SOURCES SOUGHT NOTICE

PRECLINICAL SERVICES FOR HIV THERAPEUTICS
RFP No. 75N93026R00015

Sources Sought Reference Number: SBSS75N93026R00015

Type of Requirement

☐ New Requirement
☒ Follow-on *(Contract No: See Below)*
☐ Other (specify):_____

Place of Performance

☒ Place of performance is unknown at this time
☐ Place of performance is known. Address or general location:_____

Recompetition (if applicable)

- 75N93021D00001 with SRI International (Menlo Park, CA)
- 75N93021D00002 with Alchem Laboratories Corp (Alachua, FL)
- 75N93021D00003 with University of North Carolina at Chapel Hill (Chapel Hill, NC)
- 75N93021D00004 with Research Triangle Institute (Durham, NC)
- 75N93021D00005 with Starks Associates, Inc. (Buffalo, NY)
- 75N93021D00006 with University of Nebraska Medical Center (Omaha, NE)
- 75N93021D00007 with Lovelace Biomedical and Environmental Research Institute, Inc. (Albuquerque, NM)
- 75N93021D00009 with Creagen Inc. (Woburn, MA)
- 75N93021D00010 with Southern Research Institute (Birmingham, AL)
- 75N93021D00011 with University of Texas Medical Branch at Galveston (Galveston, TX)
- 75N93021D00013 with The University of Iowa (University of Iowa Pharmaceuticals; Iowa City, IA)
- 75N93021D00014 with Colorado State University (Fort Collins, CO)
- 75N93021D00015 with Rutgers, The State University of New Jersey (Newark, NJ)

Contracting Office Address

Department of Health and Human Services, National Institutes of Health, Office of Acquisition and Logistics Management, 6701 Rockledge Drive, Bethesda, MD 20817-1816

Sources Sought Notice Information

General Information

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Introduction

This is a Small Business Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice.

Background

The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), of the Department of Health and Human Services (DHHS) supports research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. NIAID research encompasses both basic and clinical research on a broad spectrum of infectious and immune-mediated diseases. By supporting research that leverages foundational knowledge of the human immune system and pathogen biology, the Institute aims to advance diagnostic, prevention, and treatment strategies for these diseases. Through cutting-edge research and collaboration, NIAID is committed to translating scientific discoveries into tangible health benefits for those affected by infectious and immune-mediated diseases.

The NIAID Division of AIDS (DAIDS) aims to advance and apply knowledge of Human Immunodeficiency Virus (HIV)/ Acquired Immune Deficiency Syndrome (AIDS) to end the HIV epidemic through the development of safe and effective prevention, treatment, and cure strategies. The search for new HIV drugs remains a priority due to emerging resistance to existing treatments and the side effects of some current medications. DAIDS supports basic and clinical research to identify novel strategies to affect durable viral suppression, prevent HIV from infecting cells and replicating in the body, as well as preclinical and clinical research to develop novel antiretroviral therapeutics and diagnostic platforms. Priority focus areas include novel HIV treatments, strategies to cure HIV, antiretroviral drug resistance, and diagnostics and biomarkers for HIV. These priorities also expand to major co-occurring conditions in people living with HIV, including tuberculosis, viral hepatitis and non-infectious co-morbidities such as accelerated aging, type 2 diabetes, and cardiovascular disease.

The NIAID supports resources and services to assist academic, small business, and other investigators, including contracts that provide or make available research materials, *in vitro* drug screening, chemical synthesis including small scale current Good Manufacturing Practice (cGMP) synthesis, small animal efficacy models, testing, drug formulation, preclinical pharmacology and toxicology, and other discovery and preclinical services to aid the advancement of promising agents and diagnostics from bench to clinics. Over the past years, these contract activities have helped investigators to obtain critical data and materials to attract additional funding, gain prospective partnerships, fulfill regulatory requirements, and complete studies before entering clinical trials.

Some of these activities are currently being provided under thirteen NIAID "Preclinical Services for HIV Therapeutics" Indefinite Delivery/Indefinite Quantity contracts as follows:

- 75N93021D00001 with SRI International (Menlo Park, CA)
- 75N93021D00002 with Alchem Laboratories Corp (Alachua, FL)
- 75N93021D00003 with University of North Carolina at Chapel Hill (Chapel Hill, NC)
- 75N93021D00004 with Research Triangle Institute (Durham, NC)
- 75N93021D00005 with Starks Associates, Inc. (Buffalo, NY)
- 75N93021D00006 with University of Nebraska Medical Center (Omaha, NE)
- 75N93021D00007 with Lovelace Biomedical and Environmental Research Institute, Inc. (Albuquerque, NM)
- 75N93021D00009 with Creagen Inc. (Woburn, MA)
- 75N93021D00010 with Southern Research Institute (Birmingham, AL)
- 75N93021D00011 with University of Texas Medical Branch at Galveston (Galveston, TX)
- 75N93021D00013 with The University of Iowa (University of Iowa Pharmaceuticals; Iowa City, IA)
- 75N93021D00014 with Colorado State University (Fort Collins, CO)
- 75N93021D00015 with Rutgers, The State University of New Jersey (Newark, NJ)

The Government intends to solicit these services as Indefinite Delivery /Indefinite Quantity (IDIQ) multiple contract awards. The majority of activities under these awards will support preclinical research and product development for HIV therapeutics and diagnostics. The Government also anticipates potential work for the development of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and *Mycobacterium tuberculosis* therapeutics and diagnostics and reserves the right to include requirements for the development of vaccines, prevention strategies, and diagnostic products for HIV and other infectious diseases to meet emerging public health needs.

