DARPA-PS-25-12
BioElectronics to Sense and Treat (BEST)
Frequently Asked Questions

Version 1
12 March 2025

General Information

1. **Has the Program Solicitation been published? Where is it posted?**
   Answer (A): Yes, it was published on 25 February 2025, and can be found at this the URL below:
   https://sam.gov/opp/e2f29ccf8e0347449b275667f4c465e5/view

2. **Will the Industry Day slides be posted online?**
   A: Yes, information provided during the Industry Day has been made available on the BEST program page:
   https://www.darpa.mil/research/programs/best-bioelectronics

3. **Is Dr. Tender available for a call or meeting to discuss how our technology may align with the program?**
   A: In the interest of fairness to all interest parties, as Dr. Tender will not have the availability in his schedule to honor all requests, we will not be scheduling and program-related calls or meetings outside of the sidebars held in conjunction with Industry Day. The best way to receive feedback on an approach is through the submission of a proposal abstract prior to the deadline specified in the Program Solicitation (PS). The PS describes the program, including metrics, in detail. Specific questions may be submitted by email to BEST@darpa.mil. Proposers should be aware that submitted questions and answers may be published on an FAQ page, with revisions to remove proprietary information.

4. **Is teaming required?**
   A: While teaming is not required, it is strongly encouraged to provide the expertise and capabilities needed to achieve the BEST program goals. Proposing teams should have a plan in place for managing team interactions and future technology transitions.

5. **Can individuals be part of multiple proposals under this solicitation, or are there any restrictions regarding team member overlap across different submissions?**
   A: Yes. Teams can be subcontractors on multiple efforts. However, if chosen for multiple awards, a clear path will be established for ensuring no conflicts are present between the efforts. Proposers who are subcontractors on multiple teams should be cognizant of the distribution of the level of effort across multiple awards and will be required to ensure that DARPA is only charged once for any potential duplicate tasking.

6. **Several BEST Industry Day presentations were given by Government laboratories and resources about technologies they have, animal models, etc. Do we need to reach out to them and include them in the proposal writing process (including their costs), or can we propose working with them using the presented capabilities without needing to formally include them in the proposal?**
   A: Members of the BEST Government team are not allowed to join individual, competitive proposals in response to the Program Solicitation. Proposers must address all aspects of the program described in the solicitation without dependence upon these organizations or other Government Entities (see Section 3.1.1 for eligibility information).

7. **Could more information be provided about the form and format of justifying unique capabilities of a potential National Lab participant?**
   A: As described in Section 3.1.1 of the Program Solicitation, Government Entities – Government Laboratories, FFRDCs, UARCs – are subject to limitations in participating as competitive performers in the BEST program. These entities are *strongly discouraged* from proposing (as prime entity or subawardee) against this solicitation as awards to Government Entities will only be made by exception. Government Entities interested in this solicitation, either as a prime or a subcontractor, should contact the Agency Point of Contact (POC) listed in the Program Solicitation's Overview section prior to the proposal (or abstract) due date to discuss potential participation as part of the Government team or eligibility as a technical performer. There is not a specific form or format for including a Government Entity in a competitive proposal, as a prime or a subcontractor organization; this would need to be heavily justified in the proposal with the understanding that "awards to Government Entities will only be made by exception."

8. **We currently collaborate with a Government Entity. Are we in conflict for the BEST program?**
   A: Current collaborations outside of the BEST program are not in conflict. However, with respect to participating as part of the performer team for the BEST program, Government Entities – Government Labs, FFRDCs, UARCs – are subject to limitations as described in Section 3.1.1 of the Program Solicitation. These entities are *strongly discouraged* from proposing against this solicitation as awards to Government Entities will only be made by exception. Government Entities interested in this solicitation, either as a prime or a subcontractor, should contact the Agency Point of Contact (POC) listed in the Program Solicitation's Overview section prior to the proposal (or abstract) due date to discuss potential participation as part of the Government team or eligibility as a technical performer.

9. **Can foreign entities/organizations participate in the program?**
   A: Yes. As stated in Section 3.1.2 of DARPA-PS-25-12, "Non-U.S. organizations and/or individuals may participate in accordance with applicable laws, regulations, and policies, including those pertaining to export controls and security."

10. **Can you provide an update on advancements in wound healing monitoring strategies and treatments that were developed by other DARPA programs, such as the BioElectronics for Tissue Regeneration (BETR) program? It would be helpful to understand the key takeaways and developments from BETR or other programs.**
    A: The BETR program is ongoing, so DARPA encourages any interested proposers to directly contact BETR performers for specific information about the technologies in development. DARPA is not requiring that BEST proposals build directly off results or technologies from the BETR program.

