FREQUENTLY ASKED QUESTIONS

GENERAL INFORMATION

1. My research is not geared specifically to meet the Focused Pharma program goals. Is there an alternate solicitation that I can respond to?

A: Yes. DARPA/BTO has an office-wide solicitation (HR001119S0048) for this purpose. Responses are being collected through April 25, 2019.

2. Is Dr. Emondi available for a call to discuss our proposed approach?

A: In the interest of fairness to all parties, as Dr. Emondi will likely not have availability in his schedule to honor all requests, we will not be taking any program-related calls/meetings. Ultimately, the best way to determine the applicability of and level of interest in your approach is through the submission of a proposal abstract. The BAA describes the program, including metrics, in detail. If you have specific questions, please submit them by email to BGPlus@darpa.mil. Please be aware that your question and its answer may be published on this FAQ page, after the question has been revised to remove proprietary information.

3. Will the Proposers Day slides be posted online? What about the webcast?

A: Yes, slides presented during the Proposers Day (not a webcast recording) will be made available on the BTO section of the DARPA Opportunities page: http://www.darpa.mil/work-with-us/opportunities.

4. Do I need to submit an abstract? What is the advantage of submitting an abstract? Does my abstract need to match the full proposal submitted?

A: Abstracts are strongly encouraged, but not required, to submit a full proposal. DARPA will provide feedback for each abstract submitted.

DARPA intends to respond to abstracts with a statement as to whether DARPA is interested in the idea within 5-10 business days of receipt. If DARPA does not recommend the proposer submit a full proposal, DARPA will provide feedback to the proposer regarding the rationale for this decision. 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.

Finally, DARPA understands that final proposals and team make-up may vary somewhat from initial abstracts as content of teams and concepts proposed matures during preparation of the proposals.

5. Can a performer or individual participate on more than one team?

A: Yes. Proposers may join any number of teams as a subcontractor and still submit a separate proposal as the Principal Investigator (PI) (with or without subcontractors). The proposer should be very clear as to how hours will be charged in each proposed effort and describe what safeguards are in place to ensure that time is not double billed.
6. Can a subcontractor have subcontractors?
A: Yes.

7. Can Federally Funded Research and Development Centers (FFRDCs) or other Government Entities submit proposals or apply as prime organizations?
A: Yes, FFRDCs and government entities can submit proposals if they meet certain criteria specified in BAA Section 3.1.1. Note that to avoid potential conflicts of interest, FFRDCs and other government entities, if selected for proposer work, will not be eligible for IV&V work.

8. Is there a preference for collaboration with multiple institutions/industry versus collaboration within one organization?
A: There is no preference and we cannot provide further comment on teaming. Ultimately, the proposers are responsible for developing a team that can accomplish the goals of the program.

9. Would a university or lab be considered a good system integrator or should a company fill this role?
A: Teams can chose their system integrator and should justify this choice.

CONTRACTING/COST

10. How much funding is available? What is the expected size of an award?
A: DARPA has not predetermined award amounts. Proposers are required to provide a well-justified budget appropriate for the scope of the proposed work. Cost should be based upon how much money is required to perform the tasks you feel are necessary to meet the objectives of Focused Pharma. Proposals will be scrutinized for unnecessary or inflated expenses. If the proposal is selected for award, a government contracting officer will negotiate the terms of the contract. During this negotiation, every aspect of the statement of work and cost proposal will be reviewed. Please ensure that all of the instructions in HR001120S0004, including the required checklist in Appendix 1. This will enable the government contract office to expedite negotiations.

PROGRAM STRUCTURE

11. Will there be an “advanced studies” mechanism/track under BG+?
A: No, not at this time.

12. Is DARPA thinking about this program as being 6.1 and 6.2? Beyond?
A: BG+ is an Applied Research (6.2) program.

13. How many teams are expected?
A: Multiple awards are anticipated.

14. Can teams provide a proposal that describe alternate solution paths that the teams will chose from as the program progresses?
A: While alternative approaches can help with risk mitigation, they may also be costly to run. Critical experiments and down selection should happen early in the effort. The rationale for alternative approaches must also be justified in the proposal.
15. For eventual implantation into patients, does the subject recruitment and implantation need to occur in the U.S.?