Task Orders will be issued in the following Task Areas:

- *In Vitro* Testing and Screening Resource for Therapeutics (Task Area A)
- Synthesis of Therapeutic Agents for Treatment of Infectious Diseases (Task Area B)
- Efficacy Models for Human Immunodeficiency Virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) (Task Area C)
- Efficacy Models of *Mycobacterium* infection (Task Area D)
- Formulation Development and Manufacture of Clinical Dosage Forms (Task Area E)
- Preclinical Pharmacology and Toxicology Services (Task Area F)
- Diagnostic Development Services (Task Area G)

It is anticipated that NIAID will award Base contracts to one or multiple contractors for each of the Task Areas listed (A, B, C, D, E, F, and G).

Purpose and Objectives

The purpose of the proposed Indefinite Delivery/Indefinite Quantity contracts is to provide the extramural scientific community with research materials and preclinical product development support for candidate products that emerge from investigator-initiated research studies or from collaborations with private sector or academic partners. The scope of work encompasses activities that range from basic research and initial product discovery to activities required for clinical trials and/or product licensure. These services may also be used to support product discovery and development leading to Investigational New Drug Application (IND), Investigational Device Exemption (IDE), and/or New Drug Application (NDA) filings

with the United States (U.S.) Food and Drug Administration (FDA). NIAID will primarily use these contracts to fill critical development and resource gaps more rapidly and efficiently and advance promising products into clinical testing. Although the focus of these contracts will be development of therapeutic products for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and *Mycobacterium tuberculosis* (MTB) complex, as well as providing diagnostic development resources, at the discretion of NIAID, these contracts may also be used to advance vaccines, antivirals, and preventive strategies for these and other infectious diseases. Throughout this Sources Sought Notice, these candidate products and/or strategies will collectively be referenced as "products."

Throughout this contract, preclinical (i.e., undertaken before testing in humans) and nonclinical (i.e., undertaken to address specific regulatory requirements during clinical testing) studies will collectively be referenced as "preclinical".

A. Scope

The Contractor shall provide preclinical development services for candidate therapeutic or diagnostic products. The scope of work encompasses activities that range from initial product discovery to those required to support clinical trials and/or product licensure. The contract also provides for the acquisition and distribution of research materials in support of basic, drug discovery, diagnostic development, and translational research.

This IDIQ contract will be administered and used primarily to support the NIAID, Division of AIDS (DAIDS) Basic Sciences and Therapeutics Research Programs to advance basic and pre-clinical research associated with therapeutic and diagnostic product development for HIV, tuberculosis (TB) and hepatitis B and C. However, other NIAID programs may initiate Task Orders under this contract as necessary to help accomplish their mission.

NOTE: This contract will not provide funds to support clinical trials.

B. General Technical Requirements:

The following requirements shall apply to all Task Orders, as applicable:

1. Intellectual Property

   As applicable and upon direction of the Contracting Officer's Representative (COR), the Contractor shall ensure the protection of third-party intellectual property, information provided by third parties or by the Government, as well as data generated through this contract. Information shall be deemed as proprietary and shall not be used or distributed without the expressed consent from the third party or as authorized in Agreements between NIAID and the provider.

   The Contractor shall develop a plan for how intellectual property will be handled, as well as the disposition of data and/or materials developed under Task Orders. This includes any intellectual property that may pre-exist or be developed during performance of work. Included in the plan shall be the assignment of such rights and obtaining concurrence from any interested parties, including maintenance of security for confidential and/or proprietary data. A copy of the plan shall be provided to the COR within 30 days of initiation of the Task Order. The Contractor shall also consult and coordinate with the third-party providers of proprietary materials or data throughout the development process and complete a material transfer agreement with the third-party provider, if needed.

2. Technology Transfer

   As required by the Task Order and as specified by the COR, the Contractor shall prepare and

submit to the COR for review and approval, technology transfer packages for the transfer of assays, processes, methods, Standard Operating Procedures (SOPs), reagents, animal models, and/or any other material or documentation generated under the contract, to any third party designated by the COR, or directly to the COR. The technology transfer packages may include material, reagents, and training of others at the Contractor's or Subcontractors' site. All technology transfer packages must be sufficient to completely and effectively transfer the technology.

3. Document and Data Management
   The Contractor shall provide an Information Technology (IT) system infrastructure to meet the requirements outlined below and institute such systems as required to transfer required and/or specified data materials to a database designated by the COR.

   a. Provide and maintain a secure document and data management system that supports all data types generated by, or related to, the requirements of the contract and submit documents and data in an electronic format specified by the COR to a Government-owned, secure database. Some or all the data may be transferred into the NIAID data management system.

   b. If a Task Order requires the development and maintenance of a database, the Government reserves the right to have complete access, provide access to third parties, and to transfer all rights and custody to a successor contractor.

   c. Maintain the computerized system security documentation as required by Office of Management and Budget (OMB) Circular A- 130, Appendix III and the Federal Information Security Management Act (FISMA). This requirement shall include a comprehensive assessment of the management, operational, and technical security controls in the system to determine the extent to which the controls are implemented correctly, operating as intended, and producing the desired outcome with respect to meeting a specified set of security requirements for the system. These actions are referred to as System Assessment and Authorization (SA&A). The NIAID Information System Security Officer (ISSO) performs the Assessment to support the NIAID Chief Information Officer decision to authorize operation of an information system and to explicitly accept the risk to NIAID data based on the implementation of an agreed-upon set of security controls.

   d. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: https://www.hhs.gov/accessibility/index.html.

   e. Written communications shall be electronic. The Contractor shall minimize the use of paper documents and paper information distribution to the greatest extent possible. Paper documentation shall be used only when required by federal, state, local or international law or where validated electronic systems are not available. The duration of electronic documentation storage is as required by regulation.

   f. NIAID reserves the right to maintain backup data storage at NIAID facilities. Transfer of data to NIAID shall occur on an as-needed basis as described in individual Task Orders.

