DARPA-PS-26-124
Resuscitation and Prevention of Ischemia-Induced Dysfunction (RAPIID)

Task Area-1: Blood Analog Components and
Task Area-2: Fielding Technologies Development

Frequently Asked Questions

Version 1
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Clarifications

- The Task Areas (TAs) are not subgroupings of tasks expected to be accomplished by one performer. TA-3 and TA-4 are not continuations of TA-1 and TA-2 but separate tasks areas that will be running concurrently to support the clinical, regulatory, commercialization, and manufacturing aspects of RAPIID. TA-3 is not a further development TA for TA-1 components and TA-2 devices. All TAs will be active in both phases of the program. TA-1 and TA-2 performers cannot apply to TA-3 and/or TA-4.
- We use Arabic numerals (Phase 1 and Phase 2) for the phases of the RAPIID program and Roman numerals (Phase I and II) when discussing clinical trial phases.
- The Food & Drug Administration (FDA) is an independent Government agency that is not a participant in the RAPIID program. DARPA will defer to FDA on regulatory matters as this is the mandate for their Agency.
- Technology Readiness Levels (TRLs) relevant to the RAPIID program are defined here:
  - Link to Integrated Technology Readiness Levels For Medical Countermeasure Products (Drugs and Biologics)
  - Link to TECHNOLOGY READINESS LEVELS FOR MEDICAL COUNTERMEASURE PRODUCTS (DIAGNOSTICS AND MEDICAL DEVICES)

Administrative, Legal, and Financial Questions

Engagement with DARPA

1. **Q:** Does DARPA anticipate hosting a Proposers Day or pre-proposal teleconference for DARPA-PS-26-124, or is written Q&A the primary mechanism for pre-proposal clarification?

   A: No. The Government will not host a Proposer's Day for RAPIID. The written Q&A is the only mechanism for pre-proposal clarification.

Eligibility

2. **Q:** Are Federally Funded Research and Development Centers (FFRDCs) or National Labs eligible to apply?

   A: No. FFRDCs, University Affiliated Research Centers (UARCs), and Government Entities (including National Laboratories) are strictly NOT eligible to propose, nor are they eligible to act as subcontractors or consultants on a proposal. Additional information regarding eligibility can be found in Section 4.

3. **Q:** Are their limitations or considerations for co-Investigators or Key Personnel on proposed projects?

   A: Proposers should assemble the team necessary to complete the proposed work. Personnel from FFRDCs, UARCs, and/or or other Government Entities are not eligible to participate as proposers, subcontractors, or consultants. It is recommended that the Principal Investigator commit at least 20% effort to the project as well as other Key Personnel.

4. **Q:** Why is DARPA including overseas entities in this solicitation given the many domestic companies working in this space?

   A: DARPA is open to all solutions to the problems outlined in the RAPIID solicitation. See Section 4.1 for full details.

5. **Q:** Does DARPA have experience investing in overseas performers (e.g., universities, companies)?

   A: Yes. DARPA has a long history working with partners and allies around the world, specifically universities. Currently, DARPA has approximately 90 universities or industries from other countries participating in various DARPA programs.

6. **Q:** Can products that were not included in the FSHARP program be proposed for TA-1?

   A: Yes. Prior participation in FSHARP is not a prerequisite for eligibility to propose to RAPIID nor does it make a product ineligible. Any product that is not out-of-scope as outlined in Section 2.2.3 of the Program Solicitation and is at TRL/MRL 3-4 can apply to one of the tracks. TRL/MRL should be assessed using the links in the "Clarifications" section at the top of this FAQ document.

7. **Q:** Does a proposed technology need to already be in a Good Manufacturing Practice (GMP)-manufacturable and scalable status?

   A: No. Technologies proposed to the RAPIID program do not need to have prior demonstration of GMP-manufacturability and/or scalability; however, proposers should consider whether their product would be able to achieve this status within the accelerated timeframe of the program.

8. **Q:** Does a proposed technology need to have completed IND-enabling studies for components or IDE-enabling studies for devices to participate in RAPIID?

   A: No. Technologies proposed to the RAPIID program do not need to have completed preclinical regulatory studies (e.g., IND/IDE-enabling studies); however, proposers should consider whether they will be ready to complete these studies within the accelerated timeframe of the program.

9. **Q:** If a performer is already funded by the DoW for development of some tasks described in TA-1 or TA-2 for a blood analog component, is it still eligible to be considered for funding under TA-1 through TA-4 for tasks not currently included in existing funding?

   A: Yes, tasks that are not currently funded by another U.S. Government agency, including the DoW, can be proposed to the RAPIID program. It is recommended that any metrics, milestones, or deliverables that have previously been completed or will be completed with other funding be addressed in Attachment A – Technical and Management Proposal.

General Proposal

10. **Q:** Are NIH-style biosketches required for the PI, key personnel, consultants, or subcontract leads? If yes, is there a preferred format or page limit?

    A: No, an NIH-style biosketch is not required. Information about Key Personnel may be presented in the proposer's preferred format as long as it conforms to the formatting requirements listed in the solicitation for the proposal. The Team Member Identification is not part of the page limit.

11. **Q:** Are Letters of Support or Letters of Commitment required or recommended from subcontractors, CROs, GMP manufacturers, regulatory consultants, clinical sites, or commercialization partners? If included, should they be placed in the optional Appendix?

    A: These are not required, but if a proposer has them in support of the proposed technical plan, the information can be provided in the optional Appendix portion of the Attachment A – Technical and Management Proposal.

12. **Q:** Are Facilities and Other Resources documents required as separate attachments, or should relevant facilities and capabilities be summarized within Attachment A, Section 4, and optional Appendix materials?

    A: The only required attachments are the ones provided alongside the PS. Please provide facility, capability, and resource information in the appropriate sections of the Attachment A – Technical and Management Proposal.

13. **Q:** If vertebrate animal studies are proposed during Phase 1, is a separate Vertebrate Animal Document or equivalent narrative required at proposal submission?

    A: DARPA does not require a Vertebrate Animal Document or similar submission in proposals. It is expected that proposers will describe any relevant animal studies that are part of the technical approach in the Attachment A – Technical and Management Proposal and be prepared to meet the Institutional Animal Care and Use Committee (IACUC and) and DHA's Animal Care and Use Review Office (ACURO) protocol approval milestones and deliverables outlined in Section 2.3.

14. **Q:** What is the page limit for the Technical and Management Proposal (Attachment A)?

    A: Proposal guidelines are described in Section 5. The page limit will depend on the proposed scope:

    - Proposals covering only TA-1 (i.e., proposing a plasma solution) or only TA-2 are limited to a maximum of 8 pages.
    - Proposals addressing both TA-1 and TA-2 (i.e., proposing an oxygen carrier or platelet-like particle and its required companion device) are limited to a maximum of 12 pages.

Contracting & Budget

15. **Q:** What type of contract or agreement will be awarded?

    A: The Government anticipates awarding an Other Transaction (OT) for Prototype agreement based on fixed payable milestones.

16. **Q:** What is the expected start date?

    A: To prepare the technical and cost proposals, proposers should use a start date of 01 Oct 2026. This is not a fixed date and is subject to change based on the proposal selection and contract negotiation process.

17. **Q:** Can proposers apply for Phase 2 funding through this solicitation?

    A: No. This solicitation is exclusively requesting proposals for Phase 1 of Task Area 1 (TA-1) and/or Task Area 2 (TA-2). Proposals should only include technical plans and cost estimates for activities in

Phase 1. Details regarding the anticipated Phase 2 are provided for informational purposes and are subject to change. Invited proposers will receive Phase 2 proposal instructions during Month 8 of Phase 1.

18. **Q:** Can a potential TA-1 performer apply directly to Phase 2?

    A: No. The RAPIID program plans to conduct combination testing of products during Phase 1 to ensure that the best candidates for the blood analog advance to Phase 2. If all technical metrics described in Table 2 have been met and appropriately justified, proposals for that product should focus on the remaining milestones and deliverables that address the sharing of information and materials to support the combination testing as well as other programmatic items. All potential candidates for the complete blood analog must be involved in Phase 1, regardless of the current level of technological development, to proceed to Phase 2.

19. **Q:** Are there anticipated budget ranges, ceilings, or target award sizes for Phase 1 or Phase 2? What about proposals that include both a TA-1 component and the required TA-2 point-of-care diagnostic device?

    A: No, DARPA does not have anticipated budget ceilings or target funding ranges. The cost proposal should accurately reflect the costs needed to complete the proposed technical work. Cost proposals will be evaluated following the "Cost and Schedule Realism" evaluation criteria described in Section 5.3.

20. **Q:** For proposals that include both TA-1 and TA-2, should the cost proposal provide separate cost breakdowns by task area, or should all costs be presented as one integrated Phase 1 budget with task-level detail?

    A: Proposals addressing TA-1 and TA-2 should have a clear delineation/breakdown of costs by TA as well as by individual Tasks. These should clearly align across all documents in the cost proposal as well as with the Attachment E – Task Description Document and Attachment F – Schedule of Milestones and Payments.

21. **Q:** Are proposers expected to budget for clinical pilot studies within TA-2 during Phase 1, if such studies are proposed to support device validation, or should clinical studies be deferred to TA-3/Phase 2 unless explicitly required for the TA-2 device?

    A: Clinical studies are not expected in Phase 1 unless clearly justified to meet the objectives, metrics, and milestones on the timeline outlined in Section 2.3.

22. **Q:** How should TA-1 performers budget for TA-3 testing activities, and are they responsible for the costs of conducting these studies?

    A: In Phase 1, TA-1 performers will be expected to supply the required materials (e.g., test units, components) and standard operating procedures for storage and usage of components to the TA-3 performer(s). For budgeting purposes, we have provided key metrics for combination testing to be conducted by TA-3. Proposers should include an estimate of required product. If selected, awards will be negotiated to reflect the necessary amounts of TA-1 products by TA-3. However, TA-1

performers should NOT budget for the actual conduct of the studies or acquisition of test units by TA-3/TA-4, as those activities are funded separately.

23. **Q:** The Attachment A cover sheet requests "Total Proposed Cost" by contractor fiscal year for Years 1, 2, and 3. For this Phase 1-only submission, should we complete only Year 1 and leave Years 2-3 blank, or should we provide estimated future option costs for Years 2-3?

    A: Proposers should only include the number of years relevant to the proposed Phase 1 project on the Attachment A and B cover sheets. Please note that these years are based on the "contractor fiscal year" and those dates must be specified in the Attachment C spreadsheet. Proposers should NOT include estimated costs for potential Phase 2 work. To prepare the technical and cost proposals, proposers should use a start date of 01 Oct 2026.

24. **Q:** Are TA-1 performers allowed to include a profit (fee) in the proposed budget?

    A: Yes. The cost proposal should accurately reflect the costs needed to complete the proposed technical work.

25. **Q:** Regarding cost sharing, does DARPA require or strongly prefer that performers contribute cost share in this program? If cost share is not required, will its inclusion positively affect proposal evaluation?

    A: Section 3 states which entities are required to include cost sharing in their proposals. Any proposals including cost sharing will be evaluated per the "Cost and Schedule Realism" criteria described in Section 5.3.

26. **Q:** If a proposer is partnering with a Government laboratory for testing, should an alternative site for large-animal studies be identified? If not, should an animal studies budget be included in the proposal?

    A: Proposals should budget for and include all studies necessary to complete the objectives, milestones, and metrics of the RAPIID program on the timeline outlined in the Section 2.3. As described in Section 4.1.1, Government entities are not eligible to propose to this solicitation, nor are they eligible to be included as subcontractors or consultants as part of a proposal; therefore, non-Government partners should be identified to complete any proposed studies.

Intellectual Property (IP) & Data Rights

27. **Q:** Am I required to share data and intellectual property with other performers?

    A: Yes. Performers must enter into Associate Performer Agreements (APAs) with other RAPIID performers, except for those in direct competition, within three months of the contract award to facilitate sharing of data and components for combination testing and by TA-3 performers and development of commercialization and manufacturing strategies with TA-4 performers. Failure to comply may result in award termination. Performers will not be expected to share proprietary information with direct competitors but will be expected to share non-proprietary results during annual meetings where other performers will be present. Please see Section 2.5 of the solicitation for additional information.

28. **Q:** How will intellectual property, regulatory data rights, and future commercialization rights be protected for performers participating in the program?

    A: See Section 6, particularly Sections 6.4-6.10 in the PS for full details.

29. **Q:** Will performers be able to assert Limited Rights or Restricted Rights on proprietary background intellectual property incorporated into deliverables?

    A: See Sections 6.5 to 6.6.3 and the model OT for full details.

30. **Q:** Will performers retain commercial rights to products and manufacturing processes developed under the RAPIID program, or does DARPA retain march-in rights or licensing rights to commercialized outputs?

    A: See Sections 6.5 to 6.6.3 and model OT for full details.

31. **Q:** Please clarify whether submission or delivery of pre-existing, unpublished, or prospective proprietary data to support TA-1 evaluation would cause those data to become subject to unlimited Government rights, or whether such data may be treated as Background RAPIID Technology and provided under limited, restricted, Government Purpose, NDA-protected, or otherwise negotiated rights sufficient for DARPA evaluation, IV&V, TA-3/TA-4 coordination, regulatory planning, and transition assessment.

    A: Government rights may only be exercised upon award of the Other Transaction agreement.

Technical Scope & Task Areas Questions

Scope

32. **Q:** For dried plasmas, would adding a stabilizer be out of scope or is this to be interpreted as methods to extend conventional whole blood or its components?

    A: Adding a stabilizer to dried plasmas is in scope. The intent of the related bullet in Section 2.2.3 was to exclude methods of extending conventional whole blood or its components.

33. **Q:** Are shelf-stable, stem cell-derived oxygen carriers and hemostatic agents (e.g., red blood cells, platelets) acceptable?

    A: No. RAPIID is focusing on non-blood-pharmed products for oxygen carriers and hemostatic agents.

34. **Q:** Are platelet-derived blood components considered to be platelet-like particles or does this only pertain to synthetically-produced platelets? Does the term “synthetically produced blood analog” apply to products using human platelets, red cells/HGB, or plasma as starting material for a product classified as a biologic vs a blood product by FDA?

    A: As stated in Section 1.4 of the solicitation, platelet derived products are in scope. The categorization or nomenclature used by DARPA is not necessarily the same as terminology used by the FDA nor does it influence or supersede FDA’s authority.

35. **Q:** My product is out-of-scope for RAPIID. Are there other ways to engage with DARPA on this subject?

    A: If your product is out-of-scope according to Section 2.2.3 of the solicitation, feel free to review the BTO Office-Wide BAA on SAM.gov (HR001126S0003) and/or the Expedited Research Innovation System (ERIS) Marketplace website for information on additional research and development opportunities.

TRL/MRL Expectations

36. **Q:** What is the expected TRL for TA-1 components and TA-2 devices at the end of Phase 1 and Phase 2?

    A: TA-1 components are expected to reach TRL 6B (IND submission) at the end of Phase 1 and TRL 7 (Scale-up and Phase II Clinical Trials) at the end of Phase 2. TA-2 devices are expected to reach TRL 5 (Product development) at the end of Phase 1 and TRL 8 (Clinical studies complete) at the end of Phase 2.

37. **Q:** Do diagnostics/devices for TA-2 need to be at TRL/MRL 3-4 to apply to the RAPIID program?

