Request for Information (RFI)

Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases (CRID)
Solicitation Number:
Issuing Office: National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID)
Posted: June 10, 2026
Response Due: No later than July 8, 2026, at 5:00 p.m. EDT.

THIS IS A REQUEST FOR INFORMATION (RFI) ONLY

In accordance with RFO 15.101(c), this RFI is issued solely for information and planning purposes. It does **not** constitute a solicitation for proposals, quotations, or abstracts, nor does it obligate the Government to award a contract or pay for any information provided. Responses will not be returned. No reimbursement will be made for costs associated with responding to this notice.

1. Background

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (HHS), strives to understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents, an essential component of U.S. efforts to ensure the health and safety of the American people. Through multiple grant- and contract-funded research programs, NIAID supports a broad range of clinical research, including single-site and multi-center trials spanning Phase 0-4 therapeutics and vaccines, new vaccine formulations, schedules, and modes of delivery; surveillance or natural history / cohort studies for pathogens of interest; evaluation of novel diagnostics; and clinical trials designed to find additional uses for already approved therapies for selected infectious diseases. The portfolio includes primarily domestic clinical sites, with the ability to support international studies.

As part of clinical research portfolio, NIAID has regulatory obligations for clinical trials that include standardized deliverables, reporting, safety oversight, and monitoring. NIAID therefore requires resources to support its clinical research activities in compliance with regulatory requirements. One of those resources is a Statistical and Data Coordinating Center (SDCC) which provides centralized data management, statistical, and specimen tracking services essential to this clinical research portfolio. NIAID is exploring the re-competition of its Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases (CRID) contract.

2. Purpose

The Government is issuing this RFI to:

1. Facilitate early engagement with industry prior to release of a formal Request for Proposals (RFP), in accordance with RFO 15.101(c).
2. Assess current market capabilities and vendor offerings relevant to SDCC services.
3. Gather input on industry best practices to inform development of a future Statement of Work (SOW).
4. Support fair and open competition in accordance with FAR 5.401.

3. Summary of Anticipated Scope and Targeted Feedback

The anticipated SDCC contract encompasses the following broad functional areas. Respondents are encouraged to provide specific feedback on each area, including comments on feasibility, gaps, ambiguities, industry best practices, and any suggested refinements.

3.1. Overall Questions

Targeted feedback requested:

- To what extent can or should Artificial Intelligence (AI) tools or platforms be incorporated into the SOW while maintaining confidentially of participant data?

3.2. Data Collection and Management

The contractor will operate and maintain a state-of-the-art, 21 CFR Part 11-compliant clinical data system supporting data collection, automated data transfer, validation, storage, and submission to the FDA, from a large portfolio of domestic clinical sites, with the ability to support international studies.

Targeted feedback requested:

- What commercial or proprietary platforms are best suited to support a portfolio of this scale and diversity while also meeting the standards of government-funded computer systems and Food and Drug Administration (FDA) regulatory submissions? What are their strengths and limitations in: an international setting; multi-site protocols; multi-protocol environments; and data collection methods from multiple sources, including electronic health records (EHR), electronic source, and paper source?
- How should the Statement of Work (SOW) address data system transition and continuity of operations at contract start-up to minimize disruption to ongoing studies?

3.3. Data Quality Assurance and Control

The contractor shall provide and maintain a quality control system for monitoring the accuracy, completeness, and timeliness of the data, by study sites at each stage of a study, beginning with study initiation/participant enrollment and proceeding to the generation of final data sets. The system shall provide for verification of 100 percent of study data for audit readiness.

Targeted feedback requested:

- What contractor involvement with development of data standards (i.e., via CDISC working groups and committees) should the SOW require to ensure innovation and continuous improvement in how data are collected?
- As CDISC and other standards continue to evolve, what mechanisms should the SOW require to ensure ongoing compliance without cost or schedule impact to the Government?

3.4. Protocol and Other Study-Related Materials

The contractor shall provide services in the preparation, writing, review, revision, and distribution of protocol-related documents and materials (i.e., Manual of Procedures (MOP)) in collaboration with the study team and in support of implementation of the clinical protocol.

Targeted feedback requested:

- What are industry standard timelines for development of clinical protocols and other study related materials, and what should the SOW require for their delivery schedule?
- What are industry standard timelines for the development of study data system(s), what best practices are recommended to facilitate rapid development of the data system, and what should the SOW require for the delivery schedule?

3.5. Communication, Collaboration, and Reporting

The Contractor shall coordinate and collaborate with NIAID and other NIAID Clinical Research Infrastructure contractors and grant recipients to facilitate study implementation and assess study progress. The Contractor shall operate and maintain a web-based resource to share clinical research information and study materials with the NIAID, the study team, and participating study sites.

