AGENCY: HHS/OS/ASPR/BARDA

ACTION: RESEARCH & DEVELOPMENT SOURCES SOUGHT NOTICE

SUMMARY:

This notice is hereby issued in accordance with FAR Part FAR 5.205. 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 Research & Development Sources Sought Notice to collect feedback from current and potential biopharmaceutical partners. Information collected from this notice will serve as continued market research for a possible program where BARDA would partner with multiple organizations to achieve the preparedness goals set forth by the U.S. Government (USG).

BARDA is interested in advancing microarray patch (MAP) technology as an alternative to traditional needle/syringe administration of vaccines and is seeking to establish partnerships with licensed or late-stage (Phase 3) vaccine developers that will collaborate with MAP developer(s) to bring forward one or more of their licensed or late-stage (validated process) vaccines to be administered via MAP for eventual licensure.

BACKGROUND:

Within the USG, HHS/ASPR/BARDA is tasked with protecting the civilian population by providing leadership in research, development, acquisition, deployment, and use of effective medical countermeasures to treat the adverse health effects resulting from intentional exposure to chemical, biological, radiological, and nuclear threat agents, and natural exposure(s) to pandemic influenza and emerging infectious diseases.

The new BARDA strategic plan, released in May 2022, is built on four strategic goals to fortify, and strengthen BARDA:

1. Enhancing PREPAREDNESS by investing in development of a robust pipeline of innovative MCMs
2. Embracing our role as an agile RESPONSE organization
3. Expanding and sustaining public-private PARTNERSHIPS
4. Continuing to invest in the organization's WORKFORCE.

Within Goal 1, Objective 1.3, BARDA intends to support the development and commercialization of alternative delivery technologies that improve clinical performance and/or reduce the need for cold chain distribution and manufacturing of needles and syringes, with the goal of having at least one alternative vaccine delivery/administration product FDA-licensed and integrated into a vaccine.

Although there are several technologies that offer alternatives to traditional needles and syringe for administration of vaccines, BARDA is currently focusing on microarray patch (MAP) technology for the purposes of this sources sought notice.

During, and in the after-action report (AAR) to, the 2009 H1N1 pandemic response, the availability of needles and syringes, vials, and other ancillary equipment along with the availability of filling lines, were noted to be an issue.* Having alternatives to the standard methods of vaccine filling and administration would enhance the availability of vaccines to the greatest number of people in the shortest time possible. These issues identified over a decade ago continued during the SARS-CoV-2 response.

Additionally, MAP technology raises the possibility of vaccine doses being shipped directly to patients making vaccines more accessible to more patients. Such an approach has potential to greatly streamline the last mile of vaccine administration. Vaccines administered via MAP technology also have the potential to elicit a more robust and durable immune response than those via the traditional intramuscular route of immunization, which may be critical in threat spaces that require high efficacy products with more rapid onset to protection.

The USG will consider a range of vaccines for administration with MAP, including any licensed or late-stage vaccines against a threat that is within the BARDA mission space to include CBRN threats, pandemic influenza, or emerging infectious diseases. Phase 3 clinical programs will be considered if the sponsor has a pathway to licensure with a defined immune correlate.

BARDA is requesting the following responses: description of the type of MAP technology; any current or pending partnerships; indication; stage of development (brief synopsis of any nonclinical and clinical data); regulatory interactions (synopsis of discussions with US FDA or other regulatory authorities); pros and cons of the technology; and an outline of sustainability plans for the company/technology.

As part of your submission, please also indicate the number of employees within your organization. The North American Industry Classification System (NAICS) code for this acquisition is 541714, which establishes a small business size standard of 1,000 employees. A determination by the Government on how to proceed with a potential acquisition may be based upon responses to this notice and remains solely within the discretion of the Government. This notice does not commit the Government to solicit for, or award, any contract or agreement. Please submit a white paper, no longer than 5 pages, to the attention of Connie Song at Connie.Song@hhs.gov by Monday, October 31, 2022 :1:00 PM Eastern Time.

For further information please contact Connie Song, BARDA DRIVe Agreements Branch, at Connie.Song@hhs.gov.

* https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf