Special Notice (SN) DARPA-SN-26-91

Resuscitation and Prevention of Ischemia-Induced Dysfunction (RAPIID)

Defense Advanced Research Projects Agency (DARPA)

Biological Technologies Office (BTO) – Commercialization and Sustainment

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1. INTRODUCTION

The Defense Advanced Research Projects Agency (DARPA) is seeking support for commercialization of technologies to be developed under the upcoming Resuscitation and Prevention of Ischemia-Induced Dysfunction (RAPIID) program. The RAPIID program aims to deliver a shelf-stable, blood analog system that can be manufactured at scale and rapidly advance toward regulatory authorization.

The purpose of this announcement is to notify the community of the RAPIID commercialization goals, initiate dialogue to address program needs, and share the timetable for full proposal submission.

This special notice is released under the current DARPA BTO Office Wide Broad Agency Announcement (BAA) HR001126S0003, titled "Biological Technologies," which can be viewed on SAM.gov. The topic relevant to this notice is "Research into market opportunities, constraints, and communities affecting financing and commercialization of bioindustrial and biomedical technologies."

Prior to any proposal submission through the BAA, interested parties must first submit an abstract and receive from DARPA a notification to submit a full proposal. The requirements for the abstract, full proposal submission, evaluation, and award of any resulting contracts will be subject to the terms described in HR001126S0003 in combination with additional evaluation criteria described in this special notice in Section 4. EVALUATION CRITERIA below.

- Proposal Abstract Due Date: June 29, 2026 by 3:00 PM Eastern Time (ET)
- Full Proposal Package: due approximately 3 weeks after invitation

These submission dates will be a key factor for invitations to proposers and for funding decisions. Late abstract submissions will not be encouraged to submit proposals, and proposals received after the deadline will be considered non-compliant. **Please note that the above deadlines differ from those listed in HR001126S0003.**

2. TOPIC DESCRIPTION

The goal of Task Area 4 (TA-4) in the RAPIID program is to identify challenges and mitigation strategies for ensuring the long-term viability and military-civilian adoption of the technologies developed within the program. DARPA intends to select a single performer to serve as the program's commercialization lead and strategic integrator.

The selected performer will work across the RAPIID portfolio, providing the expertise and frameworks necessary to identify market opportunities beneficial for the transition of biosynthetic components and devices from research and development into sustainable, scalable products.

DARPA seeks a performer for Task Area 4 (TA-4) to lead commercialization and manufacturing strategies for the RAPIID program. The TA-4 lead will ensure that blood analog components and devices developed under RAPIID successfully transition to the market and remain commercially viable after DARPA funding ends.

In this role, the selected performer will help program participants research and overcome market-entry and manufacturing hurdles. Responsibilities include conducting military and civilian market research to support both commercialization and manufacturing strategy development, including manufacturing plan assessment, pricing and procurement analysis, and supply chain strengthening strategy development. Additionally, the TA-4 lead will recruit subject matter experts, connect performers with potential investors, draft program reports, and keep all commercialization efforts aligned with DARPA's objectives.

2.1. RAPIID Program Overview

The DARPA RAPIID program aims to deliver a shelf-stable, blood analog system that is authorized for use (e.g., Emergency Use Authorization (EUA) or Food & Drug Administration (FDA) Approval) within the next three years and can be manufactured at scale. Specifically, RAPIID seeks to do this by supporting studies necessary for regulatory approval of high technology readiness level (TRL)/material readiness level (MRL) blood analog components, including, but not limited to, oxygen carriers, dried plasma, and platelets or platelet-like particles, and development of devices and guidelines to facilitate administration in the field.

The RAPIID program is designed to be completed in two phases across 36 months:

RAPIID Phase 1 (months 1-12, total of 12 months) – Performers will develop blood analog components and auxiliary fielding technologies and demonstrate their pre-clinical safety and efficacy. Evaluations for blood analog components will include *in vivo* models of traumatic hemorrhage and studies to support FDA regulatory filings (e.g., Investigational New Drug (IND), Investigational Device Exemption (IDE)). In addition, performers must demonstrate scalable Good Manufacturing Practice (GMP)-ready manufacturing and coordinate across Task Areas (see Figure 1) to develop clinical trial, commercialization, and manufacturing plans. Performance against technical metrics will be used to identify technologies invited to proceed to RAPIID Phase 2.