Targeted feedback requested:

- What should the SOW require to ensure productive collaborations with multiple other contractors and grant recipients?
- What are industry standards for resources and platforms that can be used to share clinical research information at fixed costs to the Government?

3.6. Statistical Design and Analysis

The Contractor shall provide expertise, advice, and assistance in the development of statistical designs of clinical concepts, statistical analysis plans, and in preparation of interim and final analyses for clinical research activities.

Targeted feedback requested:

- What emerging statistical methodologies (e.g., adaptive trial designs, Bayesian approaches) should the SOW explicitly accommodate, and how should the Government structure tasking to access these capabilities efficiently?
- What should the SOW require for approaches or platforms for statistical analysis that encompass:
    - standard clinical trial analysis,
    - broad range of –Omics datasets, and
    - generation of publication-ready tables and figures.

3.7. Clinical Site Training and Technical Assistance

The Contractor shall train clinical site personnel on data systems and procedures, maintain a 24/7 help desk accessible from domestic and international locations, and assess site capabilities for studies not using SDCC systems.

Targeted feedback requested:

- What are the most significant challenges in supporting clinical sites with respect to data system access, connectivity, and training, and how should the SOW account for them?

3.8. Electronic Specimen Tracking

The Contractor shall provide and maintain an electronic specimen tracking system, for use by the SDCC, study sites, laboratories, and NIAID, to track study specimens in real time.

Targeted feedback requested:

- Are there commercially available specimen tracking platforms that integrate natively with clinical data management systems, and should the SOW require such integration or permit modular solutions?

3.9. Data Storage

The contractor shall maintain a secure and validated data storage system for clinical research and clinical trial data and analyses from current and future trials.

Targeted feedback requested:

- What should the SOW include as requirements for data storage that allow for occasional data access for analysis while limiting cost to the Government?
- What should the SOW require for the maintenance of data from completed studies, such that results and performance metrics can be readily accessed from across all studies?

3.10. Data Sharing

The contractor shall distribute, transfer, and/or share data and metadata to NIH and NIAID-designated repositories following completion of the clinical trial while ensuring data are appropriately and commensurately de-identified.

Targeted feedback requested:

- What should the SOW require for methods and procedures to reliably de-identify clinical trial data?

3.11. Project Management

The contractor shall provide for the overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out under subcontracts if applicable

Targeted feedback requested:

- What are critical elements of program and project management necessary to operate a resource to provide centralized data management and statistical services essential to support a wide variety of clinical research activities across multiple infectious disease programs involving domestic and international sites?

4. Requested Vendor Information

In addition to SOW feedback above, respondents are asked to provide:

1. **Organizational Overview:** Company name, address, UEI number, applicable NAICS code(s), and business size designation.
2. **Relevant Experience:** Summary of prior or current experience managing SDCC or comparable data coordinating center functions, including scale (number of studies/sites) and therapeutic areas supported.
3. **Technical Capabilities:** Description of systems, infrastructure, and personnel available to support the functional areas described above.
4. **International Experience:** Demonstrated capability to support clinical trials at sites outside the United States.
5. **Teaming and Subcontracting:** Whether your organization anticipates teaming agreements, or subcontracting, and in what functional areas.

5. Submission Instructions

Responses should be limited to **ten (10) pages or fewer**, excluding cover page and organizational information. Submissions must be in PDF format and sent electronically to:
Point of Contact: Miranda Adams, Contracting Officer
Email: miranda.adams@nih.gov
Responses are due no later than July 8, 2026, at 5:00 p.m. EDT.

Telephone responses will **not** be accepted. The Government reserves the right to use any non-proprietary information received for acquisition planning purposes.

Confidentiality

No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s). All submissions become Government property and will not be returned.

Disclaimer

This RFI is issued solely for information and planning purposes to facilitate the acquisition planning process. It does not constitute a Request for Proposal (RFP) or a promise to issue an RFP in the future, nor does it restrict the Government as to the ultimate acquisition approach. This notice does NOT obligate the Government to award a contract or otherwise pay for the information provided in response. Further, NIAID is not seeking proposals through this RFI and will not accept unsolicited proposals. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Information provided will be used to assess tradeoffs and alternatives available for the potential requirement and may lead to the development of a solicitation. Any contract that might be awarded based on information received or derived from this RFI will be the outcome of a competitive process. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback with respect to any information submitted. Potential respondents should continue to monitor SAM.gov for any follow-on solicitation or additional information related to this requirement.