4. Material Receipt, Storage, Shipping, and Inventory

a. Develop and maintain effective procedures to support contract activities for receiving, storing, shipping and inventory of products (i.e., Active Pharmaceutical Ingredients (APIs), formulations, or investigative drug products), pathogens (e.g., HIV, Simian immunodeficiency virus (SIV), HBV, HCV, TB, etc.), human and animal specimens (e.g., biological cells, fluids, tissues, etc.), and reagents (e.g., common assay controls, kit components, etc.); including the secure, safe, and stable storage of these contract materials under the required conditions (e.g., Biosafety Level, aseptic, controlled temperature, Good Laboratory Practice (GLP) or current Good Manufacturing Practice (cGMP), etc.) and according to specifications provided by the supplier, as applicable.

b. Obtain and maintain the appropriate licenses and permits required by international, federal, state, and local authorities for the safe storage and shipping, of products, drugs, biologics, pathogens, specimens and reagents for the safe import or export, storage, handling, transportation, and distribution.

c. Provide for safe packing, labeling, and shipment of products, pathogens, specimens and reagents, so that shipments are coordinated for timely receipt.

d. Provide shipping containers that comply with domestic and international postal requirements, and pertinent International Air Transport Association (www.iata.org); and the International Civil Aviation Organization (www.icao.int) requirements. The shipping containers shall provide safety for maintaining appropriate environmental safeguards and desired temperatures for specific products in transit, depending on the mode of transportation employed.

e. Establish and maintain an electronic inventory of specific contract materials as designated by the COR or in the Task Order Statement of Work (SOW), such as in an Excel spreadsheet or database, that includes searchable information, such as compound identifiers, amounts available, storage locations, shipping data and other biological and chemical characteristics of the materials, source and relevant material transfer agreements, or animal inventories and animal data.

5. Regulatory Compliance
When required, all activities supporting specific regulatory requirements shall be conducted in compliance with Good Laboratory Practice (GLP; 21 CFR 58), current Good Manufacturing Practice (cGMP; 21 CFR 210-211), International Conference on Harmonization (ICH) guidelines, or other local, state, Federal, or non-U.S. product quality development regulations. For FDA submissions, this shall require performance of studies at a level of quality that is sufficient for incorporation into pre-IND, IND, IDE, and NDA documents. Although studies that support product development outside of regulatory requirements (i.e., non-GLP or non-cGMP) may also be performed, the resulting data, processes and data/record keeping shall be well-documented and of sufficient quality to be acceptable for inclusion in an IND/IDE/NDA filing.

When applicable, the preclinical development services should meet the FDA recommended preclinical requirements for the product (e.g. for antiviral products: Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency).

6. Site Visits
If required in the Task Order Statement of Work, arrange for and conduct site visits (e.g., study initiation, interim, or termination visits) for Contractor and subcontractor staff, NIAID

staff, contract consultants, and/or other third-party individuals designated by the COR to review and discuss activities related to the Task Order SOW.

The following types of discussions may occur in these meetings, but other topics may be included as specified by the COR or in the Task Order SOW: project progress; approaches to overcoming identified problems and obstacles; recommendations for modifications to project timelines, objectives, and research approaches and methodologies based on outcomes to date; future plans; and financial issues.

7. Quality Assurance/Quality Control (QA/QC)
   a. The Contractor shall have and implement a written Quality Plan and program to monitor all operations and processes, develop, implement and evaluate SOPs; define metrics to assess performance; specify methods to identify and address deficiencies and resolution of issues; and for QA training of staff. Project-specific QA/QC requirements will be specified in each Task Order.

   b. The COR may require an external audit of the QA/QC infrastructure before awarding a Task Order. The COR may authorize, at any time during the contract period of performance, independent audits of the Contractor with one (1) week advance notice of the scheduled audit. For-cause audits or IND file audits may be performed at any time and without advance notice to the Contractor. The Contractor shall comply with audits authorized by the COR.

   c. When applicable and as required by the Task Order, the Contractor shall implement and have in place the appropriate QA/QC infrastructure (facilities, processes and training) to ensure compliance with GLP and cGMP regulations. When performance under strict GLP/cGMP is not possible, sufficient QA/QC shall be performed and documented to ensure that all data is acceptable for inclusion in an IND/NDA filing.

   d. QA/QC infrastructure must include SOPs for establishing and maintaining the QA/QC processes and approaches and/or methods to document, identify the source(s) for, and address problems and deviations as they occur, as well as recommendations for the resolution of problems and correction of deviations.

   e. Maintain a system for quality control of data.

