Hemorrhage Countermeasure Evaluation Capabilities **RFI – DARPA-SN-26-61**
Responses due 15 days after posting, 4:00 PM ET
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URL: http://www.darpa.mil/work-with-us/opportunities

The Biological Technologies Office (BTO) of the Defense Advanced Research Projects Agency (DARPA) seeks input from industry and academia regarding capabilities for providing independent verification and validation, clinical trial, and commercialization support for hemorrhage countermeasures. This Request for Information (RFI) is a preliminary step to identify potential partners capable of providing third-party assessments of safety and efficacy of potential hemorrhage countermeasures and assisting in development strategies to ensure said products transition from the laboratory to civilian and government markets after research, development, testing, and evaluation (RDT&E) efforts have ended. DARPA is particularly interested in respondents who can address all the above task domains to allow one provider to have comprehensive knowledge about the data for efficiency and to tailor commercialization and regulatory strategies.

This RFI is solely for information gathering and planning purposes. It does not constitute a solicitation for proposals, abstracts, or quotations nor indicate an intent to fund those who respond.

Information Requested

Respondents are requested to submit a white paper detailing their organization's experience, facilities, and overall approach to supporting the capabilities listed below, with a specific focus on testing and evaluating hemorrhage countermeasures and resuscitation products using synthetic or biosynthetic components. Responses should demonstrate expertise and proposed strategies rooted in this domain, not in unrelated fields (e.g., oncology). For any capabilities that currently cannot be addressed by in-house resources, please include an approach (e.g., subcontracting; additional funding for facilities, equipment, personnel, etc.) and timeline for how you would provide a holistic solution. Please structure your response to address the following sections:

1. Organizational Capabilities and Past Performance
    - Provide a summary of your organization's core competencies as they relate to medical countermeasure development against hemorrhage and testing using synthetic or biosynthetic components.
    - Describe relevant preclinical and clinical research facilities, including animal vivarium accreditation, capacity (specifically for large animal models), and any specialized laboratory capabilities.
    - Summarize past performance in executing preclinical studies and clinical trials of a similar scope and nature, noting any experience with DoD, DARPA, or other U.S. Government agencies.
2. Preclinical Evaluation Capabilities

- Describe your proposed technical approach for executing *in vitro* and *in vivo* studies to assess the safety and efficacy of hemorrhage countermeasures in both small and large animal models.
- Provide detailed information on your organization's Good Laboratory Practice (GLP) capabilities. If your facility is not currently GLP-compliant, you must provide evidence of being able to execute such work in partnership with another organization. A detailed plan and timeline to achieve full compliance, including necessary steps for developing infrastructure, hiring personnel, and establishing a quality management system is optional.

3. Clinical Trial Support
   - Outline your experience and approach for designing and managing Phase I and Phase II clinical trials. If your organization does not have its own clinical trial network, you must provide evidence of being able to execute such work in partnership with another organization.
   - Detail your organization's expertise in clinical regulatory affairs, including experience with Institutional Review Boards (IRBs), managing Investigational New Drug (IND) submissions to the FDA, and strategies for patient enrollment and consent (including Exception from Informed Consent, if applicable).
4. Technology Commercialization and Transition Support
   - Describe your experience and process for conducting technical and financial due diligence on third-party technologies, including assessments of commercialization strategies, intellectual property (IP) landscapes, and market potential.
   - Descriptions should include work and processes for drugs, biologics, and combination products and necessary devices and diagnostics for holistic resuscitation strategies.
5. Program Management and Key Personnel
   - Provide brief summaries of expertise for key scientific and management personnel who would be assigned to this effort.
   - Include a notional high-level timeline for a 3-year program that includes preclinical studies, GLP-compliance setup (if needed), Phase I & II clinical trials, and ongoing company/product analysis for the submission of an emergency use authorization package to the FDA.
6. Rough Order of Magnitude (ROM) Estimate
   - Provide a ROM estimate to provide the full scope of capabilities described in your response. The ROM should be broken down by major phase (e.g., Preclinical Efficacy Testing, GLP Preclinical Testing, Phase I Clinical Trial, Phase II Clinical Trial) and include an estimated budget by year for a notional 5-year effort.

Format

DARPA strongly encourages focused and concise submissions that provide actionable insight. Limit technical descriptions of capabilities to 10 pages. Use 12-point font with 1-inch margins on 8.5 x 11-inch page size.

Respondents are encouraged to submit non-proprietary information. If proprietary information is included, respondents are responsible for clearly identifying both text and graphics containing proprietary information with labels such as "Proprietary" or "Company Proprietary". Do not use "CONFIDENTIAL" as this is a classification for national security information. DO NOT INCLUDE CLASSIFIED INFORMATION IN THE RFI RESPONSE.

Deliver submissions electronically in PDF format to DARPA-SN-26-61@darpa.mil.

Submission

All technical and administrative correspondence, questions regarding this announcement, how to respond to this RFI, and submissions themselves should be sent to DARPA-SN-26-61@darpa.mil. Please refer to ***Hemorrhage Countermeasures Support*** **RFI** in all correspondence. Emails sent directly to the Program Manager may result in a delayed response or no response.

Disclaimers and Important Notes

This is an RFI issued solely for information and new program planning purposes; it does not constitute a formal solicitation for proposals. In accordance with FAR 15.101(c), the Government does not intend to award a contract on the basis of the RFI or otherwise pay for the information requested; and responses will be treated as information only and not as a proposal. Submission is voluntary and is not required to propose to a subsequent Broad Agency Announcement (BAA) (if any) or other research solicitation (if any) on this topic. DARPA will NOT provide reimbursement for costs incurred in responding to this RFI. NO CLASSIFIED INFORMATION SHOULD BE INCLUDED IN THE RFI RESPONSE. It is the submitter's responsibility to clearly define to the Government what is considered proprietary data. Any proprietary information should be clearly labeled as "proprietary." DARPA will disclose submission contents only for the purpose of review and evaluation. Respondents are advised that DARPA is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted under this RFI.