REQUEST FOR INFORMATION
MEDICAL COUNTERMEASURE PLATFORM TECHNOLOGIES

DEPARTMENT OF DEFENSE SOLUTION TO IMPROVE MCM DEVELOPMENT EFFICIENCY AGAINST VARIETY OF THREAT AGENTS

Objective: This is a Request for Information (RFI) for planning purposes only. It is not to be construed as a commitment by the Government nor will the Government pay for the information solicited. No solicitation document exists or is guaranteed to be issued as a result of this RFI. The medical countermeasure (MCM) Platforms Team at the Joint Program Executive Office for Chemical and Biological Defense (Medical Countermeasures Systems) and the Joint Science and Technology Office (Vaccine and Therapeutic Division) is seeking information on the capabilities and willingness of private entities (non-profit and commercial) in the areas listed below.

Background: Faced with the challenges of a constantly evolving chemical and biological threat environment, an unstable manufacturing base, and complex regulatory processes, traditional development methodologies have not enabled expeditious delivery of prophylactic and therapeutic MCMs to the Warfighter. An innovative approach is being initiated, which will accelerate MCM delivery by leveraging platform technologies to reduce developmental risk.

Requirements: MCM Platforms is seeking platform technologies that can counter a variety of chemical and biological threat agents by standardizing product discovery, design, manufacturing, and/or testing (Fig.1) to accelerate MCM delivery to the Warfighter. Once established, MCM Platforms will enable the DoD to reduce product-development risk across multiple MCMs (e.g., a robust target discovery methodology, a largely standardized manufacturing process across multiple products, a broadly applicable testing methodology). One of the anticipated outcomes of the platform approach is a streamlined regulatory pathway that reduces time to licensure. The DoD has identified several critical attributes of platforms, and while open to innovative concepts, is primarily seeking technologies that have data

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**Figure 1. Platform application to Product Development Stages**

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supporting successful use in product development (Table 1). The DoD is open to platforms applicable to large and small molecule products.

### Table 1. Critical Attributes for DoD Platforms

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<thead>
<tr>
<th>Critical Attributes</th>
<th>Acceptable Platform</th>
<th>Ideal Platform</th>
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<tr>
<td>Broad applicability across the threat landscape</td>
<td>Applicable to multiple threat agents within same category (e.g., viral)</td>
<td>Broadly applicable to multiple agents across threat categories (e.g., viral, bacterial, toxins)</td>
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<td>Maturity of discovery &amp; design technology</td>
<td>Systematic discovery &amp; design process</td>
<td>High throughput automated discovery &amp; design process</td>
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<td>Robust platform manufacturing processes</td>
<td>Platform provides moderately standardized upstream and downstream manufacturing processes, and platform-specific analytical methods</td>
<td>Platform provides highly standardized upstream and downstream manufacturing processes that are compatible with early stage clinical trial requirements, and platform-specific analytical methods</td>
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<td>Known regulatory pathway to FDA licensure</td>
<td>Interaction with the FDA is stage-appropriate to the platform maturity and safety database is stage-appropriate to the platform maturity</td>
<td>One or more FDA-approved products and large safety database with an excellent safety profile</td>
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In the coming months, MCM-Platforms may sponsor an Industry Day to gather information in anticipation of funding platform adoption for MCM development.

The Government requests that potential performers provide an up to 5 page response containing the following information regarding platforms, addressing one platform per response:

1) Description of the platform technology;
2) Stage of product development cycle that platform supports;
3) Platform conformance with the critical attributes (Table 1), as applicable to the platform;
4) Extent to which platform has been used to existing product development efforts;
5) Platform benefits to include impact on expediting the product development path;
6) Intellectual Property associated with the platform;
7) Biosafety containment/specialized facilities/unique equipment required to support the specific platform capability;
8) Willingness/ability to transfer/implement platform technology at a DoD facility.

**Administration:** The Government will retain comments and information received in response to this RFI. Proprietary information should be identified as Company Proprietary. Do not use Government security classification markings. All written responses must be received by COB on 17 July 2017. Responses should be sent by e-mail to: contracts.mcdc@ati.org, with Subject Line of Responding Organization and RFI Title. Material that is advertisement only in nature is not desired.