8. Biocontainment Facilities and Safety
   As required for all studies conducted under these Task Areas, the Contractor shall:

   Provide safe facilities and resources and conduct work with hazardous biological materials in compliance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, guideline available at: https://www.cdc.gov/labs/bmbl/index.html.

   Where applicable, address conflicts between biosafety and clean facility requirements.

9. Acquisition, Care, and Housing of Animals

   As required for all animal studies conducted under these Task Areas, the Contractor shall:

   a. Comply with all applicable laws, policies, and guidelines regarding the care and use of laboratory animals, including the PHS Policy on the Human Care and Use of Laboratory

Animals (http://grants1.nih.gov/grants/olaw/references/phspol.htm).

b. Provide routine care and health surveillance or laboratory animals including on-call veterinary coverage 24 hours per day, seven days per week. Provide at least daily observations of the health status of each animal, including weekends and holidays.

c. Record and maintain detailed records on the health status of each animal, including clinical observations and testing, any treatments received, the results of periodic weighing and any other care or procedures required during the contract.

Project requirements

Contractors will carry out Task Orders in one or more of the following Task Areas:

A. **Task Area A: *In Vitro* Testing and Screening Resource for Therapeutics**

Scope for Task Area A: Under this Task Area, the Contractor shall conduct *in vitro* evaluation of potential anti-viral therapeutic agents that block infection, inhibit gene expression and replication, or eliminate infected cells. The studies will include confirmatory and specialized *in vitro* testing using assays in standard (i.e., up to 96 wells per plate) and high throughput screening (HTS) formats (i.e., greater than 96 wells per plate). New *in vitro* assays, including New Approach Methodologies (NAMs) such as organoids or microphysiological systems for HIV pathogenesis and cure shall be developed, or transferred from third parties, and validated as needed to identify, or confirm, the activity of potential therapeutics. The Contractor shall conduct lead identification and optimization. The primary focus of this Task Area shall address HIV targets. NIAID may elect screening for HBV or HCV and/or other infectious diseases of relevance to the research agenda of NIAID.

Requirements for Task Area A: Under this Task Area, the Contractor shall conduct *in vitro* assays in standard and HTS formats to evaluate the potential of anti-viral therapeutic agents. The interventional agents used shall include, for example, small molecules, peptides, oligonucleotides, biologics, polymers, or other substances. These assays shall be developed directly by the Contractor or transferred to the Contractor from a third party specified by the COR. State-of-the-art techniques and technologies shall be used with emphasis on under-represented targets.

The specific services shall include but are not limited to:

1. Conduct confirmatory and specialized *in vitro* testing and screening of interventional agents in standard formats. The Contractor shall confirm the putative activity of interventional agents that are purchased by the Contractor or provided by the COR. Cells to be used shall be of human or mammalian origin and shall include established cell lines as well as primary cells from blood and tissue.

2. Develop, or transfer from third parties, *in vitro* assays and validate the assays as needed to identify or confirm the activity of potential therapeutics. Use state-of-the-art techniques and technologies with emphasis on under-represented targets.

3. Provide an approach to select compound libraries needed to support HTS format screening.

4. Acquire and store a library of approximately 100,000 chemical compounds to support HTS format screening.

5. Perform HTS on at least 700,000 compounds per year in cell based or biochemical assays. Activities shall include adapting standard format assays to a HTS format, plating of compound libraries for use in HTS studies, and utilizing state-of- the-art systems to perform HTS using a single compound concentration in cell-based or biochemical assays. The Contractor shall confirm all hits by dose-response evaluation in the primary assay. The Contractor shall perform confirmatory testing of anti-viral activity in continuous or primary cell types.

6. Conduct lead identification and optimization studies using *in vitro* screening and cytotoxicity studies with the objective of identifying and characterizing agents with anti-viral activity. The hit-to-lead progression studies should include one, or all, of the following activities:
    a. Analyze compound structures.
    b. Design a lead optimization scheme (LOS) for generating chemical analogues based on specific structural scaffolds of leads.
    c. Conduct structure activity relationship (SAR) studies to identify analogs of the interventional agents for subsequent lead optimization activities.
    d. Procure or synthesize chemical analogues of a selected lead compound to improve pharmacological properties.
    e. Conduct assays to determine absorption, distribution, metabolism, and excretion (ADME) characteristics.
    f. Perform optimization of chemical leads to improve a specific physiochemical or pharmacological property, such as solubility, bioavailability or metabolism.
    g. Conduct mechanism of action (MOA) studies.
    h. Conduct *in vitro* studies to determine toxic properties.
    i. Perform *in vitro* safety pharmacology evaluations.

B. **Task Area B: Synthesis of Therapeutic Agents for Treatment of Infectious Diseases**

Scope for Task Area B: The scope of this effort is small scale synthesis of compounds in quantities required for testing in either *in vitro* assays or in animals, and large scale synthesis of compounds for early Phase I clinical studies. Some compounds will require synthesis in compliance with current Good Manufacturing Practices (cGMP) regulations. This contract will provide resources for the synthesis of promising compounds for the treatment of HIV, TB, hepatitis B and C, and other infectious diseases of relevance to the research agenda of NIAID.