11. **The BEST program seems to cover different phases of wound care. Can an organization or investigator submit different abstracts that address these different phases?**
    A: The BEST program is specifically focused on preventing and managing wound infections. All abstracts and proposals should address this need. Any approach related to wound care beyond infection is out of scope.

Contracting and Cost

12. **How much funding is available for the BEST program? What is the expected size of an award? Approximately how many projects is DARPA planning to fund?**
    A: DARPA has approximately $22.8M total for performer awards and anticipates making multiple awards. DARPA has not predetermined individual award amounts. Proposers are required to provide a well-justified budget that covers the scope of the proposed work with tasks described and budgets requested to meet the

BEST program objectives. Budgets will be examined in detail for appropriateness. If the proposal is selected for award, a Government contract officer will negotiate the terms of the contract. During this negotiation, every aspect of the proposed work plan and cost proposal will be reviewed. Please follow all instructions and use all templates or attachments provided with the BEST Program Solicitation (DARPA-PS-25-12).

13. **Can DARPA partially fund a proposal?**
    A: Yes, DARPA reserves the right to fully or partially fund a proposal.

14. **Is there flexibility within the program budget? Can performers address changes in cost throughout the effort?**
    A: It is important to prepare the budget for the work you propose with sufficient justification, as described in the solicitation. This can include risk mitigation (for example, budgeting for multiple ways to accomplish a task that constitutes a technical break through).

15. **Can DARPA clarify the indirect cost rate options available to proposers?**
    A: Depending on the performer's status, the indirect rate can be negotiated or the Government would rely on a current federal negotiated indirect cost rate agreement. The rate agreement is usually provided by a government agency (e.g., DCAA, ONR, DHHS, etc.).

    For recipients and subrecipients that do not have a current federal negotiated indirect cost rate, they may elect to charge a de minimis rate of up to 15 percent of modified total direct costs (MTDC). The recipient or subrecipient is authorized to determine the appropriate rate up to this limit. Recipients and subrecipients are not required to use the de minimis rate. When applying the de minimis rate, costs must be consistently charged as either direct or indirect costs and may not be double charged or inconsistently charged as both. The de minimis rate does not require documentation to justify its use and may be used indefinitely. However, once elected, the recipient or subrecipient must use the de minimis rate for all federal awards until the recipient or subrecipient chooses to receive a negotiated rate.

16. **For budgeting purposes, how many days are anticipated to be spent at BEST Technical Interchange Meetings in each of the travel locations – Boston, San Francisco, and Arlington?**
    A: Please estimate a maximum of 3 days per trip for BEST Technical Interchange Meetings.

17. **What is Cost Realism?**
    A: Please refer to Section 5.3 in the Program Solicitation for the full definition of Cost Realism as well as other evaluation criteria.

18. **What types of award mechanisms will be executed under the BEST program?**
    A: Other Transaction for Prototype.

Program Structure

19. **How do performers address changes to the originally proposed approach during the life of the project?**
    A: Proposals will be evaluated as submitted. It is beneficial to be sufficiently flexible in your proposal and Task Description Document to meet all program metrics while accommodating potential alternatives and risk mitigation strategies where appropriate.

20. **What is an expected period of performance to reach TRL6?**

A: The Period of Performance is described in Section 1.4 of the Program Solicitation. Phase 1 is 24-months, and the developed technologies are expected to reach TRL5 on the Medical Devices scale (https://medicalcountermeasures.gov/trl/trls-for-medical-devices/). Phase 2 is 12-months, and technologies are expected to reach TRL6 on the Medical Devices scale.

Abstracts and Proposals

21. Is submitting an abstract required? What is the advantage of submitting an abstract? Does the abstract need to match the full proposal submitted?

A: Proposers are strongly encouraged, but not required, to submit an abstract. DARPA will provide feedback for each abstract submitted. DARPA will attempt to respond to abstracts with a statement indicating whether DARPA is interested in the proposed idea. Regardless of DARPA's response to an abstract, proposers may submit a full proposal. DARPA will review all full proposals submitted using the published evaluation criteria and without regard to any comments resulting from the review of an abstract. Proposers should endeavor to follow the constructive feedback provided following abstract review. Finally, DARPA understands that final concepts and team make-up may change from abstract phase to final proposal as the technical approach is solidified. Please refer to Section 4 in the Program Solicitation for information on abstracts and Section 5 for information on full proposals.

22. Should I submit via DARPA's BAA Portal or Grants.gov?

A: Abstracts and full proposals MUST be submitted via DARPA's BAA Portal (https://baa.darpa.mil). Proposers are strongly encouraged to submit proposals in advance of the deadline. DARPA does not anticipate awarding grants.

