

Notice Type: Special Program Announcement - Participant Basic Agreement (PBA) Opportunity

Title: Chemical, Biological, Radiological, and Nuclear (CBRN) Medical Countermeasure (MCM) Participant Basic Agreement (PBA)

Issuing Organization: Capability Program Executive for Chemical, Biological, Radiological, and Nuclear Defense (CPE CBRND) (<https://www.jpeocbrnd.osd.mil/>)

1. Strategic Opportunity:

The Capability Program Executive for Chemical, Biological, Radiological, and Nuclear Defense (CPE CBRND) invites interested parties to enter into the CBRN Medical Countermeasure (MCM) Participant Basic Agreement (PBA) ecosystem.

This PBA establishes a unified, open, and continuous network of pre-qualified partners to accelerate the development, testing, and fielding of next-generation CBRN medical defense solutions. The goal is to create streamlined, framework for awarding follow-on project agreements, fostering a long-term, collaborative relationship with the Government.

2. Program Vision: Building Holistic Threat Resilience

The overarching goal of the CBRN MCM PBA is to develop and field a comprehensive suite of MCMs to protect the warfighter within a complex and evolving CBRN threat space. This PBA is designed as an agile agreement supporting a wide range of acquisition strategies and technologies, from rapid prototyping to late-stage development and FDA licensure.

To build an integrated layered defense, the Government seeks innovative solutions across the continuum of care. This includes treatments, pre-exposure or post-exposure prophylactic countermeasures, as well ruggedized formulations, novel drug delivery systems, and adaptable platform technologies capable of rapidly pivoting to address new and emerging threats.

This integrated approach will ensure the development of a diverse and robust portfolio of MCM capabilities, preserving the Joint Force through enhanced resilience. Examples of MCM capabilities sought under this PBA include, but are not limited to:

Host-Targeted Resilience:

Development efforts focus on providing layered physiological protection and treatment by targeting critical host systems. The Government welcomes innovative, threat-agnostic MCM candidates that enhance host resilience, including investigational drugs with multi-indication potential in civilian critical care, establishing a sustainable, long-term therapeutic pipeline. To meet the demands of far-forward operations, priority is placed on drug candidates designed for rapid employment in austere environments. This includes formulations featuring simplified routes of administration (such as oral, intranasal, or autoinjector delivery) that can be administered without specialized medical infrastructure. Examples of sought-after mechanisms of action include, but are not limited to, neurological protection, respiratory stabilization, immune modulation, hematologic and vascular function, and cellular stress and repair pathways.

Threat-Targeted Neutralization:

Complementing host resilience, efforts focus on developing broad-spectrum medical countermeasures designed to rapidly target, neutralize, and mitigate the effects of CBRN threats. The Government welcomes MCMs and adaptable platform technologies utilized for pre-exposure prophylaxis, post-exposure prophylaxis, or acute treatment. Preferred therapeutic candidates must possess robust environmental stability, eliminating reliance on cold-chain logistics, and be designed for immediate employment in austere, operational environments. This includes formulations featuring simplified routes of administration (such as oral, intranasal, or autoinjector delivery) that can be administered without specialized medical infrastructure. Therapeutic solutions that offer rapid threat clearance, agent inactivation, disruption of lethal injury cascades, or the immediate cessation of cellular damage through a highly simplified dosing regimens are highly sought after to preserve combat power and maximize return-to-duty rates.

3. Call for Collaborators: Who Should Apply?

This announcement serves as an invitation to the full spectrum of MCM developers and support organizations to join the CBRN MCM PBA partner ecosystem.

- **A. MCM Development Collaborators:** We invite submissions from developers of MCM candidates relevant to CBRN defense at all stages of advanced development (from Phase I-enabled products through Phase II/III clinical trials and FDA licensure).
- **B. MCM Development Support Collaborators:** We also invite participation from organizations specializing in contract research, development, and manufacturing (CROs/CDMOs) and other firms with expertise in preclinical testing (e.g., efficacy, pharmacology, toxicology), clinical trial execution, cGMP manufacturing, regulatory

submissions, and advanced modeling. Collaboration with expert service providers is essential to accelerate development.

4. Submission Requirements & Process

Interested entities shall submit a white paper (not to exceed five pages, not including a cover page) that addresses the areas outlined below. In addition, companies shall state entity's willingness to team or collaborate with other entities within this PBA.

A. For MCM Development Collaborators:

Your submission should provide a comprehensive overview including:

- **Product Description:** A clear description of the product, its mechanism of action, intended use and proposed FDA indication.
- **Efficacy Data:** A summary of all significant *in vivo* and *in vitro* data and a description of well-controlled and/or good laboratory practices (GLP) data generated in validated animal models against CBRN threats.
- **Regulatory & Clinical Status:** A history of U.S. Food and Drug Administration (FDA) sponsor experience and engagements (including IND status), and a summary of completed or ongoing clinical trials (Phase I, II, III), including safety and pharmacokinetic/pharmacodynamic (PK/PD) data.
- **Manufacturing:** A description of current manufacturing capacity (scale, good manufacturing practices (GMP) status) and the strategy for scaling production.
- **Company Profile:** A summary of your company's experience in advanced product development, commercialization, and relevant intellectual property rights.

B. For MCM Development Support Collaborators:

Interested service providers should submit a summary of their core capabilities, relevant experience with complex biologics or small molecules, FDA regulatory experience, available infrastructure, and capacity or technology that can accelerate the development of advanced medical countermeasures.

C. Awards

Acceptance into the PBA allows for award of project orders under any program supported by this PBA.

5. Administrative Information & Organizational Background

- **Submission of White Papers:** Please submit all white papers to: usarmy.detrick.cpe-cbrnd.mbx.cbrn-mcm-pba@army.mil
- **Points of Contact:** Please direct all technical and administrative questions to:
 - Hunter Robinson (hunter.t.robinson4.civ@army.mil).
 - Alexander Mayatte (alexander.z.mayatte.civ@army.mil)
- **Issuing Organization Mission:** CPE CBRND advances the development of CBRN defense capabilities to enable the Joint Force to fight and win in a CBRN-contested environment, contributing toward National Defense Strategy priorities.
- **Authority:** Projects may be awarded under the authority of 10 U.S.C §4021, 10 U.S.C. §4022, and 10 U.S.C. §4023. These agreements are not subject to the provisions of the Competition in Contracting Act of 1984.
- **SAM Registration:** Prospective awardees MUST be registered in the System for Award Management (SAM) database prior to submitting an invoice and through final payment.