    A: No. Diagnostics/devices do not need to be at TRL/MRL 3-4 to enter. TA-2 proposers should demonstrate a credible plan to get their diagnostic/device to TRL/MRL 5 by the end of the month 12. The TRL/MRL for devices can be determined using the links in the "Clarifications" section at the top of this FAQ document.

38. **Q:** Are point-of-contact devices that have achieved TRL-3 with testing on blood products but not blood analog components eligible to submit to RAPIID?

    A: Yes. Technology does not need to have achieved TRL-3 with blood analog components prior to submitting to the RAPIID program. However, proposers should consider whether they will be able to achieve the expected TRL within the accelerated timeframe of the RAPIID program.

39. **Q:** Is historical *in vitro* functional data sufficient to satisfy the TRL 3-4 entry requirement for TA-1 products?

    A: No, it is expected that proposers will have some amount of *in vivo* data prior to submission to the RAPIID program. Proposers are encouraged to reference all previous data (*in vitro* and/or *in vivo*) that can support a classification of TRL 3-4. It is not expected for proposers to generate new *in vivo* data before submission. Please see the TRL/MRL links in the "Clarifications" section at the top of this FAQ document to accurately assess the level of your potential technology solution.

40. **Q:** Will prior historical, pre-clinical, clinical, and/or IND data be accepted toward meeting RAPIID Phase 1 metrics, milestones, and deliverables without generating new prospective data?

    A: Yes, leveraging prior data is acceptable and in scope as long as it is justified. Any previously completed metrics, milestones, or deliverables should be detailed and supported by materials in the optional Appendix section of the Attachment A – Technical and Management Proposal (TMP). The main portion of the TMP, along with the schedule and cost proposal, should clearly outline what work has already been completed and what work still needs to be done.

Cross-TA Dependencies

41. **Q:** If I am proposing an oxygen carrier or platelet-like particle for TA-1, do I also need to propose a TA-2 technology?

    A: Yes. Proposers developing an oxygen carrier or a platelet-like particle under TA-1 must also include the development of a TA-2 technology to detect their TA-1 component within the same proposal (see Section 2.2). Given the interdisciplinary nature of these combination proposals, proposers may choose to subcontract different tasks or portions of the project.

42. **Q:** Can my organization propose solutions for all four Task Areas (TA-1 through TA-4)?

    A: No. Organizations or individuals awarded funding under TA-1 and/or TA-2 are explicitly prohibited from receiving awards for TA-3 and/or TA-4 due to strict Organizational Conflict of Interest (OCI) rules. Any proposal that aims to carry out TA-3 and/or TA-4 functions alongside TA-1 and/or TA-2 will be considered non-conforming and rejected without review. Additional information can be found in Sections 2.2 and 4.2 of the Solicitation.

43. **Q:** In section 2.2 and 4.2.1 the solicitation states “Organization and/or individuals that are -awarded funding under TA-1 and/or TA-2 are not eligible to receive awards / funding to conduct work under TA-3 and TA-4”. Can you please add details and explanation?

    A: Please see Section 4.2 Conflicts of Interest for details and rationale for this decision.

TA-1

44. **Q:** For TA-1, do the components need to be dry, or can they be wet, as long as the wet product is stable?

    A: The form-factor for blood analog components is not prescribed so long as it can achieve the shelf-stability and other metrics described in Section 2.3.2.1, Table 2.

45. **Q:** Can a sub-awardee on a TA-1 proposal also be a prime awardee on a TA-2 proposal, as long as the work is non-overlapping?

    A: Within the scope of this solicitation, as long as the TA-1 subawardee the license holder for the device to be developed under TA-2, they can be a TA-2 prime.

46. **Q:** If a product has already achieved many of the objectives outlined for Phase 1 (including in vitro and in vivo efficacy studies, IND-enabling safety studies, manufacturing development and stability, and FDA interactions), will DARPA consider it an appropriate candidate for this solicitation?

    A: The minimum TRL/MRL to apply is 3-4, and DARPA welcomes proposals at higher TRLs/MRLs. To assess the TRL/MRL of your product, please use the links in the “Clarifications” section at the top of this FAQ document.

    For higher TRL/MRL products, any metrics, milestones, or deliverables that have already been completed should be supported by materials provided in the Appendix section of the Attachment A – Technical and Management Proposal. If all technical metrics described in Table 2 and/or Table 3 have been met and appropriately justified, proposals for that product should focus on the remaining

programmatic milestones and deliverables. All potential candidates for the complete blood analog must be involved in Phase 1, regardless of the current level of technological development, to proceed to Phase 2.

47. **Q:** If there are multiple TA-1 performers for each component type, does a TA-1 performer need to test orthogonally in each combination and in multiple doses? For example, if there are multiple plasma performers, do the platelet and oxygen carrier performers need to test their component with each plasma component?

    A: Combination testing of components will be executed by the TA-3 performer. TA-1 performers will not be required to test combinations.

48. **Q:** Is the expected regulatory endpoint the ability to submit an Emergency Use Authorization (EUA) with completion of a Phase 2 clinical study to support military use? If not, what is the goal?

    A: See Section 1.2 RAPIID Program Description for information on the program goals. DARPA will defer to FDA guidance on all data necessary to pursue an Emergency Use Authorization.