RAPIID Phase 2 (months 13-36, total of 24 months) – Performers will coordinate across TAs to further validate the blood analog system for trauma/hemorrhage indications in early-stage, human clinical trials. In parallel, performers will demonstrate GMP-compliant manufacturing scale-up to ensure the system is ready for fielding and coordinate across TAs to finalize commercialization and manufacturing strategies.

The RAPIID program will include four (4) Task Areas (TAs):

- TA-1: Individual Blood Analog Components***,
- TA-2: Blood Analog System (BAS) Fielding Technologies***,
- TA-3: Regulatory Advancement & Program Infrastructure***, and
- TA-4: Commercialization & Sustainment.

*****Please note that this solicitation requests proposals addressing ONLY work in Phase 1 of TA-4. Information regarding other TAs and Phase 2 is provided to inform proposers about program goals and is subject to change.**

Proposers intending to submit abstracts in response to this Special Notice for TA-4 are strongly encouraged to review the related program solicitation DARPA-PS-26-124 for TA-1 and TA-2 to ensure their proposal demonstrates a clear understanding of the expected products and RAPIID program objectives and goals.

Proposers are not expected to cover all technical areas. To mitigate conflicts of interest, those who propose to TA-4 cannot propose to TA-1 and/or TA-2.

2.2. Objective of TA-4

The TA-4 performer will research, design, and maintain a single, overarching commercialization, manufacturing, and transition framework that integrates and coordinates the activities of blood analog component developers (TA-1) and device developers (TA-2) to ensure viability after the program ends. Rather than a static, one-time deliverable, this framework will be modular and adaptable – capable of accommodating the differing maturity levels, business models, and commercialization needs of diverse performer organizations (e.g., academic institutions, start-ups, and established companies) and of evolving as the program progresses. The framework will achieve the commercialization goals of RAPIID by integrating, at a minimum, the following modular components:

- **A financing and investor engagement module** that identifies and cultivates the capital sources needed to sustain development and transition, tailored to the distinct funding pathways of each performer;
- **A scalability module** that establishes a credible, coordinated path to sufficient and reliable manufacturing capacity at the volumes required for fielding;
- **A market entry module** that anticipates and addresses the regulatory, competitive, reimbursement, and adoption challenges to bringing the integrated blood analog to market; and
- **A licensing and transition module** that ensures the individual blood analog components can be licensed for use and manufactured in combination across performers—outside of and following the research, development, testing, and evaluation (RDT&E) activities of the program.

Because these components are produced and owned by multiple distinct entities, a well researched framework will explicitly define how each module aligns the responsibilities, contributions, and interdependencies of TA-1 and TA-2 performers, so that the individually developed components cohere into a single, transition-ready blood analog system.

The TA-4 performer will lead research in support of commercialization and manufacturing strategy development and serve as a resource to support TA-1 and TA-2 performers in these efforts. In addition to performing market research, the TA-4 performer will provide TA-1 and TA-2 performers with the tools, training materials, and critical feedback necessary to develop compelling pitches and scalable manufacturing strategies that attract future investors. The TA-4 performer will provide DARPA with assessments of TA-1 and TA-2 performer supply-chain resilience, market access challenges, pricing, manufacturing, and procurement strategies. The TA-

4 performer will also identify a strategy for licensing products developed in TA-1 to allow for the blood analog to be available for purchase by the Department of War (DoW) and provide assessments of potential licensees, including non-profit and for-profit organizations, to protect from adversarial capital.

TA-4 will require assembling a group of investment professionals, entrepreneurs, and industry consultants with relevant backgrounds and knowledge suitable for advising on commercialization and manufacturing of technologies under development on RAPIID. The TA-4 performer will be responsible for recruiting and vetting members to ensure they are not backed by adversarial capital and that all conflicts of interest with RAPIID performers can be avoided or appropriately managed. The TA-4 performer will provide feedback on RAPIID performer pitches, market opportunities, business models, funding strategies, scalable manufacturing strategies, and pricing strategies.

RAPIID TA-1 and TA-2 performers may include a range of organizations (e.g., academics, start-ups, and/or established companies) that will require differing levels of commercialization support to provide guidance on markets, business cases, and financial pathways required to support the commercial and industrial transition of technologies, identify a specific market, and protect successful DARPA investments from adversarial capital. TA-4 will provide guidance to performers on markets, business cases, and financial pathways required to support the commercial and industrial transition of technologies developed in the RAPIID program. This guidance will include support for developing pricing strategies and price points that are compatible with both commercial and government markets. This support will include educational resources to develop pitch decks, intellectual property (IP) strategies, product reimbursement strategies, funding strategies, and manufacturing strategies that are necessary when communicating with potential investors. The TA-4 performer will provide these resources via regular mentorship throughout the program.

