

## **Articles of Collaboration**

Background. The Biomedical Advanced Research and Development Authority (BARDA) selected Advanced Technology International (ATI) as the Consortium Management Firm (CMF) to organize and operate their Biopharmaceutical Manufacturing Preparedness (BioMaP) Consortium supported by the Pharmaceutical Countermeasure Infrastructure (PCI) Division and BioMaP Branch of BARDA. The consortium will comprise industry partners across the drug and vaccine manufacturing supply chain, including the manufacturers of required raw materials and consumables, drug substance manufacturers, suppliers of fill-finish services, and innovators of advanced manufacturing technologies.

Objectives. ATI and BARDA have entered into the BioMaP Consortium Agreement No: 75A50123D00003. This vehicle will be leveraged to support future BARDA acquisitions as BARDA implements new programs in alignment with National (e.g., National Biodefense Strategy, American Pandemic Preparedness Plan [APPP]) and HHS strategies (e.g., ASPR Strategic Plan for 2022-2026, BARDA Strategic Plan, HHS Pandemic Influenza Plan 2017 Update), subject to appropriations and need. The purpose of this Consortium is to establish and maintain cooperative partnerships with participating members to ensure that there are adequate manufacturing capabilities to provide and make available requisite products and materials, so that countermeasures and therapies can be delivered to civilian populations addressing threats to the nation's public health or other security interests.

There are no membership dues required to join the BioMaP-Consortium. Minimum requirements to join the Consortium are a) possessing technology and/or capabilities relevant to the BioMaP mission of supporting, maintaining, and improving domestic manufacturing of products and countermeasures, and b) not being barred from conducting business with, or receiving funds from, the US Government. Final approval of membership resides with the Government. Members may terminate membership at any time by written notice to the CMF at least 30 days in advance. Members with an active Project Award who request membership termination will be required to complete the active Project unless terminated in accordance with the terms and conditions of the Project Award(s). Membership may be terminated by the CMF upon written notice to a member for failure to comply with the Membership Obligations contained herein. The Government reserves the right to unilaterally remove any member from the Consortium if it determines their removal to be in the best interest of the Government and provides the member with 10 days' notice of its decision. Except for continuing rights and obligations specified in an individual Project Award, from and after the effective withdrawal date, the terminated Consortium member shall cease to have any rights or obligations as a BioMaP Consortium member. In the event of a withdrawal in which the Consortium member is currently executing any Project Award, the Consortium member's obligation shall continue in accordance with the previously agreed-to performance and/or other terms and conditions until its completion or until the Government and Consortium member come to an agreement to terminate the task, whichever is first.

The relationship of the members established by these Articles is that of independent contractors. Nothing contained herein shall be construed to (i) give any member hereto the power to direct or



control the day-to-day activities of another member hereto, (ii) constitute the members as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking unless explicitly stated in a jointly executed Project Award, or (iii) allow any of the members hereto to create, discharge or assume any obligation on behalf of another member hereto for any purpose whatsoever. Each member retains the right to engage independent research and activities that may compete with, or be contrary to, the goals of the Consortium.

**Consortium Management Firm (CMF) Obligations.** ATI, as the Consortium Management Firm (CMF), shall administer the affairs of the Consortium, and is responsible for fulfilling the following obligations:

- Be responsible for the daily management of the BioMaP Consortium;
- Promote collaboration with Government customers and other members to address BioMaP technical objectives a.
- Provide customer support for members throughout the lifecycle of the project development process (training, guidance and process facilitation of the solicitation, award, and project execution phases);
- When appropriate file with the U.S. Attorney General and the Federal Trade Commission changes in membership in accordance with the provisions of the National Cooperative Research Act of 1993;
- Host periodic collaborative, membership meetings, as needed;
- Execute recruitment campaigns, industry days, etc. in collaboration with BARDA;
- Execute contract, program, and financial management of project awards issued to members of the Consortium:
- Engage in business-development activity to identify and recruit members to establish a robust collective of companies/institutions from across the biopharmaceutical manufacturing and development enterprise. When needed, form sub-memberships in specific problem/solution domains.
- Form and manage, in conjunction with BARDA a Bio-MaP Consortium Executive Steering Committee (ESC). Representation will be drawn from Consortium member organizations, including ex officio representation from the CMF and HHS BARDA.

**Consortium Member Obligations.** The Parties agree that members have the following obligations:

- Clearly demonstrate in their membership application that they are capable of making a contribution to BioMaP technical objectives and other relevant subjects, technology, and capability domains as may be required in order to fully support the needs of the U.S Government;
- Contribute their respective talents and resources to the Consortium for activities such as periodic meeting attendance, committee and subcommittee participation, and other activities as may be appropriate;
- Not transfer membership to any third party;
- Commitment to domestic U.S. investment for work executed under the Consortium (e.g. infrastructure, manufacturing, technology development, etc.);
- International sourcing is acceptable, when necessary, but commitment to US domestic supply sourcing to the maximum practical extent is desired;
- Not be barred or suspended from contracting with or receiving funds from the U.S. Government;
- Not be included on the U.S. Department of Treasury and/or Department of Commerce's prohibited source list of embargoed and sanctioned countries under their Project Agreements, nor utilize any



such prohibited source in any work related to a USG funded Project Agreement under this Consortium;

- Comply with all applicable export control laws and regulations of the United States, including the Arms Export Control Act ("AECA"), the International Traffic in Arms Regulations ("ITAR"), the Export Administration Regulations ("EAR"), and other U.S. Government directives related to export control;
- · Comply with all applicable U.S. antitrust laws;
- Respond to periodic CMF requests for verification of membership capability profile information;
- Abide by the terms of these Articles of Collaboration; and,
- Make good faith effort to execute the BioMaP Base Agreement upon entering the consortium, to
  include potential mandatory ASPR and/or sponsor security requirements and associated
  deliverables. Security requirements and associated deliverables will be determined by ASPR and
  sponsors at the project level with specific requirements to be included in the project solicitation.