49. **Q:** Is FDA feedback on an EUA-enabling clinical strategy necessary to support Phase 2 clinical trial design?

    A: Regulatory Authorization/Approval is a final goal of this program. DARPA will defer to FDA's authority on all regulatory submissions.

50. **Q:** Is it appropriate to include studies typically required to support an EUA/NDA in Phase 1 (e.g., expanded GLP toxicology, CMC validation, commercial batch PPQ, process validation, analytical qualification, long-term stability, and manufacturing readiness activities)?

    A: Potential performers should include all studies necessary to meet the proposed metrics, objectives, and timeline for Phase 1 of the RAPIID program.

51. **Q:** Does the clinical trial population have to be trauma? Or will other clinical indications be considered?

    A: This solicitation for TA-1and TA-2 does not include the clinical trial. The clinical trial will be addressed by the TA-3 performer. For RAPIID, we expect that the clinical trial population and design must be acceptable to FDA to support a trauma indication.

52. **Q:** If the Phase I clinical trial is complete before Phase 2 initiates, does the TA-1 performer have to supply material and support conduct of an additional Phase 1 clinical trial?

    A: Clinical trials and materials to support Phase 2 activities are out of scope for this proposal.

53. **Q:** Should TA-1 performers plan to integrate their own, internal Phase II clinical trial in their chosen indication into the Phase 2 of the RAPIID proposal?

    A: Proposals to RAPIID Phase 2 are out of scope for this solicitation. Proposal instructions for the anticipated Phase 2 will be provided to invited performers during Month 8 and will include information on RAPIID's intended clinical indication.

54. **Q:** Assuming the intent of the blood analog components is not to replace donor-derived products but act as an adjunctive treatment, the target metric of "non-inferiority to relevant blood component" seems inappropriate/not required for FDA approval. Is there room for negotiation on product-specific performance metrics?

    A: No. As a reminder, these RAPIID Phase 1 metrics are for pre-clinical work. Any changes to target metrics are at DARPA's discretion, and DARPA may adjust metrics related to data generation for regulatory packages based on advice from the FDA.

55. **Q:** What shelf-life duration is DARPA targeting for blood products under the RAPIID program? Does the program distinguish between ambient-temperature storage and cold chain storage requirements when evaluating shelf-life requirements?

    A: Please see Section 2.3.2.1, Table 2 for full information on shelf-stability requirements in RAPIID Phase 1. Additionally, Section 9.2, Table 4 provides anticipated requirements for shelf-stability for RAPIID Phase 2 though this is subject to change.

56. **Q:** Can DARPA provide anticipated requirements, constraints, or selection criteria for the Government-chosen packaging, including container type, dose volume, diluent interface, barrier properties, compatibility with reconstitution, administration set compatibility, sterility expectations, and whether the package must support direct infusion?

    A: Requirements for the packaging have not currently been defined and will not be until later in the program. Potential performers should include full details about their current or planned packaging system for review. In general, the packaging should enable the product to meet the outlined shelf-stability and reconstitution requirements outlined in the program solicitation as well as all requirements for regulatory submissions. Additionally, preparation of components should be easy to do by any individual to include those with and without medical training. Note, preparation of components for use is not the same as administrating components.

57. **Q:** If a TA-1 performer has already committed to a specific formulation and packaging system, is it expected that they will have to realign to meet a government-specified solution?

    A: Any product formulations are acceptable provided they meet the metrics outlined in Section 2.3.2.1, Table 2. Packaging systems will be reviewed by DARPA and deemed acceptable or not. Packaging deemed unacceptable will need to be realigned to meet/use Government-chosen solutions.

58. **Q:** At what point will the government-chosen packaging solution be selected and made available to TA-1 performers?

    A: Packaging approach will be assessed as part of the proposal. Proposers should assess packing and delivery format of their products. Selected performers will be notified if they must change their packaging solution to a government chosen alternative.

59. **Q:** What input will the TA-1 performers have in selecting the packaging solution for their own component?

A: TA-1 performers will be assessed on their current packaging and delivery format. If selected for award negotiation, the government will work with the TA-1 performer to approve or choose a suitable packaging solution. Metrics and milestones for TA-1 performers should consider the time necessary to choose a packaging solution.

60. **Q:** Is the government providing the packaging solution, or is the performer obligated to purchase the government-chosen solution for testing?

    A: The TA-1 performer should consider their current manufacturing and packaging approach. The government will review existing packaging, and work with TA-1 performers to choose a prototypical packaging solution (if current packaging is not acceptable) and the performer will be obligated to integrate their product into the packaging.

61. **Q:** If a TA-1 performer has already executed some of the activities identified in TA-3 for their individual blood analog component under an FDA-compliant quality system, are they expected to repeat these studies using the performers designated for TA-3, or only when used in combination with other components as part of the Blood Analog System (BAS)?

    A: Work conducted by TA-1 will be independent of work conducted by TA-3 though performers are required to collaborate and cooperate across the TAs. Any metrics, milestones, or deliverables listed in Section 2.3.2.1 that have already been completed by TA-1 should be described and supported in the appropriate sections of the Attachment A – Technical and Management Proposal.

