



Dear Potential Offerors:

BARDA is releasing an RFP in support of the Biological Capabilities of the Nonclinical Studies Network. Through this RFP, BARDA seeks to acquire services in three separate areas:

1. Animal Model Testing
2. Analytical Services
3. Toxicology Services

Offerors may submit proposals for any single, combination or all three areas. Please note Offerors must submit a separate proposal for each area of interest. An Offeror IS NOT required to submit proposals in all three areas.

The purpose of this the IDIQ contract is to maintain a network of GLP laboratories that will provide capability for nonclinical animal studies, analytical services, and toxicology services in support of the BARDA portfolio.



## FEDERAL BUSINESS OPPORTUNITIES PRESOLICITATION NOTICE

### Title

BARDA Biological Animal Model Development

### General Information

Document Type:	Presolicitation Notice
Solicitation Number:	RFP-16-100-SOL-00008
Posted Date:	TBD
Classification Code:	A – Research & Development
NAICS Code:	541 – Professional, Scientific, and Technical Services/541711 - Research and Development in Biotechnology

### Contracting Office Address

Office of the Assistant Secretary for Preparedness & Response (ASPR)  
Department of Health and Human Services  
330 Independence Ave. SW G640  
Washington, District of Columbia 20201  
United States

### Description

Within the Federal government, the Department of Health and Human Services (HHS) is tasked with protecting the civilian population by providing leadership in research, development, acquisition, deployment, and use of effective medical countermeasures for the adverse health effects resulting from intentional exposure to CBRN threat agents, pandemics and emerging infectious disease threats.

HHS, through the interagency Public Health Emergency and Medical Countermeasure Enterprise (PHEMCE) is responsible for the integration of requirements for the advanced development and procurement of medical countermeasures for CBRN, pandemic influenza and emerging infectious disease threats. The 2014 HHS PHEMCE Strategy and Implementation Plan describes the strategic policy goals and objectives for identifying requirements and establishes the priorities for the development of the medical countermeasures against chemical, biological, radiological, and nuclear threats, pandemic influenza and emerging infectious diseases.

The Nonclinical Studies Network is a key element in the successful development of medical countermeasures for biological threats, particularly since efficacy of products directed against most of these threats cannot be verified using clinical studies. The United States Government (USG) therefore seeks appropriate Good Laboratory Practices (GLP) facilities that are adequate and available to support establishing new or existing animal tests and/or models for the development of Biological Medical Countermeasures (MCMs) against biological threats, influenza and emerging infectious diseases.

The United States Government (USG) seeks to maintain a network of GLP laboratories that will provide capability for nonclinical animal studies, analytical services, and toxicology services in support of the BARDA portfolio. In these models, the challenge dose generally should be the same as that which produces the human disease or condition and the pathophysiological mechanism of its toxicity should be reasonably well-understood and mimic the human disease/condition as closely as possible. When these models are used to test the efficacy of potential MCMs for CRN agents, the mechanism of action of the countermeasure will need to establish the utility of the animal model as a surrogate for humans. BARDA anticipates that contracts awarded from this RFP will serve to facilitate the animal model development of medical countermeasures and/or supportive reagents and assays for regulatory acceptance in the U.S.

HHS, through ASPR and BARDA, anticipates 9-12 contract awards will be made to establish capabilities in toxicology, analytical services and nonclinical (animal) testing through Indefinite Delivery Indefinite Quantity (IDIQ) contracts. The anticipated period of performance for any resultant contracts will be for a total of up to 60 months. Additional details and requirements will be described in the solicitation. Offeror's will be required to respond to Sample Request for Task Order Response (RTOR) documents as part of their proposal.

### **Mandatory Criteria for Eligibility**

Offerors must meet the following mandatory criterion for eligibility for an **Analytical Services** award:

1. **GLP Capabilities:** To demonstrate compliance with the mandatory requirement to have existing GLP capabilities, the Offeror must have at least one completed GLP study. Provide a list of all GLP studies conducted in the past three years. (Confidential information can be redacted.)

Offerors must meet the following mandatory criterion for eligibility for an **Animal Model Testing** award:

1. **GLP Capabilities:** To demonstrate compliance with the mandatory requirement to have existing GLP capabilities, the Offeror must have at least one completed GLP study. Provide a list of all GLP studies conducted in the past three years. (Confidential information can be redacted.)
2. The Offeror shall be a part of the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation or equivalent. The Offeror shall provide evidence of these required licenses.
3. The Offeror shall have a U.S. Department of Agriculture (USDA) animal research facility license, or equivalent. The Offeror shall provide evidence of having a USDA licensed facility or equivalent (OLAW Assurance).

4. The Offeror shall have Federal, State, and/or local licenses as required for the storage, use, and disposal of select agents and training of all associated staff responsible for the use of such material. The Offeror shall provide documentation of CDC/USDA Select Agent registration.

Offerors must meet the following mandatory criterion for eligibility for a **Toxicology Services** award:

1. **GLP Capabilities:** To demonstrate compliance with the mandatory requirement to have existing GLP capabilities, the Offeror must have at least one completed GLP study. Provide a list of all GLP studies conducted in the past three years. (Confidential information can be redacted.)
2. The Offeror shall be a part of the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation or equivalent. The Offeror shall provide evidence of these required licenses.
3. The Offeror shall have a U.S. Department of Agriculture (USDA) animal research facility license, or equivalent. The Offeror shall provide evidence of having a USDA licensed facility or equivalent.(OLAW Assurance).

### **Pre-solicitation Notice Objective**

This Pre-solicitation Notice is issued pursuant to FAR Subpart 5.2. It does not constitute a Request for Proposal (RFP) or a promise to issue an RFP in the future. This Pre-solicitation Notice does not commit the Government to contract for any supply or service whatsoever. Further, AMCG is not at this time seeking proposals, and will not accept unsolicited proposals.

It is anticipated that an RFP will be available electronically through the FedBizOpps website on or about February 15, 2016, with proposals being due on or about March 29, 2016. Any responsible offeror may submit a proposal that will be considered by the Government. It is the offeror's responsibility to monitor this internet site ([www.fbo.gov](http://www.fbo.gov)) for the release of this solicitation as well as any amendments. Potential offerors will be responsible for downloading their own copy of the solicitation and any amendments via this website. No collect calls will be accepted. No facsimile transmissions will be accepted. All responses should be identified with the RFP number, name of firm, size standard of the firm, name of requestor, mailing address, telephone number, fax number, and email address, and should be submitted to the Point of Contact(s) identified in this notice.

Multiple awards may result from this solicitation with an estimated award date in June 2016.

Furthermore, all respondents must be registered in the System for Award Management (SAM) <https://www.sam.gov> and have their records updated in the Central Contractor Registry (CCR).

### **Point of Contact**

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