<u>Updates</u> May 21, 2024 BioMaP-Consortium Hosts Inaugural Industry Day



In previous Updates, we discussed the <u>formation</u> and <u>growth</u> of the Biopharmaceutical Manufacturing Preparedness Consortium (BioMaP-Consortium), which was started by the Biomedical Advanced Research and Development Authority (BARDA) in the wake of COVID-19 to ensure that the country is prepared to cope with future biomedical threats.

Since BioMaP-Consortium's inception, its growth has steadily continued; as of this Update, it has over 160 members, including eight nonprofit organizations and three institutions of higher education.

BARDA has continued its industry outreach efforts, holding several collaboration events related to specific Requests for Project Proposals (RPPs) and exhibiting at both the World Vaccine Congress meeting in Washington, D.C., and the INTERPHEX Conference in New York City. Notably, on April 5, 2024, the BioMaP-Consortium hosted the first ever BioMaP-Consortium Industry Day in Arlington, Virginia.

In addition to the BioMaP-Consortium Industry Day bringing the U.S. Department of Health and Human Services and industry together in one room, BARDA also presented its strategic goals and priorities for the BioMaP-Consortium, which includes the potential for \$20 billion of funding over the next 10 years on BioMaP initiatives. The BioMaP-Consortium's presentation also included an overview of the Industrial Base Management and Supply Chain (IBMSC) Office within the Administration for Strategic Preparedness and Response (ASPR), which establishes a permanent capability to ensure a strong domestic industrial base to address public health emergencies. BARDA provided an overview of its Pharmaceutical Countermeasures Infrastructure (PCI) Division, which falls under the Medical Countermeasures (MCM) Program within the Office of the Director of BARDA. The PCI Division is tasked with ensuring that the United States maintains the manufacturing capabilities necessary to respond to another pandemic or other public health emergencies. Many BioMaP-Consortium members were also given the opportunity to introduce their companies and technologies in presentations. BioMaP will also be exhibiting at the BIO International Convention, held in San Diego from June 3 to June 6. As discussed in our previous Updates, BioMaP-Consortium membership requires a prospective member to complete the membership application and commit to executing the BioMaP Base Agreement soon after. The BioMaP Base Agreement is based, in part, on the Other Transaction Authority Agreement (OTA) between BARDA and its Consortium Manager, Advanced Technologies International (ATI), and addresses matters such as intellectual property, data rights, foreign access to technology, and contract administration matters such as payment and record retention.

If a BioMaP-Consortium member receives an award under an RPP, the member will then negotiate a Project Agreement with ATI (with BARDA's input). Because the Project Agreement is a subaward under ATI's OTA, it is not subject to the Federal Acquisition Regulation (FAR), and awardees will have the opportunity to try and negotiate the Project Agreement in a more familiar commercial framework. For example, the Base Agreement explicitly states that the parties may negotiate differing rights in data and subject inventions at the Project Agreement level that would supersede the Base Agreement's default provisions. However, it remains to be seen how far a Project Agreement can deviate from the BioMaP Base Agreement. Potential members of the BioMaP-Consortium should become familiar with the requirements of both the membership application and the BioMaP Base Agreement to ensure that they are prepared in the event they become interested in competing for an RPP and negotiating a Project Agreement in the future.

The BioMaP-Consortium will continue to grow, opportunities for Project Agreement awards will expand, and the government's use of industry consortia and OTAs will continue to evolve. Perkins Coie's Government Contracts team advises on legal issues related to OTAs and consortium participation, including the negotiation of—and compliance with—resulting Project Agreements.

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