The TA-4 performer will coordinate with government organizations to identify and mitigate industrial risk, develop guaranteed-purchase agreements, and assess the secondary market demands from civilian trauma care, disaster response, and austere medicine. The participation of these government subject matter experts will be arranged by DARPA.

Collaboration across TAs is required to meet the RAPIID program goals. Performers will be required to interact and collaborate across TAs as summarized in Figure 1. TA-4 will coordinate with TA-1 and TA-2 as part of its research to develop commercialization and manufacturing plans.

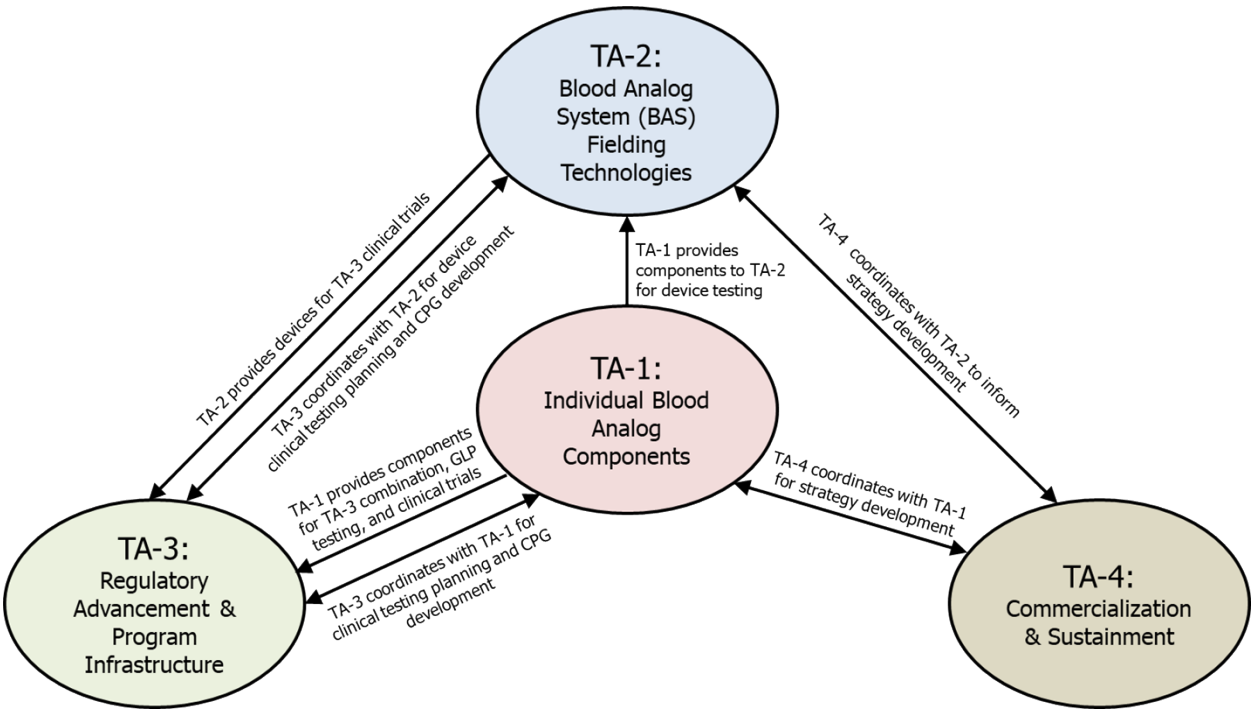

Figure 1. Anticipated data/information flow between TAs for the RAPIID program. GLP: Good Laboratory Practices. CPG: Clinical Practice Guidelines

To facilitate collaboration as summarized in Figure 1Figure 1, performers will enter into an Associate Performer Agreement (APA) with other select RAPIID performers. The APA will include the basis for sharing information, data, technical knowledge, expertise and/or resources essential to the integration of the program technical areas and components. This APA will ensure appropriate coordination and integration of work by program contractors, ensure complete compatibility between data, tools and services, and prevent unnecessary duplication of efforts and maximize commonality. Awardees must timely support and participate in the development, negotiation, and execution of any required APAs. The Government expects required APAs to be completed within three months of award unless an extension is approved by the Government. **Failure to make reasonable, good-faith efforts to complete required APAs, or failure to comply with Government-directed APA requirements, may result in corrective action, up to and including termination, in accordance with the terms and conditions of the award.**

