

1.0 Purpose

The Portfolio Management Executive for Chemical, Biological, Radiological and Nuclear Defense (PME CBRND), through the Chemical, Biological, Radiological, Nuclear (CBRN) Medical - Accelerated Defense Pharmaceuticals (ADP) program, is seeking information from qualified commercial and academic product developers.

The ADP program requests information regarding the design, manufacturing, non-clinical testing, and clinical testing of advanced prophylactic platform technologies directed against one or more specific CBRN threats of concern (see **Appendix 1 below**). The intent is to understand industry capabilities to accelerate platform innovation and/or expansion of an existing platform technology, support rapid response against biological and chemical threats, and progress existing candidate platforms toward Phase I or Phase II clinical trials regulatory and operational milestones.

2.0 Background

The JPM for CBRN Medical, operating under the PME CBRND, serves as the Department of War's (DoW) premier program management office for the development, acquisition, and fielding of safe, effective, and innovative medical solutions to safeguard service members against CBRN threats. JPM CBRN Medical leads medical countermeasure (MCM) development across three operational pillars:

Prophylactic Platforms (pre-exposure and post-exposure prophylaxis)

Diagnostics (rapid detection and clinical identification)

Therapeutics (post-exposure medical intervention)

These pillars form critical elements of an integrated, layered defense strategy. Within this portfolio, the ADP program focuses on accelerating the timeline from threat identification to safe, scalable, and deployable prophylactic platform countermeasure availability.

The primary objective of this initiative is to advance to Phase I or Phase II clinical trials the maturation of existing prophylactic MCMs built on proven platform technologies that have established clinical safety profiles and/or demonstrate robust preclinical immunogenicity, safety, and efficacy data.

The objective of the program is to progress the development of existing prophylactic MCMs manufactured on existing platform technologies that support clinical safety and/or possess strong preclinical immunogenicity, safety, and efficacy data. Development of the prophylactic MCM will be through a modular approach completing through Phase I or Phase II clinical trial while building opportunities for incremental/interim fielding capabilities for the warfighter [e.g., Expanded Access Protocol (EAP), pre-Emergency Use Authorization (pre-EUA)]. Novel MCM candidates will be considered if on proven manufacturing platform technologies. Companies

with MCM candidates that cross-reference or use established Master Files with the FDA for platform technology are encouraged to respond to the RFI.

3.0 Broad Areas of Technical Interest

The Government is specifically seeking information and market capabilities addressing the following focus areas:

Proven Prophylactic Platform Technologies: Utilization of mature, modular, and/or extensible platform technologies (e.g., nucleic acid platforms, viral vectors, recombinant protein platforms, nanoparticle systems, etc) capable of rapid re-targeting and manufacturing response upon emergence of biothreat agents.

Broad-Spectrum Countermeasures: Prophylactic solutions providing cross-protection against two or more agent classes, engineered variants, or emerging biological/chemical threats.

Biological Response Modifiers & Adjuvants: Novel or established immune modulators, adjuvants, and/or host-directed factors that enhance the immunogenicity, protective efficacy, durability, or dose-sparing capabilities of candidate prophylaxes.

Alternative Routes of Administration: Prototype candidates engineered for non-invasive or field-expedient administration that eliminate reliance on traditional needle-and-syringe intramuscular (IM) or subcutaneous (SC) delivery. Modalities of interest include, but are not limited to:

- Dissolvable or solid microneedle array patches (MAPs)
- Intranasal (IN) formulations and mucosal delivery devices
- Sublingual or oral delivery mechanisms
- Inhaled aerosol or dry-powder delivery systems

4.0 Required Capability Description Content

Specifically, PME CBRND is interested in Prophylactic Platform Technology Capability Descriptions covering the following topic areas in reply to this RFI (no more than 4 pages). Respondents must address the following topic structure within the four-page limit:

a. Technical Approach and Product Maturity

- **i. Product Description:** Overview of the platform technology, mechanism of action, target CBRN threat(s) of concern, delivery route/device, and formulation stability profile.
- **ii. Technology Readiness Level (TRL):** Current assessed TRL and Manufacturing Readiness Level (MRL), with supporting technical rationale.