62. **Q:** Section 2.2 states that "proposers may submit multiple proposals, provided they are the license holder for each component or technology proposed. Proposals in which the prime performer is not the license holder of the proposed component or technology will not be considered." How is license holder defined?

    A: The license holder is the one who has or is expected to have the legal permission (patent, trademark, copyright) to commercialize a product. The intent is to have the prime be the entity with which the Government can negotiate directly for procurement contracts.

63. **Q:** Will TA-1 performers be able to work with TA-3 Regulatory performer(s) prior to Month 1 to assemble the Pre-IND Meeting request submission (with agenda and proposed questions) due in Month 1?

    A: No, this pre-clinical milestone focuses on the individual components and will be the responsibility of the TA-1 performers. Unless directly specified in the PS as requiring collaboration, TA-1 metrics, milestones, and deliverables are expected to be completed independently without additional TA support.

64. **Q:** Will TA-1 performers be required to provide their component to all other TA-1 performers for testing, and what quantity will be required? This is a major cost driver for determining cost basis.

    A: No. TA-1 performers will be required to provide their component to the TA-3 performer for testing.

65. **Q:** For oxygen carriers, in vivo animal testing has not been completed against RBC concentrate, only against whole blood. Does an animal blood component need to be created for this comparison?

    A: It is expected that RAPIID individual blood analog components represent shelf stable solutions to currently administered products (I.e., oxygen carriers are expected to replace cold chain products like packed or frozen red blood cells). Therefore, it is expected that a similar or like comparison be made to provide sufficient pre-clinical safety and efficacy as a suitable replacement.

66. **Q:** Is there any standard for the comparator across multiple performers of the same component? Is the comparator blood component to be stored or fresh? Stored for how long and in what type of container and additives?

    A: TA-1 performers need to justify their comparator and pre-clinical testing plans. The TA-3 performer and government IV&V will create a standard comparator across like blood analog components.

67. **Q:** Does DARPA plan to name a TA-3 performer for storing the stability study samples, or may TA-1 performers conduct their own storage for stability?

    A: TA-1 performers are responsible for demonstrating the shelf-stability metrics (Section 2.3.2.1, Table 2) for their product.

TA-2

68. **Q:** Is a point-of care companion diagnostic required for a TA-1 submission of a platelet-like particle?

    A: Yes, a companion diagnostic is needed for any TA-1 oxygen carrier or platelet/platelet-like product. Please see Section 2.2.1 of the solicitation.

69. **Q:** What is the operational and regulatory rationale for the companion diagnostic requirement?

    A: The need for a point-of-care diagnostic is necessary to detect the amount of product an individual has received and may be necessary for delivery of far-forward care of injured warfighters.

70. **Q:** Is technology to detect blood analog component concentrations but does not assess coagulation status acceptable for TA-2? If so, what diagnostic value is provided by detecting the blood concentration of a blood analog component without assessing coagulation status?

    A: Detecting the amount of product an individual has received may be necessary for delivery of far-forward care of injured warfighters.

71. **Q:** If a companion diagnostic is not required for the regulatory approval or clinical use of a component developed in TA-1, would it be acceptable to develop a diagnostic for assessing coagulation status, therapeutic effect, or blood analog utilization rather than direct detection of the component itself?

    A: DARPA is interested in proposals to TA-2 that can aid in clinical decision making at point of injury regarding the use of blood analog components.

72. **Q:** In section 2.2 PS Scope it states, “Proposals for developing an oxygen carrier or platelet like particle under TA-1 must also propose development of a technology to detect that component

under TA-2 within the same proposal". Can you please define what detect means? Is the detection intended for far forward support the usage of a blood analog (meaning it was delivered and detect the half-life etc.) or a in-vitro bench test to detect that component to support development in TA-3? Or to develop the far forward diagnostic test to evaluate the effect of the component as delivered within the whole blood analog?

A: TA-2 is seeking technologies that will be able to identify the presence of a blood analog component from a biological sample (e.g., human blood) to inform transfusion decisions at Role 1 and higher levels on the military continuum of care. These technologies can include, but are not limited to, direct detection of the blood analog component or analysis of effects of blood analog products on blood functions such as coagulation so as to assess whether the blood analog component still has the desired effect. Please see Section 2.2.2 for additional information.

73. **Q:** Given the TA-2 Month 6 analytical proof-of-concept milestone and the Month 8 Government-furnished materials for in vitro testing of relevant SBCs, what level of TA-1/TA-2 technical interface is anticipated prior to Month 6 to define target analytes, sample matrices, expected concentration ranges, and potential optical or biochemical interferences?

    A: See Section 2.5. Cross-TA Interactions, Collaboration, and Data and Materials Sharing for full details on interactions between TAs to include between TA-1 and TA-2.

74. **Q:** For TA-2-only proposals, may proposers demonstrate early feasibility using representative synthetic particles, optical standards, or surrogate blood analog materials, with program-relevant synthetic blood component materials incorporated when available through RAPIID coordination, or is pre-proposal access to specific TA-1 blood analog components expected?

    A: TA-2 only proposals are not expected to have access to specific TA-1 performer technology(ies). The former option of using representative materials and standards is in scope.

75. **Q:** For the TA-2 analytical accuracy metrics requiring comparison to "gold standard, lab-based assays" at Months 6, 9, and 12, may proposers define the proposed analytes, decision-support outputs, and gold-standard comparator assays in their proposal, provided they justify relevance to transfusion decision support and synthetic blood component detection?

