Defense Health Agency
2023.4 Small Business Innovation Research (SBIR)
Proposal Submission Instructions

BAA Pre-release: 9 March 2023
BAA Open: 23 March 2023
Topic Q&A close: 7 April 2023
BAA Proposal Submission Deadline: 25 April 2023 at 1200 EST

INTRODUCTION

The Defense Health Agency (DHA) SBIR Program seeks small businesses with strong research and development capabilities to pursue and commercialize medical technologies.

Proposers responding to a topic in this Broad Agency Announcement (BAA) must follow all general instructions provided in the Department of Defense (DoD) SBIR Program BAA. DHA requirements in addition to or deviating from the DoD Program BAA are provided in the instructions below.

Only Government personnel will evaluate proposals with the exception of technical personnel from Allied Technologies and Consulting, LLC and General Dynamics Information Technology who will provide technical analysis in the evaluation of proposals submitted against DHA topic:

- Anti-Shock Drug, Pre-Hospital (ASD-PH)

Specific questions pertaining to the administration of the DHA SBIR Program and these proposal preparation instructions should be directed to:

DHA SBIR Program Management Office (PMO)
Email: usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@health.mil
Phone - (301) 619-5146

DIRECT TO PHASE II PROPOSAL GUIDELINES

The Defense SBIR/STTR Innovation Portal (DSIP) is the official portal for DoD SBIR/STTR proposal submission. Proposers are required to submit proposals via DSIP; proposals submitted by any other means will be disregarded. Detailed instructions regarding registration and proposal submission via DSIP are provided in the DoD SBIR Program BAA.

15 U.S.C. §638 (cc), as amended by NDAA FY2012, Sec. 5106, and further amended by NDAA FY2019, Sec. 854, PILOT TO ALLOW PHASE FLEXIBILITY, allows the Department of Defense to make an award to a small business concern under Phase II of the SBIR Program with respect to a project, without regard to whether the small business concern was provided an award under Phase I of an SBIR Program with respect to such project. DHA is conducting a "Direct to Phase II" implementation of this authority for this 2023.4 SBIR Announcement and does not guarantee Direct to Phase II opportunities will be offered in future Announcements. Each eligible topic requires documentation to determine that Phase I feasibility described in the Phase I section of the topic has been met.

DHA Direct to Phase II Proposals are different than traditional DHA SBIR Phase I proposals. The chart below explains some of these differences.

	STANDARD DHA SBIR PROCESS	DHA D2P2 PROCESS
PHASE 1 TYPICAL FUNDING LEVEL	$250,000	None
PHASE 1 TECHNICAL *POP DURATION	6 months	None
PHASE 2 TYPICAL FUNDING LEVEL	$3,000,000**	$3,000,000**
PHASE 2 TECHNICAL *POP DURATION	24 months	24 months

*POP= Period of Performance

**This D2P2 topic is a candidate for a potential Jumbo award of a maximum of $3,000,000.

DIRECT TO PHASE II PROPOSAL GUIDELINES

Direct to Phase II proposals must include all volumes, not to exceed maximum page limit, and must follow the formatting requirements provided in the DoD SBIR Program BAA.

a. DoD Proposal Cover Sheet (Volume 1)

b. Technical Volume (Volume 2):

Part 1: Phase I Justification (20 Pages Maximum)

Part 2: Phase II Technical Proposal (40 Pages Maximum)

c. Cost Volume (Volume 3)

d. Company Commercialization Report (Volume 4)

e. Supporting Documents (Volume 5)

f. Fraud, Waste, Abuse (Volume 6)

Technical Volume (Volume 2):

Phase I Justification: Offerors are required to provide evidence that the scientific and technical merit and feasibility have been established as described in the topic description.

Cost Volume (Volume 3):

The Cost Volume must contain a budget for the entire 24-month Direct to Phase II period. Topic DHA234-D001 is a candidate for a potential Jumbo award under the Direct to Phase II and not to exceed the maximum dollar amount of $3,000,000. Costs must be separated and clearly identified on the Proposal Cover Sheet (Volume 1) and in the Cost Volume (Volume 3).

Please review the updated Percentage of Work (POW) calculation details included in section 5.3 of the DoD Program BAA. DHA will occasionally accept deviations from the POW requirements with written approval from the Funding Agreement Officer.

Travel must be justified and relate to the project needs for direct Research Development Test & Evaluation (RDT&E) Technology Readiness Level (TRL) increasing costs. Travel costs must include the purpose of the trip(s), number of trips, origin and destination, length of trip(s), and number of personnel.

Company Commercialization Report (Volume 4):
Completion of the CCR of the proposal submission in DSIP is required. Information contained in the CCR will be considered by DHA during proposal evaluations. Please refer to the DoD SBIR Program BAA for full details on this requirement.

DISCRETIONARY TECHNICAL AND BUSINESS ASSISTANCE (TABA)
The DHA SBIR Program **does not** participate in the Technical and Business Assistance (formerly the Discretionary Technical Assistance Program). Contractors shall not submit proposals that include Technical and Business Assistance.