A: If the project involves execution of all or part of the research outside of the United States, the local IRB (or IRB equivalent of the host country) and DoD HRPO must confirm that all applicable host national laws and requirements of the foreign country have been met and also confirm that the IRB considered cultural sensitivities in the setting where the research will take place. The Principal Investigator must provide adequate information to the DoD HRPO regarding national laws and requirements and the cultural context in which the research will take place. This information can be provided through protocol review submission form or through inclusion of applicable information in the protocol. The DoD HRPO may also require that a United States IRB review the protocol (depending on the country reviewing the work, the risk level, subject population, etc). We would encourage any Performer doing HSR work outside the US to engage with us early in the process to avoid delays.

ABSTRACTS/PROPOSALS

16. Can proposers upload their abstracts directly?

A: Yes, proposers are responsible for submitting their abstracts directly through BAAT and cannot be e-mailed. Per the BAA, “Submissions may not be submitted by fax or e-mail; any so sent will be disregarded.”

HUMAN RESEARCH SUBJECTS/ANIMAL USE

17. How is human use research approved?

A: This approval is granted through a two step process: (1) first review is done at the local level (local Institutional Review Board (IRB)); (2) second review is completed by DOD Human Research Protection Office (administrative review). The Government contracting officer is responsible for ensuring that all awards that include human use research tasks contain the appropriate clauses and terms. Like animal research, no work can begin until IRB and HRPO approval is granted.

18. Can teams start experiments with human participants before Phase 3?

A: Yes, teams can start clinical experiments at any time in the program as long as all regulatory approvals have been obtained and the research and development plan is innovative and the program goals, milestones and metrics are being accomplished.

GENERAL TECHNICAL

19. What is your attitude towards (fill in the blank) technology?

A: We will not comment on specific technologies. Proposed technologies and approaches must fit within the boundaries and spirit of the BG+ Program.

20. Do the teams need to use a spinal cord injury animal model for this program?

A: Teams can choose different animal models depending on the experiment or technical area but must justify their choice in the proposal. As per the BAA, teams must describe how demonstration results are expected to translate into the clinic. Teams should chose animal models that are appropriate to support regulatory approval of the final technology. Teams should consider the translation of both scientific results and device design.

21. Is there room for spinal injury that affects nerves but not necessarily the spinal cord? i.e., sciatic nerve pinching or decreased bladder function.

A: While BG+ technologies will likely be applicable to other types of nerve injuries, the program structure, and TA1 objectives in particular, will require Performers to focus on spinal cord injuries.
22. Will structural support be considered? If not, how will decompression during procedures be ensured?
A: Yes, as long as the solution is supporting the accomplishment of the program metrics.

23. How/when would you suggest troubleshooting of device design and implementation when needing to translate from animal to human?
A: Teams should develop appropriate system design and animal models to properly tailor their system for translation from animal to human. We envision early FDA engagement will also provide critical insight for strategy development.

24. Is brain-computer interface hardware development in scope?
A: Yes.

25. Are combinatorial approaches (e.g., cell therapy and electrical stimulation) in scope?
A: Yes.

26. What role does A.I. and machine learning play in the program?
A: A.I. and machine learning based algorithm development will be key to the program. A.I.-based neural decoding and encoding algorithm development is within scope.

27. Do A.I. algorithms have to be 3rd wave A.I.?

28. Is it necessary to measure everything from a device or can teams draw samples (e.g., from CSF) for analysis?
A: The spirit of the program is to open a window directly into the penumbral zone that does not currently exist. Teams should consider and justify what is revolutionary or unique about analyzing CSF or other types of samples. While this is not a biomarker development program, biosensor development is in scope.

29. Is a biomarker that can detect evoked potentials in scope?
A: As stated in the BAA, teams can choose their biomarkers and must describe biomarker relevance to spinal cord injury. Proposed biomarkers to be tracked must also be unambiguously linked to one specific aspect of the injury or to the state of the injury site.

30. Is the proposal responsive if the therapeutic stimulation method encourages axon regrowth in a way that creates new connections and leads to a reorganization of neural signals?
A: Yes, though the team should demonstrate the functional relevance of the reorganization.

31. “Exploration” for new biomarkers is out of scope, per the BAA. Could you please elaborate on this requirement? For example, if there are known markers to track/treat, do we need to select them a priori? Are we locked into those markers for the rest of the program?
A: Proposers must identify the biomarkers in their proposals. Refining the biomarkers during program execution is valid given scientific justification. Proposed biomarkers should be chosen with the completion of the program metrics and milestones in mind.
32. What do you mean by “regrowth of injured neurons” in this program? Knowing which specific neurons are damaged and following them through recovery would be challenging and would seem beyond what this program is going after. Would improving functional metrics and having circumstantial anatomical evidence (e.g., MR) supporting neural regrowth be sufficient?