    A: Yes, that is in scope.

76. **Q:** Our understanding from the solicitation is that the TA-2 performer would need to first demonstrate that the proposed device is effective to detect blood component deficiencies in whole blood, followed by demonstrating feasibility and dose-response sensitivity to the relevant SBCs in whole blood as identified by DARPA — Could you please confirm that our understanding is correct?

    A: Please see Sections 1.4. RAPIID Technical Objectives and Task Areas (TA-1, TA-2) and 2.2.2. TA-2 Scope and Technical Objectives for details on the scope and objectives for TA-2.

77. **Q:** In Phase 1, is the TA-2 performer expected to perform initial testing on the proposed device using the relevant SBCs as identified by DARPA? If yes, should this be limited to in vitro testing since that will be part of the Government Furnished Materials in Phase 1?

A: Yes, the TA-2 performer is expected to perform testing on their device. If the device is designed to detect a TA-1 blood analog component, it ideally will be tested with that component.

78. **Q:** Can the requirement to propose a new point of care diagnostic device be satisfied by referencing the currently available portable diagnostic products and describing their relevance to the administration of our product?

    A: If the proposer can justify that there is an available portable diagnostic that either meets the TA-2 metrics within the solicitation or can be further developed to meet the metrics within the timeframe of the program, this will satisfy the requirement.

79. **Q:** Can the requirement to propose a new point of care diagnostic device be satisfied by describing the characteristics of our field deployable packaging?

    A: Field deployable packaging and describing it are not in scope for TA-2.

80. **Q:** If a TA-1 performer does not have the expertise to propose a device, are we expected/allowed to partner with a potential TA-2 performer? How can we otherwise satisfy the requirement of PS Sec.2.2 to submit a proposal for a diagnostic device?

    A: It is in scope for TA-1 proposers to partner with developers of potential TA-2 devices to propose solutions that address the RAPIID TA-2 requirements outlined in this solicitation.

81. **Q:** Can performers submit independent proposals solely focused on packaging solutions, or should they be integrated into TA-1?

    A: This solicitation is not seeking separate packaging entity proposals, and proposals specifically focused on a packaging solution alone are out of scope. However, a TA-1 performer may submit an integrated solution that includes packaging or a packaging partner. Packaging systems for TA-1 components will be reviewed by DARPA and deemed acceptable or not. Packaging deemed unacceptable will need to be realigned to meet/use Government-chosen solutions.

TA-3/TA-4

82. **Q:** Can a performer NOT apply for TA -1 and/or TA-2 but participate in TA-3 and/or TA-4 activities?

    A: Performers in the RAPIID program can only propose and participate in accordance with the compliance information provided in Section 2.2, Table 1. TA-1 and TA-2 performers cannot participate as TA-3 or TA-4 performers and vice versa. The support provided by TA-3 and TA-4 activities will only be available to RAPIID TA-1 and TA-2 performers.

83. **Q:** How will regulatory sponsorship, study oversight, and data ownership be structured under RAPIID?

    A: Regulatory sponsorship is anticipated to remain with the companies who generate the individual components. However, other unique arrangements may be explored or utilized to meet the objectives and timeline of the RAPIID program. Information on data rights can be found in Sections 6.7 and 6.8 of the solicitation.

84. **Q:** Will there be an opportunity for early phase assessment of potential risks when combining blood analog components?

    A: Yes. Testing of combinations of TA-1 blood analog components will be performed as part of TA-3, starting in Phase 1.

85. **Q:** Will TA-1 performers have oversight and approval authority regarding study design, protocol development, statistical analysis plans, and regulatory submissions that directly impact their product?

    A: We expect TA-1 performers to collaborate with TA-3 to develop plans for GLP-studies to support IND-submissions for their components and clinical trial plans for combinations that include their components.

86. **Q:** Is there a distinction between product development activities and independent validation studies?

    A: Yes. Product development activities are undertaken by the performers to optimize their individual components toward meeting metrics and milestones. Independent validation studies will be undertaken by the TA-3 performer and Government Independent Validation and Verification team to obtain data about safety and efficacy of blood analog combinations. Results from both sets of testing will inform decisions regarding progressing to Phase 2 of the RAPIID program.

87. **Q:** Will TA-1 performers retain ownership of and full access to all data generated by TA-3 activities, including GLP studies, IND submissions, FDA correspondence, and clinical trial data?

    A: The exact data sharing requirements for regulatory activities will be addressed in the coordination plan and the APA and agreed to by the government.

88. **Q:** What steps is DARPA taking to ensure that all TA-3 testing sites, CROs, and clinical sites are fully qualified and compliant with applicable GLP, GCP, and GMP requirements necessary to support FDA submissions? Will DARPA be sharing these quality assurance findings with TA-1 performers?

    A: It is in the best interest of the RAPIID program to select a TA-3 performer capable and meeting all necessary requirements for those metrics and milestones. All necessary information for product development and regulatory evaluations by the FDA will be mutually shared across all parties, including ensuring the selection of a qualified performer to conduct GLP/GCP compliant studies.

89. **Q:** Is the TA-3 performer the same as the IV&V performer?