Focus Area 1: Sense

23. For "high-resolution" and "continuous" sensing, what sort of time and spatial scales are required for measurement?

A: DARPA will rely upon proposers to describe and justify the spatiotemporal decisions for their approaches and system. These should be physiologically relevant to wounds and wound infections as well as able to meet the end of phase metrics described in Section 1.5.1 of the Program Solicitation.

24. How many bacterial strains should the platform be able to sense/detect to meet program requirements?

A: For *in vitro* demonstrations, the sensing approach(es) will need to detect all ESKAPE pathogens in mono and mixed cultures. For *in vivo* demonstrations, the sensing approach(es) will need to detect one or more ESKAPE pathogens in mono and/or mixed cultures (to be determined by the DARPA team). The metrics can be found in Section 1.5.1, Figure 2 of the Program Solicitation.

25. Would technologies for non-invasive internal organ diagnostics fall outside the scope of this project?

A: This program is focused on infections in surface exposed wounds (lacerations, abrasions, blast injuries, burns, compound fractures, etc.), so all approaches must address that topic. Everything else is out of scope. Additionally, we want to emphasize that infectious disease is a broad category, but this program is narrowly focused on wound infections.

Focus Area 2: Treat

26. During the Industry Day, it was mentioned that if a wound is going to heal on its own the preference is to leave the wound to heal on its own. What is the reason behind this?

A: Many wounds go on to heal on their own, including wounds that are highly colonized with bacteria. The current standard of care for battlefield wounds is to provide broad-spectrum and high-dose antibiotics regardless of the infection or healing status of the wound. This can lead to unnecessary treatment of wounds, drive antibiotic resistance, have toxic side effects, and increase the burden on limited resources and military medical professionals. One goal of the BEST program is to predict which wounds will heal versus fail due to infection and be able to provide treatment only when necessary.

27. **If the proposed treatment is non-antibiotic, but effective across a broad-range of pathogens, does the device still need to also administer antibiotics?**
A: All novel treatments should be well described and justified in the proposal to ensure alignment with the metrics described in Section 1.5.1 of the Program Solicitation. As stated in Figure 2, antibiotic solutions are meant to provide risk mitigation to the innovations and novel approaches for the Treatment (Focus Area 2) portion of the BEST devices.

28. **Are novel antibiotics in scope as a treatment option?**
A: Section 1.4 in the Program Solicitation provides a description of the types of treatments to be developed in the BEST program. “Treatments are expected to be novel and electronically regulated approaches to alter microbial colonization, virulence, biofilm formation and/or other features of infection to prevent a predicted infection and resolve an existing infection. Using the same or separate hardware, the capability to also deliver established, narrow-spectrum antibiotic drugs will be required for risk mitigation.” These treatments need not be directly electrical but should be controllable via an electrical circuit. Furthermore, the solicitation seeks treatments to which microbes cannot develop resistance (Section 1.2 of the Program Solicitation). In this context, any proposed use of novel antibiotics will need to be strongly justified.

29. **Does the term "novel treatments" explicitly rule out the use of established, broadly acting antimicrobials such as silver, copper, iodine, or riboflavin?**
A: Correct, novel treatments should not include the use of established, broadly acting antimicrobials. The BEST program seeks revolutionary advances in antimicrobial treatments and excludes research that primarily results in iterative improvements to the existing state of practice.

30. **Is it permissible for therapeutic delivery to be manually administered by a care provider who is automatically alerted upon infection detection, or will only proposals with entirely automated, bandage-integrated deliveries be selected?**
A: The overall BEST vision is to develop a closed-loop, automated system that can function without user or care provider input. Human-in-the-loop is allowed during Phase 1, but all approaches must address the integration into a closed-loop system for Phase 2.

31. **Are there any restrictions on the types of therapeutic modalities that will be considered in this application (e.g., therapeutic lead molecules which are not mAbs, small molecules, or bacteriophage)?**
A: DARPA is not prescriptive about the potential treatment approaches that can be used to meet the BEST program goals so long as they are “novel and electronically regulated approaches to alter microbial colonization, virulence, biofilm formation and/or other features of infection to prevent a predicted infection and resolve an existing infection. Using the same or separate hardware, the capability to also deliver established, narrow-spectrum antibiotic drugs will be required for risk mitigation.”

32. **Are there any requirements on the lead therapeutic molecule being FDA approved or are molecules in advanced preclinical development acceptable?**

A: Proposed treatments do not need to be FDA approved.

Focus Area 3: Closed-Loop Control

33. **Does the solution need to be a single, self-contained system with no user input, or can a solution come as a kit with a user following instructions provided by device?**
    A: The overall BEST vision is to develop a closed-loop, automated system that can function without user input. A multi-step kit or instruction process that requires user or medical provider engagement after initial application is not in scope.

34. **Does the program require a distinct intervention step after infection detection, or is a continuous infection management and healing process aligned with the program's intent?**
    A: Continual characterization of the wound state and infections as well as automated, real-time delivery of treatments is the intent of the BEST program.