Additionally, RAPIID will require that performer data and analysis be shared with DARPA, the Government teams, and U.S. Government stakeholders with a minimum of Government Purpose Rights (GPR). Unlimited government rights are preferred. Performers are strongly encouraged to establish the appropriate agreements to enable collaboration and data sharing with and beyond these organizations. DARPA encourages sharing of pre-existing data, including those generated through funding from other sources, although this is not a requirement of the program.

Since verification and validation, regulatory sponsorship, combination testing, and clinical trial execution of products will be developed by multiple RAPIID performers, integration of products into a blood analog is inherently sensitive to Organizational Conflicts of Interest (OCI). The credibility of the integrated RAPIID system, its regulatory submissions to the FDA, and ultimately its acceptance by the Government depend on the demonstrable independence of TA-4 performers

from the developers of the products being evaluated. For these reasons, organizations that propose to TA-4 will be ineligible for awards under TA-1 and/or TA-2 and vice versa.

2.3. Metrics, Milestones, and Deliverables

2.3.1. RAPIID Meetings and Reporting Deliverables

RAPIID performers will be expected to participate in regular meetings with DARPA, the Government team, and other performers throughout the program. Meeting and reporting milestones are to include rigorous analysis and critical evaluation of results and progress.

Minimum deliverables for TA-4 include:

- **Phase 1 Kick-off Meeting:** The performer is expected to participate in a kick-off meeting at the beginning of the RAPIID program. This meeting may be held with individual or all performer teams, to be determined by DARPA. The TA-4 performer will present a draft plan regarding the method for assessment and development of commercialization and manufacturing strategies, processes to identify and mitigate potential conflicts of interest, best practices, and schedule of meetings.
- **Monthly Reports:** The performer is expected to meet monthly with the DARPA and Government teams to review their progress toward the goals of the RAPIID program. Deliverables will be a monthly briefing describing efforts and a monthly financial report that includes the project expenditures and spend plan.
- **Annual Reports:** At the end of each year the performer is expected to provide a written progress report describing the work completed within the reporting period toward the tasks, key results and findings, and risks encountered and mitigations taken. If the project does not continue into the anticipated RAPIID Phase 2, this will also serve as the **Final Report**.
- **Annual Meetings:** The performer is required to participate in an annual meeting (1 total over the 12-month RAPIID Phase 1) to provide updates to the DARPA program management team, relevant Government stakeholders, and other performers in the RAPIID program. Deliverables will be presentations that describe progress towards the milestones and summarize outstanding challenges and mitigations.
- **Site Visits:** The performer is expected to host the DARPA and Government teams at least once annually for a site visit. Estimated timing for this visit will be Month 6 but is subject to change. These site visits may coincide with Milestones and Deliverables described in section 2.3.2. The TA-4 performer may be requested to participate in other performer site visits in a virtual capacity at the discretion of the DARPA team.
- **Final Report:** At the conclusion of the project, the performer is expected to provide a written technical report describing the completed efforts, key results and findings, challenges and limitations to the project, and potential next steps. This will be in lieu of the Annual Report. The TA-4 performer will include a summary of the outcome of the final expo, discussed further below, and feedback from investors, including challenges/blockers for commercialization that may reflect regulatory or other policy barriers.

2.3.2. TA-4, RAPIID Phase 1 (Base, Months 1-12)

Milestones

Milestones for TA-4 are focused on research for and development of TA-1 and TA-2 scalable manufacturing and commercialization strategies. As a feasible plan for scalable manufacturing is considered integral for demonstrating viability beyond the duration of the program, the TA-4 performer is expected to address both facets of this task area. Coordination with TA-1 and TA-2 teams will be required for meeting several of these milestones. Therefore, it is expected that the TA-4 performer will routinely engage with TA-1 and TA-2 teams throughout the program to gather information on technical progress and strategy development.