A: Yes, reporting functional improvement is sufficient for meeting the program metrics. However, it should be noted that the therapeutic stimulation solution will need to be approved by the FDA. The FDA may require supporting efficacy data.

33. In the metrics, it states that ≥3 channels of stimulation are required. It then provides as example: electrical stim, drug elution, etc. Does the word “channel” refer to say electrodes of electrical stimulation, ports for drug elution, etc. or does the word “channel” refer to modalities of stimulation?

A: Proposers must define and justify their definition of a channel of stimulation. Channels can be achieved across modalities (electrical, drug, etc.) or within the same modality. If within the same modality, each channel must operate independently. For example, three electrodes that can only provide the same stimulation trains would not count as separate channels.

TECHNICAL AREA 2

34. Is there a preference for a specific type of function for TA2?

A: No.

35. Can functional restoration be related to functional restoration of the pain system to address chronic pain and would it count as one of the three functions in animals and one of two in human research participants?

A: If appropriate, teams are encouraged to discuss how proposed technologies may help mitigate other known complications from spinal cord injury. However, pain mitigation does not count as a function for meeting the TA2 metrics.

36. Does spasticity count as a function for meeting the TA2 metrics?

A: If appropriate, teams are encouraged to discuss how proposed technologies may help mitigate other known complications from spinal cord injury. Addressing spasticity is in scope provided it enables functional restoration (e.g., of movement) but it does not count as one of the three TA2 functions by itself.

37. Does addressing immunosuppression count as a function for meeting the TA2 metrics?

A: Addressing immunosuppression is in scope, provided it facilitates functional restoration but it does not count as one of the three TA2 functions by itself.

38. If a team addresses upper and lower extremity movement/somatosensory restoration, does this count as two separate functions?

A: No.

39. With respect to restoring proprioception, is sensory substitution in scope?

A: The proprioceptive signal should give feedback about limb location in space. The device(s) should stimulate the appropriate neural pathways associated with the limb where possible. Devices(s) that bypass these pathways and stimulate brain areas to provide proprioceptive feedback are within scope.

40. The BAA states that possible functions are movement with somatosensory feedback and posture control with proprioceptive feedback, would movement with proprioceptive feedback be responsive to the BAA?

A: Movement with somatosensory feedback should include restoration of cutaneous and/or
proprioceptive signals as appropriate. Proposers should justify in their proposals why a particular feedback is paired with a particular movement or control function.

41. **TA2 Phase 2: latency – what does this refer to? Closed-loop operations or the entire bidirectional operations?**

A: Per the BAA, system latency is defined as the ability to record residual commands and stimulate the injured circuit within the specified time.

**DATA, OPEN-SOURCE STANDARDS, IP**

42. **The BAA states that the software development kit (SDK) must be on an open-source platform, can you clarify?**

A: Teams do not need to reveal their proprietary information (e.g., code, component design) behind the SDK, they simply must provide an open-source toolkit to allow others (IV&V team, other researchers, etc.) to use the system.

43. **Are there any important pieces of information regarding IP that we should know?**

A: The Government’s license rights to technical data and software developed under an award will be negotiated specifically for each award. Proposers must complete the IP assertions table provided in the BAA on page 32 and submit this as part of their complete proposal package.

44. **Will data be made open along with software? Seems like you need both to get future help from outside and beyond the program’s life.**

A: The Government will not require Performers to produce open source software and data. Performers may elect to release data and software at their discretion, but any release must be in accordance with the terms of the Performer’s Government contract. An amendment to the BAA clarifying this topic is forthcoming.

45. **Will collected data from all phases/areas be preserved beyond program life?**

A: Decisions regarding the preservation and dissemination of copies of data generated and developed by a performing team will be at the discretion of the Performer, but any dissemination must be in accordance with the terms of the Performer’s Government contract.

46. **The announcement encourages commercial translation and possible submission of business plans. Are we allowed to budget for intellectual property/patent fees?**

A: Organizations can propose costs for Government review and consideration. That being said, in this example, it is possible that costs related to IP and patent fees might be considered indirect costs that would typically not be charged direct to a specific Government contract but rather recovered through an organization’s indirect rates.