    A: No. IV&V is a specific service that is completed by the Government Team. See Section 2.4.1. Independent Validation & Verification (IV&V) for details. Activities by the TA-3 performer are described in Section 1.5. RAPIID Transition Objectives and Task Areas (TA-3, TA-4).

90. **Q:** Page 8 indicates that TA-3 performers are responsible for “Demonstration of GMP manufacturing.” What specific activities does this include?

    A: The mention of “Demonstration of GMP manufacturing” was part of the list of regulatory goals for the RAPIID program, most of which TA-3 activities support. However, TA-3 performers will not be

responsible for demonstrating GMP manufacturing of TA-1 components or TA-2 devices. Manufacturing metrics for RAPIID Phase 1 are described in Table 2.

91. **Q:** Does DARPA expect a performer to accept DARPA selection of a CDMO/CRO performer for manufacturing or clinical trial management and execution without input or involvement in the selection process?

    A: DARPA is not specifically selecting a CDMO during RAPIID. However, the CRO to support TA-3 activities will be selected by DARPA via a separate solicitation and will focus on preparation for clinical trials of the components and the blood analog for a trauma indication.

92. **Q:** Is there a leapfrog process to accelerate a performer whose product has completed a number of TA-1 or TA-2 tasks to initiate TA-3 or TA-4? If select government requested tasks in TA-1, TA-2, or TA-3 are needed to augment data already collected by a performer, can existing data be used to augment a proposal and accelerate advancement to TA-3 and TA-4?

    A: No. The four RAPIID Task Areas (TAs) will be running concurrently throughout the program and are not staggered or sequential continuations of the work flow. TA-3 and TA-4 are separate tasks area that will be running concurrently in Phase 1 to support the regulatory, commercialization, and manufacturing aspects of TA-1, TA-2, and the overall RAPIID program. As a reminder, TA-1 and TA-2 proposers cannot apply to TA-3 and/or TA-4.

    If your TA-1 and/or TA-2 solution has already achieved metrics, milestones, and deliverables described in Sections 2.3.2 and 2.3.3, these should be described and supported in the Attachment A – Technical and Management Proposal.

93. **Q:** How will the Government ensure that the TA-3 performers meet the testing milestones and schedule required by the TA-1 performers to meet their program milestones?

    A: DARPA is the overall manager of all performers within the RAPIID program and will work to ensure coordination and collaboration across the different TAs. The TA-3 performers testing and their milestones are largely independent of TA-1. There are testing milestones in TA-1 that will have to be met that do not affect the schedule and milestones for TA-3.

94. **Q:** If a TA-1 performer has already conducted their due diligence and identified trusted vendors and Contract Development and Manufacturing Organizations (CDMOs) or Contract Research Organizations (CROs) to support their GMP manufacturing or clinical trial needs, are they expected to realign their efforts to sources identified by TA-4 performers?

    A: TA-4 is designed to assist with recommendations for commercialization and manufacturing strategies, including introducing TA-1 and TA-2 performers to potential CDMOs. If a TA-1 performer has already identified a CDMO to support their GMP manufacturing, they will not automatically be expected to replace them for RAPIID; however, if manufacturing metrics cannot be met by the selected CDMO, DARPA will assess the TA-1 performer's ability to continue in the program if they do not realign CDMO efforts.

95. **Q:** When will TA-3 and TA-4 performers be identified and available to support TA-1 and TA-2 performers during Phase 1?

A: Performers for TA-3 and TA-4 are being solicited separately and will be identified prior to the start of the RAPIID program, ensuring their capabilities are available to TA-1 and TA-2 performers when Phase 1 begins.

Regulatory

96. **Q:** If the outcome of this program is expected to be a fielded Blood Analog System (BAS), what is the proposed regulatory strategy? Does the Government intend to use the BAS as an "off-label" solution, composed of individually FDA licensed components, or as a separately licensed combination product? If the latter, who is intended to be the FDA license-holder: the Government or a commercial entity?

    A: DARPA intends to seek a BAS that is authorized for use by the FDA in 2029.

97. **Q:** Will DARPA provide regulatory science support or access to FDA liaisons to facilitate and expedite IND submissions or pre-IND meetings for performers during the program? If so, what form does that support take?

    A: The FDA is an independent entity that is not directly participating in the RAPIID program. Performers will be required to engage with the FDA in accordance with the milestones in the solicitation. TA-3 performers will provide support for required testing to support FDA submissions as outlined in the solicitation.

98. **Q:** Does the government intend to fund studies for the approval of an individual component prior to or in parallel with BAS development as individual component approval may proceed more rapidly than BAS development?

    A: Yes, in parallel. These studies will commence during Phase 1 of RAPIID and will be used to determine the components that will advance to Phase 2 and clinical trials.

99. **Q:** How will BAS regulatory meetings be conducted to protect proprietary data, manufacturing methods and other proprietary information from being revealed to other performers?

    A: Any meetings regarding regulatory matters (e.g., clinical trial planning discussions, outcomes from FDA meetings) will occur only between the TA-1/TA-2 performer, the DARPA RAPIID team, Government SMEs, and/or the TA-3 performer, who will be bound to non-disclosure by the terms of the APA. Performers should plan to invite the DARPA RAPIID team to FDA meetings for awareness.