Center for the Biomedical Advanced Research and Development Authority (BARDA)

Administration for Strategic Preparedness & Response (ASPR)

U.S. Department of Health and Human Services (HHS)

Request for Information (RFI) for

"Biosafety Level 4 Preclinical and Nonclinical Support for Medical Countermeasure Development (BSL4)"

Issued: July 9, 2026

Responses Due: July 24, 2026, by 1pm ET

Center for the Biomedical Advanced Research and Development Authority (BARDA)

Contracts Management & Acquisition (CMA)

400 7th Street, SW, Washington, DC 20024

MedicalCountermeasures.gov

1. Purpose

The Rapid Response Partnership Vehicle (RRPV), on behalf of the Biomedical Advanced Research and Development Authority (BARDA), is issuing this Request for Information (RFI) to assess the current landscape of partners capable of supporting preclinical and nonclinical studies in Biosafety Level 4 (BSL4), to include execution of studies in the BSL4 laboratories as well as support services external to the BSL4 labs.

2. Background

BARDA has a requirement to develop medical countermeasures for high consequence pathogens including, but not limited to, filoviruses like Ebola virus, Bundibugyo virus, Sudan virus, and Marburg viruses. To assess the potential efficacy of investigative countermeasures, it is essential to test products in relevant animal models of infection. These studies must be executed at BSL4, which limits the number of offerors capable of supporting the studies. Studies potentially required to support product evaluation include, but are not limited to, mouse, guinea pig, ferret, and nonhuman primate (macaque) models of infection. Studies include model characterization, early "proof of concept" evaluations, and the adequate and well-controlled efficacy studies required to support product licensure or approval as set forth in FDA's Animal Rule and in the FDA Animal Rule Compliance Program. Studies will be required to minimally be conducted under a quality management system sufficient to meet Animal Rule Compliance Program 7348.007 components and ideally conducted according to Good Laboratory Practice regulations (21 CFR Part 58) to the extent practicable.

3. Request for Information

The objective of this RFI is to solicit feedback from industry, academia, and other stakeholders to assist BARDA in conducting market research to identify organizations capable of executing BSL4 studies as well as organizations capable of partnering with BSL4 laboratories for study execution and/or providing support services including, but not limited to, assay development and preparation of reports and data to support regulatory submissions.

Respondents do not have to be a member of the Rapid Response Partnership Vehicle (RRPV) consortium to submit a response for this RFI; however, they must be a member of the consortium to respond to any future Request for Project Proposals (RPP) for this requirement. Please visit RRPV.org to learn more about the RRPV consortium and how to apply to become a member.

Please submit via the RFI Submission Form here by

1pm ET July 24, 2026

Late responses will not be considered.

This RFI is for information gathering purposes only. It does not constitute a Request for Project Proposal (RPP), nor does it imply any obligation to issue a future solicitation, make any award, or pay any costs associated with responding to this RFI. Submission is voluntary and does not commit the responder to propose to any subsequent opportunities (if any) related to this topic. The RRPV Consortium will not return or provide feedback on any submissions to this RFI, however, BARDA reserves the right to further engage with respondents in a Market Research Call to clarify understanding of submitted information, as applicable. All responses to this RFI will be treated as sensitive information and confidentiality will be protected accordingly.

4. Requested Information

Respondents are invited to provide concise information describing the following:

BSL4 Nonclinical Study Capabilities

- Your organization's BSL4 laboratory capabilities including execution of animal model studies with mouse, guinea pig, ferret, macaque, or other models of filovirus infection.
- If your institute can conduct BSL4 animal model studies, please provide the following information:
    - A list of animal models available and the maximum number of animals that can be housed at BSL4 and enrolled in a study at one time, per species.
    - Number of BSL4 NHP studies that can be conducted annually, assuming only one study is active at a time, each study includes a 28 day in-life phase, and accounting for suite turnover times and scheduled laboratory shutdowns.
        - Please indicate if the type of study – i.e. GLP versus early research and development – will impact the number of studies that can be conducted annually, and if so, describe the impact.
    - Capabilities for the use of vascular access ports (VAPs), or comparable technologies, to minimize the need for anesthesia, and animal models in which these systems can be utilized. Include length of the executed studies and success in maintaining VAPs during the study.
    - Experience executing Good Laboratory Practices (GLP) animal studies at a BSL4, including:
        - The animal model used
        - Whether the report was submitted to FDA
        - The year the most recent GLP study was completed
        - Approximate timeline (post in-life) for generating the audited, draft final report for a GLP filovirus study using nonhuman primates
        - Any challenges your institute experienced, or anticipates experiencing, in conducting GLP studies
        - If GLP studies have not been conducted, but the organization has conducted studies and/or has been inspected by FDA under the Animal

Rule Compliance Program, please detail those experiences and capabilities

- Key personnel resources and challenges including:
  - number of experienced BSL4/filo study directors
  - number of in vivo staff qualified for BSL4
  - number of qualified staff for assay conduct (e.g., viral assays and ELISA) not including study director
  - number of experienced QA staff for auditing BSL4 studies and assay conduct
  - number of QC staff
  - specific challenges in maintaining key personnel
- In-house capabilities, including:
  - project management
  - statistical support
  - pathology services
  - technical and report writing
  - SENDIG-AR dataset generation
- Examples when partnering with external organizations improved your organization's ability to execute Animal Rule Compliance Program or GLP studies in a BSL4 (e.g. statistical analysis, report preparation, sample testing, assay development or validation, SENDIG-AR dataset generation, regulatory submission support)
- Any challenges your organization foresees conducting studies involving medical countermeasures, whether proof-of-concept or GLP studies. Consider factors such as complex study designs involving interventions, engagement with the product sponsors, IACUC/ethics review processes, study reporting requirement, or other operational regulatory or scientific considerations

Study Support Capabilities

In addition to understanding capabilities of institutes with BSL4 capabilities, BARDA is interested in understanding the capabilities of organizations that can partner with BSL4 laboratories to distribute the workload, enhance operational efficiencies, expand study execution capabilities and reduce study completion times.

- Does your organization provide support services or expertise to support BSL4 laboratories executing animal studies?
- If so, please describe the capabilities to support the following:
  - Project management
  - Study Director support
  - Quality Assurance
  - Quality Control
  - Critical phase monitoring

    - Data audits
    - Statistical analysis
    - Technical and report writing
    - Preparation of regulatory documents and FDA submissions, including documents compliant with the eCTD specification.
    - Preparation of SENDIG-AR compliant datasets
    - Assay development, qualification, and validation; capabilities to support tech transfer of validated assays to the BSL4 laboratory
    - Virus stock characterization or reagent characterization
- Other relevant capabilities that could support the execution of BSL4 animal studies

5. Response Instructions

Interested organizations should submit a concise written response addressing the requested information. Proprietary information should be clearly marked.

Responses should include:

- Organization name and contact information
- Relevant capabilities and experience

Responses should be no more than three (3) pages, excluding references.

Responses should be submitted in PDF or Microsoft Word formats using the submission form within this RFI.

6. Disclaimer

This RFI is issued for information and planning purposes only and does not constitute a solicitation or obligation on the part of the Government, BARDA, or ATI. Responses will not be reimbursed and will be used solely for market research and planning purposes.