standards.

C. DELIVERABLES

CDISC shall provide a Platinum membership to CDER that provides access to[2]:

- CDISC Standards, defined above
- Unlimited access to the Members Only Area for all employees to leverage a variety of resources
- CDISC SHARE, the online global repository for developing, integrating and accessing CDISC metadata standards to improve data flow, quality, speed, efficiency and capabilities in clinical trials.
- Monthly Members Only Mini-Training webinars that address industry hot topics

[2] https://www.cdisc.org/membership/benefits-and-rates

- Opportunity to become a CDISC Registered Solution Provider; RSPs serve as subject matter resources to organizations who want to implement CDISC Standards
- Participation in the CDISC Licensed Training Program, allowing staff to become authorized instructors to train fellow staff on CDISC Standards
- Opportunity for database tools to be Operational Data Model (ODM) certified to improve the quality of metadata and data interchange throughout the clinical development process
- 'Symposium: Unlocking a Global Language for Smarter Research' offered at each Interchange (Europe, Japan, and International) for two people, or for a team of up to twenty-five (25), delivered at your organization
- Discount off all CDISC Training Courses and CDISC Events
- Representation on the CDISC Advisory Council (CAC) with opportunities to actively engage in CDISC.

D. Inspection and Acceptance

Pursuant to the Inspection and acceptance terms in clause 52.212-4, inspection and acceptance will be performed at the delivery location by the Contracting Officer Representative (COR). If a deliverable is rejected, the Contractor shall correct any deficiencies within five (5) business days from the time the Government notifies the Contractor of the problem. If the Contractor cannot correct the deficiencies within this time frame, the contractor shall immediately notify the (COR) of the reason for the delay and provide a proposed corrective action plan within three (3) business days.

E. Place of Performance

Food and Drug Administration

F. PERIOD OF PERFORMANCE

One-year Platinum CDISC membership to include option years.

Base Year: August 1, 2022 – July 31, 2023

Option Year 1 - August 1, 2023 – July 31, 2024

Option Year 2 - August 1, 2024 – July 31, 2025
Option Year 3 - August 1, 2025 – July 31, 2026
Option Year 4 - August 1, 2026 – July 31, 2027

G. Contract Type

Firm Fixed Price

H. Government Points of Contact

Contracting Officer (CO):
TBD

Contract Specialist
Nakita Putty
Food and Drug Administration
Email: Nakita.Putty@fda.hhs.gov

Contracting Officer Representative (COR):
TBD

I. Contracting Officer's Authority

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Contractor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the delivery order terms and conditions, including price.

The CO shall be the only individual authorized to accept nonconforming work waive any requirement of the order and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.

The Contracting Officer's Representative {COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the Contractor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the delivery order.

J. Clauses

52.252-2 Clauses Incorporated by Reference (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): https://www.acquisition.gov/far/part-52#FAR_52_215_1

52.203-19 Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017)

52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018)

52.204.24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (Oct 2020)

52.204-25 – Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020)

52.222-26 Equal Opportunity (Sept 2016)

52.232-39 – Unenforceability of Unauthorized Obligations (Jun 2013)

52.232-40: Providing Accelerated Payment to Small Business Subcontractors (Dec 2013)

HHSAR CLAUSES

352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)

352.232-71 Electronic Submission of Payment Requests (FEB 2022)

1. Definitions. As used in this clause-

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must

comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at **Error! Hyperlink reference not valid.** or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

a. FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP). http://www.ipp.gov/vendors/index.htm

b. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions - Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov

c. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank

of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.
Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
If your company is already registered to use IPP, you will not be required to re-register.
If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.
d. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).
e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
(a) list of all invoices submitted to date under the subject award, including the following:

(1) invoice number, amount, & date submitted
(2) corresponding payment amount & date received
(b) total amount of all payments received to date under the subject contract or order
(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.
g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.
h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.
i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.
j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.
k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

(END OF CLAUSE)

352.239-74 – Electronic Information and Technology Accessibility (December 2015)

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also

referred to as the “Access Board”) in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508- standards.

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) The Section 508 accessibility standards applicable to this contract are:

- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping
- Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping)
- 302 Functional Performance Criteria (Appendix C, Application and Scoping
- Requirements)
- Chapter 6 Support Documentation

(d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the

Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508.

If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

K. Provisions

52.252-1 – Solicitation Provisions Incorporated by Reference (Feb 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address https://www.acquisition.gov/far/current/html/FARTOCP52.html#wp372482

(End of Provision)

52.203-18 – Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements—Representation (Jan 2017)

52.204-24 – Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (Dec 2019)

52.204-26 – Covered Telecommunications Equipment or Services-Representation (Dec 2019) 52.211-6 –

352.239-73: Electronic and Information Technology Accessibility Notice (Dec2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees

who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access- board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS website http://www.hhs.gov/web/508.
In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.
(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

L. Special Notice and Agreement regarding Software EULA/TOS

Computer software and services are often subject to license agreements, referred to as End User License Agreements (EULA), Terms of Service (TOS), or other similar legal instruments or agreements. Many of these agreements contain indemnification clauses that are inconsistent with Federal law and unenforceable, but which could create a violation of the Anti-Deficiency Act (31 U.S.C. 1341) if agreed to by the Government.

Therefore, by submitting a quotation the quoter shall agree that the inclusion of any Limitation of Liability, Indemnification, and any other clauses that conflict with Federal law or regulation in any EULA or TOS are NULL AND VOID. The quoter agrees that any EULA/TOS clauses conflicting with Federal law or regulation and are not agreed to by the Government if included with the submission of a quotation. Additionally, by submission of the quotation the quoter must agree to the inclusion of FAR 52.232-39 Unenforceability of Unauthorized Obligations in any resulting contract or order, if awarded.