Requirements for Task Area B: Under this Task Area, the Contractor shall:

1. Acquire or conduct synthesis of small scale (10mg - 10g) and large (10-1000g) batches of compounds of purity greater than 95 percent for subsequent biological and biochemical analyses, *in vitro* and *in vivo* testing. Compounds will be candidates for treatment of infectious disease and may include but are not limited to antiviral or antimicrobial agents and immune regulatory molecules (e.g., host-directed therapeutics (HDTs)). The focus of this Task Area will be for the synthesis of small molecules. When requested, the Contractor shall develop experimental design(s) and methodology for synthesis and/or analytics and identify or develop specific route(s) or procedure(s) for synthesis of compounds.

2. When requested, the Contractor shall conduct synthesis of compounds for use in human subjects or laboratory animals requiring full cGMP compliance. Upon completion of the studies, the Contractor shall provide the reports and documentation to support regulatory submissions and shall be fully compliant with cGMP manufacturing regulations and standards (refer to Guidance Documents Q7, Q8, Q9, Q10, and Q11 of ICH) and must maintain all the facilities, procedures, and documentation in compliance with cGMP.

3. Purify and/or characterize compounds or therapeutic agents for purity, perform chemical screens for physiochemical properties, confirm chemical identity and purity of compounds by established methods such as 1H-nuclear magnetic resonance (NMR), infrared (IR) and ultraviolet- visible (UV-VIS) spectroscopy, and elemental analysis. When requested, methods shall include mass spectroscopy (MS), 13C NMR, optical purity, or high-performance liquid chromatography (HPLC)-UV or HPLC-MS chromatography.

4. As applicable, develop and/or provide data sheets and preparative methods, provide Material Safety Data Sheets (MSDS) for all compounds and maintain documentation needed for regulatory requirements.

C. **Task Area C: Efficacy Models for HIV, HBV and HCV**:

Minimum requirement: Biosafety Level 2 (BSL-2) and Animal Biosafety Level 2 (ABSL-2) facilities and Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) full accreditation.

Scope for Task Area C: The Contractor shall provide and refine or improve small animal models for HIV, HBV, and HCV and perform testing of single products or combinations of products in these animal models. This Task Area also includes other activities associated with small animal studies, such as obtaining and/or shipping biosamples, endpoint assays, histopathology, data documentation, and reports, etc. Primates are excluded from this Task Area. The use of *ex vivo* tissue models or other New Approach Methodologies (NAMs) to supplement animal studies is also within scope.

Requirements for Task Area C: The Contractor shall conduct small animal studies for testing of products related to the treatment, cure, or prevention of HIV, HBV, and/or HCV. Facilities shall be compliant with Biosafety Level 2 (BSL-2) and Animal Biosafety Level 2 (ABSL-2) requirements (https://www.cdc.gov/labs/bmbl/index.html) and have current full Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation. Test products will be either provided by the Government or third parties to the Contractor or shall be acquired by the Contractor as specified by the Task Order.

Specifically, the Contractor shall conduct pharmacokinetic (PK), safety, and efficacy studies in animal models of HIV, HBV, HCV in order to characterize products, inform dose selection, optimize formulations, and/or obtain other information necessary to advance or support product testing in subsequent animal or human studies. *Ex vivo* tissue models or other NAMs may be employed to help bridge results between the animal models used and potential outcome in humans.

The Contractor shall provide:

- Humanized small laboratory animals that support productive HIV, HBV and/or HCV infection.
- Unengrafted mice for PK/PD and toxicology studies.

Other models, such as *ex vivo* tissue models, NAMs, or humanized rat models are desired, but not required.

Task Orders may include up to approximately 1,000 animals, with numbers dependent upon the species and the study to be conducted. The animal species and models chosen (e.g., conventional mice, humanized knock out and knock in mouse strains, conventional and transgenic (humanized) rats, guinea pigs, and/or laboratory rabbit varieties) shall be appropriate for the proposed study. Other small animal models of similar size to rabbits and rodents are also permitted upon approval of the Contracting Officer's Representative (COR). Animal studies should be conducted as outlined under the National Institutes of Health, Office of Laboratory Animal Welfare, Policies and Laws (https://olaw.nih.gov/policies-laws). Non-human primates are excluded from this Task Area.

Tissue acquisition must be in compliance with federal, state, and local laws and regulations as well as current Department of Health and Human Services requirements and NIH policies. The Contractor shall assure that humanized animals, *ex vivo* tissue models and NAMs meet accepted model standards and/or study-specific or Task Order-specific standards for creating the humanized model (e.g., degree of engraftment of human cells and susceptibility to infection).

The Contractor shall:

1. Perform confirmatory *in vitro* assays of products to be assessed in the small animal model including *in vitro* cytotoxicity assessments to determine the therapeutic index.

2. Provide and/or refine and/or improve small animal models of HIV, HBV, and/or HCV.

3. Assess mainly therapeutics, but also vaccines, other prophylactic methods, and diagnostics for use against HIV, HBV, and HCV in small animal models.

4. Evaluate clinical manifestations, body weight, complete blood counts, and serum chemistries to determine the health of the animals.

5. Develop, standardize, and validate assays and assay components to support animal model improvement and *in vivo* product evaluation.

6. Characterize (e.g., purity, sterility, identity, concentration/titer, stability) and distribute reagents and biological samples to support infectious disease research.

7. When applicable, other activities (e.g., immunology, histopathology, *in situ* hybridization, whole body and tissue imaging, etc.) may be solicited by a specific Task Order.

D. **Task Area D: Efficacy Models of *Mycobacterium* Infection**:
Minimum requirement: Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) facility and Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation.

