

Biomedical Advanced Research and Development Authority (BARDA)

The Biomedical Advanced Research and Development Authority (BARDA) improves national preparedness for chemical, biological, radiological, and nuclear (CBRN) accidents and attacks, pandemic influenza, and emerging infectious diseases by supporting the development and acquisition of medical countermeasures (MCM) against these threats. BARDA programs and initiatives that provide support to national incident response and recovery preparedness include: Chemical, Biological, Radiological and Nuclear Medical Countermeasures, Pandemic Influenza Medical Countermeasures, Analytical Decision Support, the Fill Finish Manufacturing Network, Non-Clinical Studies Network, Clinical Studies Network, and Centers for Innovation in Advanced Development and Manufacturing.

BARDA was established by the Pandemic and All-Hazards Preparedness Act (PAHPA; PL 109-417), which was signed into law on December 19, 2006. Title IV of this law established BARDA within HHS to “coordinate the acceleration of countermeasure and product advanced research and development” by collaborating with medical countermeasures developers and manufacturers, supporting advanced research and development, facilitating exchanges with the HHS Food and Drug Administration (FDA) and other regulatory bodies, and promoting innovation to reduce the time and cost of countermeasure development (PAHPA, Title IV, Sec. 319L (4)). BARDA was created to fill a critical gap in the U.S. Government medical countermeasure development pipeline and procurement processes by providing financial and technical support for companies entering the late stages of product development, which have been called the “Valley of Death”. Using a variety of mechanisms, BARDA supports the transition of promising MCM candidates from early research through advanced development to approval and production and, where appropriate, into national stockpiles.

BARDA uses a comprehensive portfolio approach to develop and acquire a broad array of medical countermeasures including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures. BARDA coordinates its activities closely with other HHS and U.S. government agencies through the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) and, through public-private partnerships, with industry stakeholders. In addition to providing critical funding, BARDA provides technical expertise and core service assistance programs to companies developing new products through its Nonclinical Studies Network, Clinical Studies Network, and Centers for Innovation in Advanced Development and Manufacturing, and Fill-Finish Manufacturing Network. These core service assistance programs not only provide assistance to MCM developers, but can be mobilized in public health emergencies to develop, manufacture, test, and facilitate the availability of medical countermeasures. In addition to acquiring medical countermeasures for CBRN threats under Project BioShield to place in the Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS) prior to product approval by the FDA, BARDA established and has maintained national pre-pandemic influenza vaccine stockpiles with industry partners. BARDA has invested heavily in building a robust domestic manufacturing infrastructure for medical countermeasures. BARDA has also supported the growth of

influenza vaccine manufacturing capacity in developing countries with direct funding and technical expertise and is making a critical contribution to global pandemic preparedness.

In the CBRN program, BARDA manages programs that support advanced research and development of CBRN MCMs including vaccines, antivirals and antibiotics, therapeutic antibodies, therapeutic proteins, cellular therapies, peptides, small molecules, and diagnostic assays. BARDA also purchases CBRN MCMs that are mature enough for accessibility under the FDA's Emergency Use Authorization (EUA) for stockpiling at the SNS or at industry sites under vendor-managed inventory systems. The CBRN MCM portfolio includes candidates and products for smallpox, anthrax, botulism, plague, tularemia, glanders, melioidosis, typhus, hemorrhagic fever viruses, radiological and nuclear agents, nerve agents, and other threats. Early medical countermeasures were developed and acquired as single threat-based products; however, more recently BARDA has focused on repurposing existing products licensed for other indications, or new multi-purpose products with both commercial and CBRN indications. Nearly 50% of the medical countermeasures purchased under Project BioShield since 2005 are multi-purpose, with strong commercial markets.

BARDA's Pandemic Influenza program focuses on developing new and improved vaccines, antiviral medications, immunotherapeutics, diagnostics, ventilators, and respiratory protection devices and oversees the nation's stockpile of pre-pandemic H5N1 and H7N9 vaccines and adjuvants. During the 2009 H1N1 pandemic, BARDA played a key role in the public health response by coordinating the development, manufacture, and acquisition of H1N1 vaccines and antiviral drugs. In addition to supporting advanced development and procurement of MCMs, BARDA works closely with FDA, CDC, and other components of HHS to plan for the distribution, administration, and monitoring of MCMs during influenza pandemics. BARDA expanded domestic influenza vaccine manufacturing capacity to meet U.S. pandemic vaccine demand through public-private partnerships with industry and academia, leading to the retrofitting of existing vaccine manufacturing facilities, building new state-of-the-art award-winning vaccine production facilities using modern vaccine technologies, and establishing new facilities focused on novel flexible and disposable manufacturing technologies. BARDA's influenza vaccine development program works closely with NIH to support development of new universal influenza vaccine candidates to provide more effective vaccines.

BARDA anticipates expanding its mission to address the critical threat of antimicrobial resistance among public health pathogens, and envisions this new responsibility becoming one of the core elements in its Emerging Infectious Diseases program. BARDA, with its PHEMCE partners, is developing a formal risk-assessment framework to determine which emerging or re-emerging infectious diseases require development of federal medical countermeasures preparedness and response measures and should be incorporated into the PHEMCE and BARDA portfolios.

More information on the Fill Finish Manufacturing Network can be found at:
<https://www.medicalcountermeasures.gov/barda/core-services/fill-finish-manufacturing-network.aspx>

More information on Pandemic Influenza Medical Countermeasures can be found at:
<http://www.phe.gov/about/barda/Pages/influenza.aspx>

More information on the Non-Clinical Studies Network can be found at:
<https://www.medicalcountermeasures.gov/barda/core-services/animal-studies-program.aspx>

More information on Centers for Innovation in Advanced Development and Manufacturing can be found at: <https://www.medicalcountermeasures.gov/barda/core-services/ciadm.aspx>

More information on Analytical Decision Support can be found at:
<https://www.medicalcountermeasures.gov/barda/core-services/modeling-hub.aspx>

LAST UPDATED: September 17th, 2014