Commercialization

- **Month 1: Commercialization Information Request.** The TA-4 performer will provide a list of the information required from TA-1 and TA-2 performers to support development of commercialization assessments and strategies.
- **Month 4: Assessment of gaps in Centers for Medicare & Medicaid Services reimbursement and other market access obstacles.** The TA-4 performer will provide a report on the challenges for pre-hospital blood/resuscitation product reimbursement and other market access obstacles, and what needs to be done to resolve them.
- **Month 5: Review and agree to coordination plan with TA-1 and/or TA-2 performers.** The TA-4 performer will review and agree to the coordination plan generated by the TA-1 and/or TA-2 performer to ensure clear and open plan to communicate to support commercialization related tasks.
- **Month 5: Review of commercialization for components and blood analog system.** The TA-4 performer will engage with TA-1 and TA-2 performers to learn about their products prior to providing an initial assessment of the commercialization challenges for a system incorporating the blood analog components and supporting devices.
- **Month 5: Pitch event preparation.** The TA-4 performer will submit a plan for hosting pitch events and preparatory sessions to assist performers in developing strategies for engaging with investors and transition partners and crafting pitch decks. The TA-4 performer will provide templates/tools for creating effective pitch decks tailored to RAPIID objectives and a plan for vetting investors to avoid adversarial capital.
- **Month 6: Assessment of performer commercialization plans and IP strategy.** The TA-4 performer will engage TA-1 and TA-2 performers to gather information on their technical progress, commercialization strategies, IP strategies, and potential market applications prior to providing their assessment and feedback. The feedback will be provided to TA-1 and TA-2 performers to assist in developing an investor pitch deck.
- **Month 6: Assessment of approaches and acquisition strategy to provide blood analog.** The TA-4 performer will review potential organizations that can facilitate licensing of the components developed under TA-1 to enable these components to easily be packaged and provided as a complete resuscitative countermeasure combination product vs. requiring separate purchases and agreements for each component.
- **Month 7: Market landscape and commercialization report.** The TA-4 performer will build on the initial assessment of commercialization challenges for the blood analog system to provide a strategic analysis of the competitive environment, identification of key industry players, and evaluation of market trends, size, and consumer behavior for both

military and civilian cases. The report will identify growth opportunities and risk mitigations.

- **Month 9: Blood Analog licensing language.** The TA-4 performer will coordinate with TA-1 performers to draft language regarding the legal, financial, and operational terms under which the TA-1 performers grant a licensee rights to use intellectual property (IP) to produce, package and label, market, and sell their components as part of a combination to provide a blood analog.
- **Month 12: Strategy to gain support for billable blood transfusion related costs.** The TA-4 performer will present a strategy, including identification of key players and persuasive narratives, to facilitate outreach to parties that can advocate for pre-hospital blood transfusion reimbursement.

Manufacturing

- **Month 1: Manufacturing Information Request.** The TA-4 performer will provide a list of the information required from TA-1 and TA-2 performers to support development of manufacturing assessments and strategies.
- **Month 5: Review and agree to coordination plan with TA-1 and/or TA-2 performers.** The TA-4 performer will review and agree to the coordination plan generated by the TA-1 and/or TA-2 performer to ensure clear and open plan to communicate to support manufacturing related tasks.
- **Month 5: Review of manufacturing outlook.** The TA-4 performer will engage with TA-1 and TA-2 performers to learn about their products prior to providing an initial assessment of the manufacturing and commercialization challenges for a system incorporating the blood analog components and supporting devices.
- **Month 5: Contract Development and Manufacturing Organizations (CDMO) / Contract Manufacturing Organization (CMO) engagement and event preparation.** The performer will submit a plan for hosting pitch events to assist performers in engaging with CMOs and CDMOs to prepare for large-scale commercial production and preparatory sessions to assist performers in determining which type of organization is the best fit.
- **Month 6: Production cost assessment.** The performer will provide a calculation of the total expense of manufacturing a product by summing direct materials, direct labor, and manufacturing overhead (utilities, rent, depreciation) for TA-1 and TA-2 products.
- **Month 7: Manufacturing outlook report.** The performer will build on the initial assessment of manufacturing challenges for the blood analog system to provide a strategic analysis of the competitive environment, identification of key industry players, and evaluation of market trends, size, and consumer behavior for both military and civilian cases. The report will identify growth opportunities and risk mitigations.
- **Month 9: Industrial capabilities analysis completed and long-lead and key supply chain elements identified, completed.** The Performer will assess potential vulnerabilities for manufacturing, including long-lead and key supply chain elements, to identify potential mitigations that ensure that the industrial capabilities needed to meet current and future needs are available and affordable.

