

Type: Sources Sought

Product Service Code: 6505 Drugs and Biologics

Place of Performance: HHS/ASPR/BARDA

To: Prospective Partners & Interested Parties

The Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), is issuing this Request for Information (RFI) to collect feedback from current and potential biopharmaceutical industry partners.

Information collected from this RFI will serve as continued market research for the development of a possible program where BARDA would partner with industry to achieve the pandemic preparedness goals set forth by the U.S. Government (USG).

SOURCES SOUGHT TITLE

Bolstering U.S.-based Vaccine Manufacturing Capabilities that Utilize messenger Ribonucleic Acid [mRNA] Technology

BACKGROUND

The USG has delivered over 496 million doses of mRNA vaccines for domestic preparedness. Globally, the USG is committed to donating over 1.2 billion vaccines doses. To meet short- and long-term needs, both domestically and globally, the USG seeks to increase mRNA vaccine U.S.-based production capacity for domestic and global use by at least 1 billion doses annually not later than the second half of 2022 to address the current COVID-19 pandemic and prepare for future pandemic response efforts.¹

DESCRIPTION

To expand ongoing COVID-19 mRNA vaccine supply, as well as build pandemic preparedness against future infectious disease threats, BARDA is contemplating a substantial investment to partner with one or more experienced firms to bolster U.S.-based production capabilities with proven mRNA vaccine manufacturing technology for domestic and global use.

The contemplated requirement will focus on targeted investments to rapidly scale-up, scale-out, and/or otherwise intensify U.S.-based mRNA vaccine drug substance manufacturing capacity.

Investments being considered may involve costs associated with infrastructure (facilities/equipment), bolstering trained staff and long-term sustainment ('readiness') for COVID-19 vaccine, or variants of concern, and emerging infectious disease/ pandemic response at no less than 100 million doses per month over and above current U.S.-based capacity.

¹ See White House Office of Science and Technology Policy (OSTP), American Pandemic Preparedness: Transforming our Capabilities, September 2021, <https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf>

These contemplated mRNA vaccine drug substance capacity investments are expected to realize the requisite surge manufacturing capabilities no later than fourth quarter 2022. Other potential approaches and innovations that would further accelerate bolstering mRNA vaccine development and manufacturing are also of great interest to the USG.

Interested firms are requested to submit company contact information and responses that capture the following elements:

Brief description (10 pages or less) of company experience and existing infrastructure related to manufacture and supply of mRNA vaccine drug substances, plus additional pages comprising:

- Discussion/perspective on potential barriers (financial, technological, legal, etc.) to, and/or concerns over, meeting the contemplated objective(s) and timeline;
- Perspective on granting the USG access/rights to USG-funded infrastructure and technologies on a preferential basis (“priority access”) in the event of a declared public health emergency (PHE);
- Perspective on cost sharing capital investments in support of U.S.-based capacity expansion objectives;
- Perspective on sustainment of pandemic response capacities/capabilities during non-pandemic periods;
- Perspective on “preferred USG pricing” if vaccine doses were to be used to support global response efforts and support low- to middle-income countries.

THIS INFORMATION IS REQUESTED FOR INFORMATION GATHERING PURPOSES ONLY.

NO SOLICITATION CURRENTLY EXISTS.

BARDA will use this information to guide decisions and plans regarding bolstering US-based mRNA vaccine manufacturing capabilities, and to establish a contact list of potential industry participants for future outreach efforts. Please note that contractors performing advisory and assistance services that support BARDA will have access to any submission under this RFI. Please do not include proprietary information in response to this RFI without appropriate markings.

HHS BARDA POC

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CLOSING DATE

Monday, December 13, 2021 @ 16:00 EST