

Type: Sources Sought
Product Service Code: 6505 Drugs and Biologics
Place of Performance: HHS 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).

Background: The Department of Health and Human Services (DHHS) is engaging with other Federal agencies and the White House in a whole-of-Government review, update, and transformation of U.S. bio-preparedness capabilities, as outlined in the White House's September 2021 report, *American Pandemic Preparedness: Transforming our Capabilities*.¹ This effort will fundamentally transform the Nation's biodefense and pandemic readiness and address challenges experienced during the ongoing COVID-19 pandemic. Work is being organized across five pillars: (I) Transforming our Medical Defenses, (II) Ensuring Situational Awareness, (III) Strengthening Public Health Systems, (IV) Building Core Capabilities, and (V) Managing the Mission.

The subject of this Sources Sought are Goal I: Transforming our Medical Defenses and Goal IV: Building Core Capabilities, as they pertain to BARDA's ongoing effort to expand the industrial supply chain for medical countermeasure (MCM) production, manufacturing, and implementation.²

Description: To transform and build core capabilities for biodefense, BARDA is contemplating consortia comprised of industry partners across the drug and vaccine manufacturing supply chain, including the manufacturers of required raw materials and consumables as well as suppliers of fill-finish services. The consortia will establish the physical infrastructure, manufacturing platforms, and supply chain capable of producing enough vaccines for the entire United States population within 130 days and the global population within 200 days after its recognition as a potential emerging pandemic threat and expand the ability to domestically produce the therapeutics and vital supplies to halt future pandemics.

BARDA is interested in identifying industry and private-sector partners who may be interested in participating in such consortia, supported by BARDA, that will prepare for and respond to emerging and ongoing pandemic threats focused on developing, establishing, and manufacturing capabilities to handle a broad array of threats. BARDA is interested in establishing and sustaining:

- Facilities and organizations with experience supplying or manufacturing any of the following:
 - licensed vaccines and antibodies

¹ 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>.

² Gary Disbrow and Ian Watson, "Expanding the domestic public health supply chain is a matter of national security," *STAT*, 26 Aug 2021, <https://www.statnews.com/2021/08/26/expanding-domestic-public-health-supply-chain-matter-of-national-security/>

- single-use consumables such as sterile packaging, tubing, connectors, assemblies, needles
- fill-finish services and supplies (e.g., syringes, vials)
- suppliers of raw materials such as the solvents, reagents, and other materials
- small-molecule and active pharmaceutical ingredient (APIs) manufacturers
- Proven vaccine manufacturing platform technologies
- Trained biomanufacturing workforce
- Robust supply chain to support large-scale manufacturing
- Rapid contracting/agreement mechanisms

Interested firms are requested to submit company contact information and responses to the following questions relating to the establishment of, and participation in, potential consortia:

- Brief description (10 pages or less) of company experience and existing infrastructure related to manufacture or supply of any of the aforementioned resources or services; plus additional pages comprising:
- Discussion/perspective on potential barriers (financial, technological, legal, etc.) to, and/or concerns over, participating in consortia of industry participants to meet the pandemic preparedness and response requirements;
- 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 sustainment of pandemic response capacities and capabilities during non-pandemic or declared PHE’s.

THIS INFORMATION IS REQUESTED FOR INFORMATION GATHERING PURPOSES ONLY. NO CONSORTIUM OR SOLICITATION CURRENTLY EXISTS. BARDA will use this information to guide decisions and plans regarding establishing domestic biopharmaceutical consortia 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.

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Closing Date: February 28, 2022.