- **Month 9: Initial gap statement.** The performer will assess the manufacturing capabilities of the TA-1 and TA-2 performer and provide an initial review on what would be needed to achieve the end of program manufacturing goals of the RAPIID program as well as the challenges of doing so.
- **Month 9: Trade Agreements Act (TAA) and National Defense Acquisition Act (NDAA) compliance review completed.** The TA-4 performer will provide a review of the sources of TA-1 and TA-2 performer materials to determine compliance with TAA and NDAA and mitigations for any issues.
- **Month 9: Manufacturing scalability review.** The TA-4 performer will provide a review of the challenges and potential mitigations to enable scalable TA-1 and TA-2 performer manufacturing, as specified in DARPA-PS-26-124; TA-1 Metrics for Manufacturing Rate.

Government Furnished Information, Materials, and/or Equipment

- **Month 3:** Information requested from TA-1 and TA-2 performers to support commercialization and manufacturing assessments and strategy development.
- **Month 4: Coordination Plan.** TA-1 and TA-2 performers will submit plans for coordination with TA-4 for the remainder of the project after APAs are established.

2.3.3. TA-4, Anticipated RAPIID Phase 2 (Months 13-36)

Phase 2 will be contingent on funding and progress in TA-1 and TA-2. Negotiation instructions for RAPIID Phase 2 will be provided in late Phase 1, and initial submissions will be expected within one month after instructions are provided. Details about the anticipated RAPIID Phase 2 are provided in Section 6 (Appendix A) for informational purposes only and are subject to change.

3. GUIDANCE FOR ABSTRACTS AND PROPOSALS

Responses to this Special Notice must submit an abstract and receive an invitation before submitting a full proposal. Abstracts for this Special Notice are limited to 5 pages and should include:

- Executive Summary (1 page)
- Background and Expertise of the proposing organization and key personnel (1.5 pages)
- Scope of work that aligns to the goals of TA-4 (2 pages)
- Rough Order of Magnitude (ROM) cost with basis of estimate (0.5 page)

Abstracts submitted in response to this Special Notice must address only TA-4. Proposers submitting for TA-4 cannot also submit proposals for TA-1 or TA-2, to avoid potential conflicts of interest. Proposers are required to self-certify that their organization and key personnel have not submitted a proposal to TA-1 or TA-2 in response to DARPA-PS-26-124.

While abstracts are limited to TA-4, they should demonstrate a clear understanding of the challenges and opportunities within other task areas and showcase the ability to collaborate effectively with others. Additional information on what is required for proposals will be provided to those invited to submit.

The award instrument for this special notice will be an Other Transaction Agreement. Please

review the following prior to submitting an abstract:

3.1. Proposer Instructions – General Terms and Conditions

Proposer instructions can be viewed on the DARPA website.

Abstracts that are not found to be applicable to DARPA-SN-26-91 as defined above may be deemed non-conforming and removed from consideration. All abstracts and full proposals must provide sufficient information to assess the validity/feasibility of their claims and comply with the requirements outlined herein for submission formatting, content, and transmission to DARPA. Abstracts and full proposals that fail to do so may be deemed non-conforming and removed from consideration.

This announcement contains a **required** abstract phase. Proposers **must** submit an abstract in response to this solicitation to be invited to submit a proposal. Proposals that are sent without a prior abstract submission and invitation will not be reviewed. Please note that the deadlines for RAPIID abstract and proposal submissions are different from the general abstract and proposal deadlines that are listed in HR001126S0003. The abstract submission deadline for this special notice is June 29, 2026 by 3:00 PM ET. If DARPA does not invite the proposer to submit a full proposal, DARPA will provide feedback to the proposer regarding the rationale for this decision. Proposers should note that an invitation to submit a full proposal is not a guarantee that a proposal based on the abstract will ultimately be selected for award negotiation. Regardless of instrument type desired, all abstracts must be submitted through the Broad Agency Announcement Tool (BAAT). For instructions on how to submit to BAAT, visit the "Unclassified Submission Instructions" section at Proposer Instructions: General Terms and Conditions. Additional instructions for abstract submission are contained within Attachment A to this Special Notice.

3.2. Other Transactions

Attachments B, C, and D to HR001126S0003 contain specific instructions and templates and constitute a full proposal submission for an Other Transaction (OT). OT proposals must be submitted through the Broad Agency Announcement Tool (BAAT).

