

**Sources Sought Notice (SSN)**  
**Marburg virus (MARV) and Sudan virus (SUDV) Vaccines**  
**SSN Number: BARDA-CBRN-10302024**

**Type:** Sources Sought Notice

**Product Service Code:** 6505 – Drugs and Biologicals

**To:** Prospective Partners & Interested Parties

**Purpose:** The Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), is issuing this Sources Sought Notice (SSN) to collect feedback from current and prospective MARV and SUDV vaccine development partners. Information from this SSN will serve as continued market research for possible future acquisitions and programs. The information collected in response to this SSN is intended to strengthen BARDA's understanding of the current and future marketplace. This notice seeks information from Other than Small Businesses (OTSB) and Small Businesses (SB) regarding their qualifications, experience, and capabilities.

**Authority:** The Office of Contracts, Management and Acquisition (CMA) is issuing this Sources Sought Notice (SSN) on behalf of the Biomedical Advanced Research and Development Authority (BARDA) pursuant to FAR paragraphs 5.205(c), 15.201(e) and FAR parts 10 and 19. Information collected in response to this SSN will enhance BARDA's ability to establish potential vendor source files and listings as well as lawfully execute the preparedness mission efficiently.

**Background:** BARDA's mission is to develop medical countermeasures (MCMs) that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents, and attacks; pandemic influenza; and emerging infectious diseases; this includes *Orthomarburgvirus marburgense* (Marburg virus or MARV) and *Orthoebolavirus sudanense* (Sudan virus or SUDV).

The subject of this Sources Sought Notice is to gain information regarding MARV and SUDV vaccines that are currently in active Phase 2 clinical trials or have completed Phase 2 clinical trials.

**Description:** BARDA is issuing this SSN to assist in understanding the landscape of MARV and SUDV vaccines. BARDA is seeking information on individual monovalent vaccines targeting MARV and SUDV separately. For the purpose of this SSN BARDA is seeking:

- MARV vaccines including those that are currently in Phase 2 clinical trials or beyond with an intended indication for the prevention of Marburg Virus Disease (MVD)
- SUDV vaccines including those that are currently in Phase 2 clinical trials or beyond with an intended indication for the prevention of Sudan Virus Disease (SVD)

Respondents are asked to provide the following information and to provide it in a separate section for each virus:

1. Overview of the vaccine candidate currently in an active Phase 2 trial:
  - a. Viral antigen targeted

- b. Antigen delivery construct (e.g., viral vector, recombinant protein, nucleic acid, etc.)
  - c. Adjuvant (if applicable)
  - d. Number of doses required for protection
  - e. Onset of protection
  - f. Target product profile
2. Overview of clinical development status
- a. Phase 1 trial(s)
    - i. Trial design; endpoints; and enrollment target summary
    - ii. Safety and immunogenicity data summary
  - b. Phase 2 trial(s)
    - i. Trial design and endpoints summary
    - ii. Enrollment target and date completed (or target completion)
    - iii. Interim analysis – date completed (or target completion) and summary of data (if available)
    - iv. Final CSR – date completed (or target completion) and summary of data (if available)
  - c. Status of immunogenicity assay validation
  - d. Status of any other supporting assays
3. Overview of nonclinical studies and status
- a. NHP efficacy and immunogenicity data summary
4. Manufacturing
- a. Process characterization – summary of current status and plans, with timelines
  - b. Stability testing – summary of stability data for drug substance (DS) and drug product (DP)
  - c. Summary of current demonstrated and planned manufacturing scale
  - d. Status of contract manufacturing organization (CMO), including location, and whether any US domestic capacity currently exists for both DS and fill/finish of DP. If US domestic capacity does not yet exist, provide a timeline and summary of approach to onshore both DS manufacturing and fill finish of DP.

Responses should be limited to five pages (or less) for the MARV vaccine-specific response and five pages (or less) for the SUDV vaccine-specific response – for a total of ten pages (or less) if providing a response for both viruses – and shall be sent electronically to: [yifan.yang@hhs.gov](mailto:yifan.yang@hhs.gov) and [greg.smith1@hhs.gov](mailto:greg.smith1@hhs.gov)

Responses are due no later than **18 November 2024 by 3PM US EDT.**

#### **DISCLAIMER AND IMPORTANT NOTES**

This notice is issued solely for information and planning purposes and does not obligate the US Government to award a contract. No entitlement to payment of direct or indirect costs or charges by the US Government will arise because of the submission of the requested information. No reimbursement will be made for any costs associated with providing information in response to this

announcement and any follow up information requests. The US 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 US Government to determine the organization's qualifications to perform the work. Respondents are advised that the US 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 on SAM.gov under Contract Opportunities in accordance with FAR part 5. However, responses to this notice will not be considered adequate responses to a solicitation.

**THIS INFORMATION IS REQUESTED FOR INFORMATION GATHERING PURPOSES ONLY.**

While the data is treated as confidential and will not be disclosed publicly, please do not include proprietary information in response to this SSN.

**HHS BARDA POCs:**

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