Scope for Task Area D: The Contractor shall provide and refine or improve small animal models for MTB complex, Nontuberculous mycobacteria (NTM), and/or HIV/MTB co-infections, and perform testing of single products or combinations of products in these animal models. The primary focus will be efficacy models for MTB. This task area also includes other

activities associated with small animal or other efficacy studies, such as obtaining and/or shipping biosamples, endpoint assays, histopathology, data documentation, and reports, etc. Nonhuman Primates are excluded from this Task Area. The use of *ex vivo* tissue models or other New Approach Methodologies (NAMs) to supplement animal studies is also within scope.

Requirements for Task Area D: The Contractor shall provide services and conduct studies to support the evaluation of potential therapeutic agents against MTB in small animal models. Task Orders on NTM and/or HIV/MTB may be issued under this Task Area as well. The therapeutic agents will be either provided by the Government or third parties to the Contractor or shall be acquired by the Contractor as specified by the Task Order. Facilities shall be compliant with BSL-3 and ABSL-3 requirements (https://www.cdc.gov/labs/bmbl/index.html) and have current full AAALAC accreditation.

The Contractor shall:

1. Provide and optimize one or more established and/or accepted small animal models of MTB and/or HIV/MTB co-infections suitable for testing combinations of therapeutic strategies. Small animal models may include mice, rabbits, ferrets or guinea pigs for TB. Small animal models for HIV/MTB co-infection studies may include humanized small animals or small animals transgenic for HIV genes. Task Orders may include up to approximately 500 animals, but numbers will be dependent on the species and the Task Order. Aerosol challenge capabilities are preferred but not required. Animal studies should be conducted as outlined under the National Institutes of Health, Office of Laboratory Animal Welfare, Policies and Laws (https://olaw.nih.gov/policies-laws). *Ex vivo* tissue models or other NAMs may be employed to help bridge results between the animal models used and potential outcome in humans.

2. Improve existing small animal models, *ex vivo* tissue models or other NAM(s) for *Mycobacterium tuberculosis* infection and/or adapt other existing or newly developed models for use in studies under the contract.

3. Evaluate mainly TB therapeutic (for active or latent disease) candidate(s), but also vaccines, other prophylactic methods, and diagnostics alone or in combination with other products for efficacy and toxicity in an appropriate small animal model for TB or HIV/TB. Products shall be administered using a variety of routes including oral, parenteral, and/or aerosol. Obtain appropriate body fluid or tissue samples for evaluation (e.g., to allow for pharmacokinetics and pharmacodynamics studies, measure viral or bacterial burden or cellular markers).

4. Evaluate clinical manifestations, body weight, complete blood counts, and serum chemistries to determine the health of the animals.

5. Provide histopathologic examinations of selected tissues to determine the extent of disease and/or tissue damage.

6. Provide appropriate bacterial or viral assays (e.g., quantitative cultures of tissue) for determination of the efficacy of the product intervention.

7. Perform safety and tolerability assessments of products in small animal models.

8. Perform other assays and studies as required by the Task Order, for example, but not limited to drug susceptibility testing, determination of minimum inhibitory concentration (MIC),

*r*RNA Synthesis Ratio (RS Ratio) assessments and alternative assays for determination of bacterial or viral levels.

9. Develop, standardize, and validate assays and assay components to support efficacy model improvement and product evaluation.

10. Characterize (e.g., purity, sterility, identity, concentration and/or titer, stability) and distribute reagents and biological samples to support *M. tuberculosis* research.

11. When applicable, other activities (e.g., immunological assays, detailed histopathology, whole body and tissue imaging, etc.) may be solicited by a specific Task Order.

E. **Task Area E: Formulation Development and Manufacture of Clinical Dosage Forms**:

Scope for Task Area E: The Contractor shall provide services and conduct studies to support the development of formulations of potential therapeutic agents and the manufacture of drug products that may include small-molecule drugs, multidrug combinations, and biologics. Targeted formulations shall include tablets, capsules, lyophilized powders, solutions, suspensions, aerosols, nanomaterials, etc., for oral, intravenous, subcutaneous, intramuscular, intranasal, vaginal or rectal delivery.

The Contractor shall also manufacture, package, label, release and ship final versions of these formulations intended for evaluation in clinical trials. Activities shall be performed in compliance with current Good Manufacturing Practice (cGMP) guidelines (21 CFAR 210-211) and other applicable regulatory guidelines when requested. Formulations shall be manufactured as sterile products when requested.

Requirements for Task Area E: Task Orders shall incorporate one or more of the following activities and/or studies:

1. Determine the physicochemical and stability properties of drug substances and formulated products.

2. Develop, validate, and/or perform analytical assays for characterization of active pharmaceutical ingredients (APIs) and degradation products.

3. Procure reference standards.

4. Develop and characterize formulations to meet one or more of the following: increased drug solubility, drug stability; bioavailability; enhancement of recipient's immune response to a supplied antigen; targeted drug delivery; sustained drug release; taste masking; alternate routes of administration; and/or alternate dosage strengths or physical dosage forms.

5. Evaluate the compatibility of APIs with potential formulation excipients.

6. Conduct *in vitro* drug absorption and/or permeability studies.

7. Conduct scale-up formulation development studies necessary for achieving the characteristics of targeted dosage forms for clinical manufacturing.

8. Develop and perform analytical assays to determine the identity, strength, quality, and purity of manufactured drug products that include (but are not limited to) stability indicating assays, drug release methods, and content uniformity assays.