35. **Does the required weight metric (25 g) include all components of the integrated system or just the portion directly covering the wound?**
    A: The weight metric described in Figure 2 of the Program Solicitation encompasses the entire, integrated device or system. Total weight is a critical concern for use on the battlefield, and the weight metric is intended to meet that use case.

Other Technical

36. **Is Human Subjects research allowed?**
    A: No.

37. **Is there a preferred animal model for testing?**
    A: Yes, large animal models are required in the BEST program with a preference for porcine and polytrauma models. See Section 1.5 of the Program Solicitation for all references to these models and associated deliverables.

38. **Is each team responsible for proposing and/or developing a large animal model upon which to test and evaluate their particular system components? If so, is it up to each team to define "infected" and "healed" in the context of their own model?**
    A: Proposer teams are expected to utilize their own animal models to address the BEST program goals and metrics. Section 1.5 of the Program Solicitation specifically describes the use of large animal models, including end of phase demonstration and validation deliverables (Section 1.5.3.1 and 1.5.4.1). All proposer-developed animal models, experiments, and definitions of wound status and outcomes will need to be clearly described and justified in the proposal.

39. **What is the role of the Government team animal model?**
    A: The organizations on the Government team may generate wound infection datasets in large animal models to be shared with BEST performer teams, but it is unlikely that the Government team will conduct experimental evaluation of performer-developed technologies.

40. **Regarding the machine learning component, will datasets be accessible through the BEST program? Or do we need to collaborate directly with the Government Entities that spoke at the BEST Industry Day as part of our team?**

A: BEST performer teams are expected to provide and generate their own datasets throughout the course of the program. Members of the BEST Government team are not allowed to join individual, competitive proposals in response to the Program Solicitation. Any Government team-generated datasets will be made available to all performers in the BEST program.

41. **Since almost all patients get surgical debridement, what is the dataset that correlates to battlefield/pre-debridement wounds?**
A: To the best of our knowledge, there are no comprehensive datasets and samples collected directly from the battlefield. Therefore, we expect that all datasets – existing or generated in the program – can be extrapolated to the combat scenario. Additionally, this program will rely upon the use of animal models and generation of *in vivo* data, that can include undebrided/pre-debrided wounds. All models must be clearly described in the proposal and aligned to the BEST problem. Any human samples or data used must NOT be considered Human Subjects Research.

42. **Can you use Bluetooth Low Energy (BLE) and a mobile device with an app to provide information to the care provider? Is signature management an issue (i.e., no BLE, WiFi, etc.)?**
A: Signature management is not a direct metric in the BEST program; however, it is an important consideration for eventual use on the battlefield. The overall BEST vision is to develop a closed-loop, automated system, so use of BLE, mobile devices, or other forms of external communication to control or manage the wound is not in scope.

43. **Wounds come in different types (e.g., burns, puncture, lacerations) and sizes. Is there a benchmark wound type or size that should be addressed?**
A: DARPA will rely upon proposers to describe and justify the wound type selected for their proposal so long as it is a surface exposed wound (laceration, abrasion, blast injury, burn, compound fracture, etc.). The metric for the minimum wound size is 25 cm^2 (Section 1.5.1, Figure 2 of the Program Solicitation) and any proposed deviations from this metric should be clearly described and justified.

44. **Is it in scope to propose modifying the packaging to allow the device to be applied to different anatomical locations (extremities, torso, joints, etc.)?**
A: As long as the BEST size, weight, and power (SWaP) metrics are met, this would be in scope.

45. **Is there a defined expectation for how quickly the wound should heal, or should proposers provide that benchmarking criteria?**
A: Accelerated healing is not in scope for the BEST program. Predicting the healing outcome of a wound and being able to adapt that prediction based on the infection status is in scope and described within the Program Solicitation. Performers are expected to justify their definition(s) of healing status and outcomes to achieve the program goals.

Transition

46. **Investigational Device Exemption (IDE) approved devices appear to require design control including verification and validation (V&V). Is it anticipated that performers will be required to conduct V&V studies for each device (FA1, FA2, FA3) supportive of an IDE application for each component?**
A: One of the transition objectives in the BEST program is for performer teams to prepare a regulatory package (IDE or other) for submission to the Food and Drug Administration (FDA). Submission and approval are beyond the scope of the BEST program.

47. **The BEST device may be viewed by the FDA as a combination device involving diagnostic and therapeutic systems that combine drugs, devices, and/or biological products. Will multiple FDA agencies be involved (CDRH/CDER/CBER) requiring additional testing beyond a device IDE?**
A: The BEST program has deliverables and milestones related to engagement with the FDA to determine the appropriate regulatory path and FDA organization for a given technology's eventual approval.