The DHA SBIR Program has a Technical Assistance Advocate (TAA) who provides technical and commercialization assistance to small businesses that have Phase I and Phase II projects.

EVALUATION AND SELECTION
The DHA SBIR Program will evaluate and select Direct to Phase II proposals using the evaluation criteria in the DoD SBIR Program BAA. Due to limited funding, the DHA SBIR Program reserves the right to limit awards under any topic and only proposals considered to be of superior quality will be funded.

Proposing firms will be notified via email to the Corporate Official of selection or non-selection status for a Direct to Phase II award within 90 days of the closing date of the BAA.

Non-selected companies may request feedback within 15 calendar days of the non-select notification. The Corporate Official identified in the firm's proposal shall submit the feedback request to the SBIR Office at usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@health.mil as specified in the non-select notification. Please note feedback is provided in an official PDF via email to the Corporate Official identified in the firm proposal within 60 days of receipt of the request. Requests for oral feedback will not be accommodated. If contact information for the Corporate Official has changed since proposal submission, a notice of the change on company letterhead signed by the Corporate Official must accompany the feedback request.

NOTE: Feedback is not the same as a FAR Part 15 debriefing. Acquisitions under this solicitation are awarded via "other competitive procedures". Therefore, offerors are neither entitled to nor will they be provided FAR Part 15 debriefs.

Refer to the DoD SBIR Program BAA for procedures to protest the Announcement.
As further prescribed in FAR 33.106(b), FAR 52.233-3, Protests after Award shall be submitted to:

Ms. Samantha L. Connors
SBIR/STTR Chief, Contracts Branch 8
Contracting Officer
U.S. Army Medical Research Acquisition Activity
Phone: (301)-619-6979
Email: Samantha.l.connors.civ@health.mil

AWARD AND CONTRACT INFORMATION
Direct to Phase II awards will typically be Firm-Fixed-Price contracts with the Contracting Officer's Representative and other contracting staff identified.

ADDITIONAL INFORMATION

RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN SPECIMENS/DATA, OR ANIMAL RESEARCH

Prior to contract award when an IRB is indicated, proposers must demonstrate compliance with relevant regulatory approval requirements that pertain to proposals involving human subjects, human specimens, or research with animals. If necessary approvals are not obtained within two months of notification of selection, the decision to award may be terminated.

Offerors are expressly forbidden to use, or subcontract for the use of, laboratory animals in any manner without the express written approval of the U.S. Army Medical Research and Development Command (USAMRDC) Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRDC ACURO to the recipient. Modifications to previously approved protocols require re-approval by ACURO prior to implementation.

Research under this award involving the use of human subjects, to include the use of human anatomical substances or human data, shall not begin until the USAMRDC's Office of Human and Animal Research Oversight (OHARO) provides formal authorization. Written approval to begin a research protocol will be issued from the USAMRDC OHARO, under separate notification to the recipient. Written approval from the USAMRDC OHARO is required for any sub-recipient using funds from this award to conduct research involving human subjects. If the Offeror intends to submit research funded by this award to the U.S. Food and Drug Administration, Offerors shall propose a regulatory strategy for review.

Non-compliance with any provision may result in withholding of funds and or termination of the award.

WAIVERS

In rare situations, the DHA SBIR Program allows for a waiver to be incorporated allowing federal facility usage for testing/evaluation. A waiver will only be permitted when it has been determined that no applicable U.S. facility has the ability or expertise to perform the specified work. The DHA SBIR Program has the right of refusal. If approved, the DHA SBIR Program will assist in establishing the waiver for approval. If approved, the proposer will subcontract directly with the federal facility and not a third party representative.

Transfer of funds between a company and a Military Lab must meet the following APAN 15-01 requirements:

1) The DoD Intramural Researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the Extramural Research project. This letter must be provided to the Extramural Organization for inclusion in the proposal or application.

2) The DoD Intramural Researcher must also coordinate with his/her local RM office (or equivalent) to prepare a sound budget and justification for the estimated costs. Where there are no DoD-established reimbursement rates [e.g., institution review board (IRB) fees, indirect cost rates, etc.], the Military Facility's RM office (or equivalent) must provide details of how the proposed rates were determined. The DoD Intramural Researcher must use the enclosed budget and justification form when developing the estimated costs and provide it to the Extramural Organization for inclusion in the proposal or application. Instructions for completing this form will be included in the FOA.

3) The Extramural Research proposal or application must include a proposed financial plan for how the Military Facility's Intramural Research costs will be supported [i.e., directly funded by DoD, resources (other than award funds) provided by the Awardee to the Military Facility, or award funds provided by the Awardee to the Military Facility (in accordance with the requirements below)].

4) The DoD Intramural Researcher should also coordinate with his/her technology transfer office.

International Traffic in Arms Regulation (ITAR)

For topics indicating ITAR restrictions or the potential for classified work, limitations are generally placed on disclosure of information involving topics of a classified nature or those involving export control restrictions, which may curtail or preclude the involvement of universities and certain non-profit institutions beyond the basic research level. Small businesses must structure their proposals to clearly identify the work that will be performed that is of a basic research nature and how it can be segregated from work that falls under the classification and export control restrictions. As a result, information must also be provided on how efforts can be performed in later phases, such as Phase III, if the university/research institution is the source of critical knowledge, effort, or infrastructure (facilities and equipment).