HR001126S0003 Attachments:

- HR001126S0003 Attachment A: Abstract Instructions and Template (required for ALL abstract submissions and prior to ANY proposal submission).
- HR001126S0003 Attachment B: Proposal Instructions and Volume I Template (Technical and Management)
- HR001126S0003 Attachment C: Proposal Instructions and Volume II Template (Cost)
- HR001126S0003 Attachment D: Streamlined Cost Proposal Spreadsheet
- HR001126S0003 Attachment G: Accelerated Award Option Election and Attestation Form (if relevant)
- HR001126S0003 Attachment H: Accelerated Baseline Model Contract Large Business (if relevant)
- HR001126S0003 Attachment I: Accelerated Baseline Model Contract Small Business (if relevant)

- HR001126S0003 Attachment J: Accelerated Contract Award Option Baseline Model Contract Addendum (if relevant)
- HR001126S0003 Attachment L: Accelerated Award Option Model OT for Research v3 (if relevant)

Teaming is encouraged to allow leveraging of the capabilities of different organizations, ultimately yielding an optimal structure to generate the most innovative, efficient, and effective solutions. One contractor must be identified as the prime.

Abstracts must follow the same content guideline as described in Attachment A, "Abstract Template" provided with this solicitation. The cover sheet should be clearly marked "ABSTRACT for DARPA-SN-26-91," and the total length should not exceed five (5) pages, excluding cover page, official transmittal letter, quad chart, and relevant appendices as outlined below. The page limitation for abstracts includes all figures, tables, and charts. No formal transmittal letter is required. All abstracts must be written in English.

Abstracts not meeting the format described above and in Attachment A will be considered nonconforming and will not be considered for review. DARPA intends to use electronic mail correspondence regarding DARPA-SN-26-91. All administrative correspondence and questions on this special notice, including requests for information on how to submit an abstract or full proposal to the BAA, should be submitted to the BAA Coordinator e-mail address: RAPIID@darpa.mil.

DARPA BTO encourages the use of the Federal Contract Opportunities website, https://www.SAM.gov, for retrieving HR001126S0003 and any other related information that may subsequently be provided.

While HR001126S0003 offers an accelerated award option for selected full proposals that do not exceed $2,000,000, ROMs should be provided with the abstract based on reasonable estimates of cost of resources required to successfully perform the proposed work and anticipated level of effort.

NO CLASSIFIED INFORMATION SHOULD BE INCLUDED IN ANY COMMUNICATIONS IN RESPONSE TO THIS SPECIAL NOTICE.

4. EVALUATION CRITERIA

Abstract evaluation criteria are listed in order of importance. Individual abstracts will be evaluated against the evaluation criteria described below:

- *Overall Scientific and Technical Merit:* The proposed technical approach is feasible, achievable, and complete. Task descriptions and associated milestones provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks, and planned mitigation efforts are clearly defined and feasible. The timeline for achieving major milestones is aggressive but rationally supported with a clear description of the requirements and risks.
- *Proposer's Capabilities or Related Experience*: The proposer's prior experience in similar efforts clearly demonstrates an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise

to manage the cost and schedule. Similar efforts completed/ongoing by the proposer in this area are fully described including identification of other Government sponsors. The successful offeror must demonstrate a proven track record of transitioning medical technologies through the FDA regulatory pipeline and into Government, especially Department of War, acquisition programs and include personnel who can address all required activities in Section 2.2

- *Potential Contribution and Relevance to the DARPA Mission:* The potential contributions of the proposed effort bolster the national security technology base and support DARPA's mission to make pivotal early technology investments that create or prevent technological surprise for U.S. National Security. The proposer clearly demonstrates its capability to transition the technology to Government and commercial entities. Any proposed intellectual property restrictions must not significantly impact the Government's ability to transition the technology.
- *Cost and Schedule Realism:* The proposed costs and schedule are realistic for the technical and management approach and accurately reflect the technical goals and objectives of the RAPIID solicitation. All proposed labor, material, and travel costs are necessary to achieve the program metrics, consistent with the proposer's statement of work and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed sub-awardees are substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs and the basis for the estimates). The proposed schedule aggressively pursues performance metrics in an efficient time frame that accurately accounts for the anticipated workload. It is expected that the effort will leverage all available relevant prior research in order to obtain the maximum benefit from the available funding.