- **iii. Efficacy Data Summary:** High-level summary of existing *in vitro* and *in vivo* data demonstrating immunogenicity, protective efficacy, challenge model survival, and toxicology/safety.

b. Regulatory and Clinical Status

- **i. U.S. Food and Drug Administration (FDA) Engagement:** History of formal FDA interactions (e.g., Pre-IND, IND, INTERACT, Animal Rule regulatory pathway alignments), designations granted (Fast Track, Breakthrough, Orphan Drug), and regulatory milestones achieved for the proposed platform technology.
- **ii. Clinical Trial History:** Summary of completed, ongoing, or planned clinical trials (Phase I and/or II), human safety/reactogenicity findings, pharmacokinetic (PK)/pharmacodynamic (PD) observations, or human challenge/biomarker data for the platform and threat(s) (please specify the specific strain(s) of the pathogen targeted if applicable).

c. Manufacturing and Supply Chain

- **i. Current Capabilities (Drug Substance / Drug Product):** Existing capacity for Current Good Manufacturing Practice (cGMP) synthesis, formulation, fill-finish, batch yield, and current release assay availability.
- **ii. Scalability and Supply Chain (Domestic/International):** Assessment of surge capacity, raw material availability, reliance on foreign suppliers or sole-source vendors, domestic onshore manufacturing capabilities, and cold-chain/ambient storage logistics.

d. Roadmap for Advanced Development

- **i. Strategy and Planned Partners:** Proposed transition pathway from current state to pivotal development, including reliance on Contract Development and Manufacturing Organizations (CDMOs), academic institutions, or strategic industry partners.
- **ii. Schedule:** Indicative high-level timeline and major critical-path milestones required to achieve regulatory approval, EUA/pre-EUA readiness, or readiness for stockpile procurement.
- **iii. Rough Order of Magnitude (ROM) Cost Estimates:** High-level budgetary cost bands covering non-clinical, clinical, manufacturing scale-up, and regulatory submission activities.

e. Company Profile and Vision

- **i. Corporate Experience:** Organizational qualifications, past performance with DoW, HHS/BARDA, NIH, or other federal/defense agencies in medical countermeasure development.
- **ii. Teaming Strategy:** Proposed subcontracting, consortium alignments, licensing arrangements, or collaborative teaming models designed to execute advanced development.

4.0 Instructions for Respondents/General Submission Guidelines

- **Format:** Single searchable PDF document. Standard 8.5" x 11" page layout, minimum 1-inch margins, minimum 12-point font (tables and graphics may utilize 9-point font).

- **Page Limit:** The core capability description must **not exceed four (4) pages in total**, inclusive of tables and figures. A separate cover page (one page) may be included and will not count toward the four-page limit.
 - **Cover Page Details:** Organization name, CAGE code, Unique Entity Identifier (UEI), primary business address, Point of Contact (name, title, telephone, email), business size status under relevant NAICS codes, and commercial/consortium affiliations.
 - **Submission Channel:** Submissions must be transmitted electronically via email to the Government Points of Contact listed at the end of this posting with the subject line:
RFI Response: PME CBRND JPM CBRN Medical ADP - [Organization Name]
-

5.0 Proprietary Information and Data Rights

The Government acknowledges that responses may contain proprietary or trade secret information. To safeguard proprietary data:

1. Respondents must clearly mark proprietary or competition-sensitive materials on each page where they appear using distinct markings (e.g., "*PROPRIETARY / BUSINESS CONFIDENTIAL*").
2. The Government will handle properly marked proprietary data with appropriate safeguards and will not disclose such data outside authorized Government evaluators and contracted advisory and assistance service (A&AS) personnel bound by non-disclosure agreements.
3. Generalized concepts, public information, or unmarked sections may be utilized by the Government without restriction for broad market analysis and program planning.

Special Notice / Disclaimer

This document is a Request for Information (RFI) issued solely for information and planning purposes, conducting market research in accordance with Federal Acquisition Regulation (FAR) Part 10. This announcement does **not** constitute a Request for Proposals (RFP), an Invitation for Bids (IFB), or an obligation on the part of the Government to issue a future solicitation or award a contract.

The Government will not pay or reimburse any costs incurred by respondents in preparing or submitting responses to this RFI. All submissions become the property of the Government and will not be returned. Any questions regarding this RFI may be submitted via email; however, a response is not guaranteed, and inquiries will be utilized solely to further inform Government planning.

6.0 Government Points of Contact

Agreements Officer: Scott I. Hoffman at scott.i.hoffman2.civ@army.mil

Agreements Specialist: Alexander Z. Mayatte at alexander.z.mayatte.civ@army.mil

7.0 List of Attachments and Appendices

The following supporting documents are associated with this announcement:

- **Appendix 1 — CBRN threats of concern:** Detailed inventory of prioritized chemical, biological, and radiological threat agents, target pathogens, and defense capability gaps.
- **Appendix 2 — Draft Statement of Objectives (SOO):** High-level objectives, criteria, and deliverables for a future solicitation