END

DHA SBIR 23.4 Topic Index
Release 1

DHA234-D001 TITLE: Anti-Shock Drug, Pre-Hospital (ASD-PH)

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Combat Casualty Care

OBJECTIVE: Develop a drug that would be useful in a pre-hospital setting for treatment of hemorrhagic shock in humans.

DESCRIPTION: Severe blood loss, such as may be experienced in combat or other settings, if left untreated, will result in a deficiency of oxygen that will lead to the death of cells, tissues, and organs, and ultimately death. A pharmaceutical solution is required to address, in a pre-hospital setting, this life-threatening situation. The desired benefits of the drug are that its administration would increase the probability of survival, reduce the need for other treatment products, and reduce the need for prompt medical evacuation. The following characteristics are considered desirable: (1) The drug would most likely be administered promptly after injury, before blood or blood components are administered; however, a drug that would be administered as a pre-treatment, prior to injury, would also be of interest. (2) The drug would be administered in a low volume, perhaps 5 to 20 milliliters, to minimize the burden of transporting it and administering it. (3) The drug would be stable (retain its effectiveness) for at least one year over a broad temperature range such as 2 to 40 degrees Celsius. (4) The drug would be amenable to administration by several routes, such as oral, intravenous, intraosseous, inhalation, and intramuscular.

PHASE I: DoD seeks the identification of an active pharmaceutical ingredient (API), administration of which will provide effective treatment of shock in a pre-hospital setting. The performer will determine the scientific, technical, and commercial merit and feasibility of such an API. Upon conclusion of Phase I, the performer will have:

- Identified a concept for the mechanism of action for the API.
- Ascertained key elements (chemical moieties) of the API.
- Produced a candidate formulation, for one or more routes of administration, for the API.
- Performed a detailed analysis of predicted performance (safety and efficacy) of the API as formulated for administration.
- Defined key technological milestones for development of the API into a drug approvable bythe Food and Drug Administration (FDA) for human use.
- Demonstrated the feasibility of analyzing the safety and efficacy of the API when formulatedfor administration and outlined the criteria for success.

This topic is accepting Direct to Phase II (DPII) proposals ONLY. Proposers submitting a DPII proposal must provide documentation to substantiate that the scientific and technical merit and feasibility described above has been met and describes the potential commercial applications.

Documentation should include all relevant information including, but not limited to, technical reports, test data, and performance goals/results.

PHASE II: The expectations and required deliverables for Phase II work are:

- Using results from Phase I, produce a batch of candidate ASD-PH formulated foradministration to one or more vertebrate species as part of pre-clinical testing.
- Test a candidate ASD-PH for efficacy in a suitable animal model. The animal model mustinvolve blood loss that, untreated, would reproducibly lead to death of most test subjectsfrom shock within approximately 60 minutes after blood loss.
- Prepare a Product Development Plan and seek comments from the FDA on its acceptability.

- Manufacture a batch of candidate ASD-PH suitable for pre-clinical testing of safety under Good Laboratory Practices (GLPs).
- Perform Investigational New Drug (IND)-enabling studies.
- Update/revise the Product Development Plan to take into account the results of pre-clinicaltesting and FDA advice.
- Deliver a Technical Data Package containing submissions to the FDA, communications fromthe FDA, and the Product Development Plan.
- Upon request by the Government sponsor, deliver a sample of candidate ASD-PH to the Government for retention and/or analyses at no cost to the performer. The quantity of sample delivered to the Government will not be so great as to interfere with the performer's plans for development.

PHASE III DUAL USE APPLICATIONS: Phase III will culminate in an FDA-approved treatment for shock suitable for use in role 1 of military health care and in similar non-military austere settings such remote areas where paramedics and other personnel provide emergency medical treatment. It will be the logical conclusion of product development conducted in phases I and II. Phase III work will include the engagement of relevant stakeholders within DoD to ensure that product labeling and packaging are accomplished with due consideration of military operational requirements and logistical support.

REFERENCES:

1. Campion EM, Pritts TA, Dorlac WC, Nguyen AQ, Fraley SM, Hanseman D, Robinson BR.Implementation of a military-derived damage-control resuscitation strategy in a civiliantrauma center decreases acute hypoxia in massively transfused patients. J Trauma Acute CareSurg. 2013 Aug;75(2 Suppl 2):S221-7. doi: 10.1097/TA.0b013e318299d59b. PMID:23883912; PMCID: PMC4245019. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4245019/
2. Huang Q, Gao S, Yao Y, Wang Y, Li J, Chen J, Guo C, Zhao D, Li X. Innate immunity andimmunotherapy for hemorrhagic shock. Front Immunol. 2022 Aug 25;13:918380. doi:10.3389/fimmu.2022.918380. PMID: 36091025; PMCID: PMC9453212. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9453212/

KEYWORDS: Trauma; energy metabolism; hemorrhagic shock; hypoxia