9. Develop robust and scalable cGMP-compliant manufacturing processes and procedures, including cleaning validation of equipment.

10. Manufacture and package pharmaceutical products and placebo in compliance with cGMP guidelines.

11. Manufacture sterile bulk injectables, including broadly neutralizing antibodies (bNAbs) or other biologics, and clinical dosage forms of injectable products, in compliance with cGMP regulations.

12. Conduct product stability studies in compliance with cGMP guidelines.

13. Retain all records as required under cGMP guidelines.

14. Other specific activities in support of this Task Area as required by FDA (21 CFR 312.23(a)(7)) to advance products into clinical testing.

15. When requested by the COR, prepare reports to be included in the Chemistry, Manufacturing and Controls (CMC) section of FDA regulatory submissions.

F. **Task Area F: Preclinical Pharmacology and Toxicology Services**

Scope for Task Area F: The Contractor shall conduct studies to assess the pharmacology and toxicology of potential therapeutics. Testing shall be conducted *in vitro*, in relevant animal species, in *ex vivo* tissue models, or using other relevant New Approach Methodologies (NAMs). When requested, the studies shall be performed in compliance with Good Laboratory Practice (GLP) guidelines (21 CFR 58). The Contractor shall conduct all animal studies in a facility accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) or its equivalent.

Requirements for Task Area F: The Contractor shall conduct activities suitable to facilitate regulatory submissions and intellectual property applications of third parties and to support decision-making by the investigator and/or sponsor and the FDA. The Contractor shall conduct GLP and non-GLP studies, as appropriate. Products may include small organic molecules, polymers, or biologics (e.g., peptides, oligonucleotides, antibodies), cellular and genetic drug products (e.g., Chimeric Antigen Receptor [CAR]-T cells), sustained-release pharmaceuticals, or products with nanomaterials in their finished dosage form, and will have been selected for further development based on their potential to advance to clinical testing.

The Contractor shall conduct the following types of activities:

1. Develop, validate, and/or perform analytical assays for characterization of active pharmaceutical ingredients (APIs), degradation products, or metabolites in biological samples (e.g., plasma, blood, urine, feces, tissues).

2. Procure reference standards.

3. Evaluate stability of APIs in formulations, biological fluids, and/or tissues.

4. Conduct pharmacology studies of potential therapeutic agents including *in vitro* studies or NAMs (e.g., physiologically based pharmacokinetic [PBPK] models) to assess absorption, distribution, metabolism and excretion (ADME); and/or plasma protein binding; *in vivo* studies in mice, rats, dogs, non-human primates, and other relevant animal species to assess pharmacokinetic parameters of ADME, bioavailability and bioequivalence; potential drug interactions.

5. Conduct toxicology studies of potential therapeutic agents including *in vitro* studies or NAMs (e.g., microphysiological systems, organs-on-a-chip or PBPK models) to assess: genotoxicity; off-target toxicity profiling (e.g., mitochondrial toxicity, cardiovascular toxicity, hepatic toxicity, renal toxicity, or vasculitis); *in vivo* studies in mice, rats, dogs, non-human primates, and/or other relevant animal species to assess genotoxicity; determination of no observed adverse effect level (NOAEL); toxicity associated with single dose and repeated dose administration; local tolerance and/or irritability; reproductive toxicity, carcinogenicity, and/or immunotoxicity.

6. Conduct safety pharmacology studies of potential therapeutic agents (e.g., pharmacodynamic effects on cardiovascular, immunologic, respiratory, gastrointestinal, genitourinary, and central nervous systems).

7. Conduct toxicogenomic, proteomic, and/or metabolomic studies of potential therapeutic agents.

8. Develop new toxicology models, NAMs and test systems, such as 3-dimensional culture, hollow-fiber cell culture, or using organ-on-a-chip technology; and/or

9. Retain all records samples and histology/microscopy slides, as required under GLP guidelines.

A. **Task Area G: Diagnostic Development Services**

Scope for Task Area G: Task Area G will support the development of *in vitro* diagnostic (IVD) technologies for clinical use, including laboratory developed tests (LDT) and biomarkers, by providing technology development guidance. Technologies include, but are not limited to, methodologies for screening, diagnosis, and monitoring of HIV and related coinfections, individually or in multiplex. Technologies may also include methodologies related to the prevention or treatment of these infections, such as monitoring of drug levels in biological samples. Guidance should be suitable for the intended use of the technology and the appropriate regulatory pathway. Guidance may include advising on the phases of IVD development, such as planning, design, development, verification, validation, and manufacture, as applicable; it may include advising on design control processes, such as quality management systems, document control, systems integration, and product stability; it may include preparation for clinical studies; or it may include regulatory strategy and planning. Task Area G will not support the conduct of laboratory or clinical evaluations and will not support the preparation or submission of documents to a regulatory agency.

Requirements for Task Area G: Task Orders shall incorporate one or more of the following activities:

As directed by the COR:

1. The Contractor shall review the current status for, and overall scientific feasibility of, the development of an IVD for clinical use.

2. The Contractor shall review the product development progress and sufficiency of proposed activities for future development of an IVD towards regulatory approval.

3. The Contractor shall review the technology developer's systems and documents and advise on strengths and opportunities to support adherence to GCP, GLP, GMP or international regulations (e.g., from the European Medicines Agency (EMA), United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), Health Canada, etc.).