5. POINTS OF CONTACT

All administrative correspondence and questions on this Special Notice, including requests for information on how to submit an abstract or full proposal to the opportunity, should be submitted to the BAA Coordinator e- mail address: RAPIID@darpa.mil. Answers to questions submitted in response to this special notice will be posted to the RAPIID Program Page. Abstracts and/or proposals submitted by any method other than the Broad Agency Announcement Tool (BAAT) (e.g., fax, e-mail) will be disregarded.

6. ACRONYMS

APA: Associate Performer Agreement
BAA: Broad Agency Announcement
BAAT: Broad Agency Announcement Tool
BAS: Blood Analog System
BTO: Biological Technologies Office
CDMO: Contract Development and Manufacturing Organizations
CMO: Contract Manufacturing Organization
CPG: Clinical Practice Guidelines
DARPA: Defense Advanced Research Projects Agency
DoW: Department of War

EUA: Emergency Use Authorization
FDA: Food and Drug Administration
GLP: Good Laboratory Practice
GMP: Good Manufacturing Practice
GPR: Government Purpose Rights
IDE: Investigational Device Exemption
IND: Investigational New Drug
IP: Intellectual Property
MRL: Material Readiness Level
NDAA: National Defense Acquisition Act
OCI: Organizational Conflicts of Interest
OT: Other Transaction
POC: Point of Contact
RAPIID: Resuscitation and Prevention of Ischemia-Induced Dysfunction
RDT&E: Research, Development, Testing and Evaluation
ROM: Rough Order of Magnitude
SN: Special Notice
TA: Task Area
TAA: Trade Agreements Act
TRL: Technology Readiness Level

7. APPENDIX A – RAPIID TA-4, Anticipated Phase 2 Milestones

This solicitation is for Phase 1 activities only. Information on Phase 2 is included to provide an overview of program goals and is subject to change. Phase 2 is subject to the availability of funds.

Commercialization

In Phase 2, the TA-4 performer will continue their engagement as in Phase I in addition to coordinating a series of pitch events where RAPIID performers brief DARPA and potential investors on their notional business case supported by their technical approach on RAPIID. The TA-4 member(s) will provide feedback to RAPIID performers on refinements to their strategy and pitch based on their expertise. Pitch events will be structured to enable performers to gain practice, including many who are investors, and this series of pitch events will culminate in an Expo during the final program workshop. To encourage commercial transition of RAPIID technologies, this Expo will serve as a capstone meant to connect program performers with a set of vetted investors beyond those on the working group.

Month 14: Identify entity to hold licenses of TA-1 components. TA-4 performers will report on the most favorable organization to enable production of blood analog components.

Month 14: Event connecting companies to investors. TA-4 performers will host a pitch event where TA-1 and TA-2 performers present a refined pitch aimed at potential investors, commercialization partners, and regulatory stakeholders to support transition and adoption. Provide final feedback on strategies and identify potential pathways for further development and investment.

Month 14: Draft go-to-market strategy. TA-4 performers will present go-to-market strategies for TA-1 and TA-2 components that define the target audience, market plan, sales strategy and value proposition to ensure a scalable system for customer acquisition and competitive advantage.

Month 36: Final event connecting component companies to investors. Second and final event for performer teams to engage with investors, commercialization partners, and regulatory stakeholders to present revised pitches in support of transition and adoption, receive final feedback on commercialization strategies, and identify potential pathways for further development and investment. TA-4 performers will provide a summary of the outcome of the expo and feedback from investors, including challenges/blockers for commercialization that may reflect regulatory or other policy barriers.

Manufacturing

In Phase 2, the TA-4 performer(s) will continue their engagement as in Phase I in addition to coordinating matching events where RAPIID performers will meet potential manufacturing organizations to assist with scaling to meet commercial and Government needs.

Month 14: CDMO/CMO Matching Event. TA-4 performers will host an event in the Washington, DC Metropolitan Area where TA-1 and TA-2 performers can meet potential CMO and CDMO partners.

Month 14: Identify investment opportunities to achieve more scalable manufacturing. TA-4 performers will host an event where TA-1 and TA-2 performers can meet investors that can financially support scalable manufacturing. This event can be combined with the commercial investor event and/or the CDMO/CMO event.

Month 36: CDMO/CMO Matching Event. Second and final event to meet potential CMO and CDMO partners.