4. The Contractor shall generate an IVD Development Plan and estimated budget for implementation for a candidate technology to obtain approval for clinical use through the United States (U.S.) Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), or non-domestic regulatory authority.

5. The Contractor shall include in the IVD Development Plan, as necessary but not limited to, guidance on:
   a. end-user requirements, design goals, and regulatory strategy;
   b. quality control and quality management systems, design traceability and risk management;
   c. process and feasibility for manufacturing activities to be undertaken for a product;
   d. analytical verification and validation;
   e. or clinical validation planning.

6. The Contractor shall provide an anticipated minimum timeline for completion of tasks related to the activity and progress reports via the use of Gantt charts or other appropriate project management tools.

Anticipated period of performance

It is anticipated that multiple Indefinite Delivery/Indefinite Quantity (ID/IQ) type contracts will be awarded on or about February 15, 2028, for a period of 7 years, through February 14, 2035. Task Orders to be issued against the Base contracts will primarily be cost-reimbursement type, both term and completion form. The Government reserves the right, however, to issue fixed-price type Task Orders, when appropriate.

The Government anticipates awarding the following number of Task Orders each year. This list is provided to indicate the general scope of work of this contract and should be considered an estimate only.

Task Area	Title	Estimated No. of Task Orders Per Year
A	*In Vitro* Testing and Screening Resource for Therapeutics	6
B	Synthesis of Therapeutic Agents for Treatment of Infectious Diseases	2
C	Efficacy Models for HIV, HBV, and HCV	2
D	Efficacy Models of *Mycobacterium* infection	2

E	Formulation Development and Manufacture of Clinical Dosage Forms	1
F	Preclinical Pharmacology and Toxicology Services	3
G	Diagnostic Development Services	2

Capability statement/information sought

Offerors may respond to one Task Area only, to several Task Areas, or to all Task Areas.

Interested contractors must submit individual capability statements for each Task Area (ten page limitation per Task Area, excluding resumes) describing their company's experience and ability to perform this effort, which includes the following: (1) a summary list of similar work previously performed; (2) the professional qualifications and specific experience of staff who may be assigned to the requirement; (3) resumes for proposed key personnel, including the Principal Investigator, which reflect education, and previous work relevant to the proposed requirement; (4) a general description of the facilities and other resources needed to perform the work; and (5) demonstrated ability to carry out the work.

Capability statements submitted as a result of this announcement should demonstrate the Offeror's qualifications, expertise and experience, specifically providing evidence as to the capability to perform this requirement. Capability Statements should clearly convey information regarding the respondent's capabilities, including: (a) staff expertise, including their availability, experience, and formal and other training; (b) current in-house capability and capacity to perform the work; (c) prior completed projects of similar nature; (d) corporate experience and management capability; and (e) examples of prior completed Government contracts, references, and other related information.

NIAID recognizes that no single organization or institution may have the expertise and facilities required to perform all the tasks mentioned above. Therefore, the Contractor may need to utilize the expertise and resources of subcontractors and specialized consultants to provide the full spectrum of requested activities. The Contractor shall be responsible for ALL work performed under this contract, including that performed by any subcontractors and consultants. The Contractor shall ensure that any and all processes meet international, federal, local and state regulations to ensure the continuity and validity of the resulting product.

Page Limitations:

Interested qualified small business organizations should submit a tailored Capability Statement, not to exceed ten (10) pages per Task Area, excluding resumes. Offerors may respond to one Task Area only, to several Task Areas, or to all Task Areas. Capability Statements must not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information. Font size must be 10 to 12 points. Spacing must be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text. Print margins must be at least one-inch on each edge of the paper. Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe). All proprietary information should be marked as such.

Required Business Information:

Each response should include the following Business Information:

- UEI number.
- Company Name.
- Company Address.
- Company Point of Contact, Phone and Email address
- Current GSA Schedules and/or Government-wide Acquisition Contracts (GWACs) appropriate to this Sources Sought.
- Do you have a Government approved accounting system? If so, please identify the agency that approved the system.
- Type of Company (i.e., small business, 8(a), woman owned, veteran owned, etc.) as validated via the System for Award Management (SAM) located at https://sam.gov/content/home. This indication should be clearly marked on the first page of your Capability Statement (preferable placed under the eligible small business concern's name and address).

Teaming Arrangements: All teaming arrangements should also include the above-cited information and certification for each entity on the proposed team. Teaming arrangements are encouraged.

Number of Copies:

Please submit one (1) electric copy of your response as follows:

All Capability Statements sent in response to this Small Business Sources Sought notice must be submitted electronically (via e-mail) to Patrick Finn, Contracting Officer at patrick.finn@nih.gov in MS Word or Adobe Portable Document Format (PDF). The e-mail subject line must specify SBSS75N93026R00015. Facsimile responses will not be accepted.

Common Cut-off Date:

Electronically submitted tailored capability statements are due no later than **3:00 PM (Eastern Prevailing Time) on 08/25/2026.** ***CAPABILITY STATEMENTS RECEIVED AFTER THIS DATE AND TIME WILL NOT BE CONSIDERED.***

Disclaimer and Important Notes

This notice does not obligate the Government to award an IDIQ contract or Task Order or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published at SAM.gov. However, responses to this notice will not be considered adequate responses to a solicitation.

The Government will not entertain questions regarding this Market Research; however, general questions may be emailed to the following address:

Contracting Officer: Patrick Finn

Email Address: patrick.finn@nih.gov

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.