DARPA-BAA-12-37

Frequently Asked Questions

Last Updated: 5/30/2012
Latest Additions in BLUE

GENERAL INFORMATION

Q: What DARPA seedlings predate this program? Are reports available?
A: There were no preceding efforts.

Q: If my research is relevant in this field, but is not geared specifically to meet these goals, is there a solicitation that I can respond to?
A: Yes. DARPA/DSO has an Open solicitation (DARPA-BAA-11-65) for which responses are being collected through 9 Aug 2012.

PROPOSALS

Q: Can a prime or collaborator be an international company?
A: Yes, international companies and universities are acceptable.

Q: Is subcontracting to a National Lab or Federally Funded Research and Development Center (FFRDC) permitted?
A: Yes. Proposer should comply with the section on FFRDCs as stated within the BAA.

Q: Will any response be provided to abstracts?
A: It is anticipated that replies will be made on whether proposals are encouraged or discouraged as well as limited feedback on the encourage/discourage decision.

COST

Q: What is the overall DARPA budget for Biologically-derived Medicines on Demand? Are there funding limits for individual proposals?
A: The investment profile for Biologically-derived Medicines on Demand has not been fixed at this time. The final program will depend on the proposals selected for funding. At this time, no single-project funding limits have been set.

PROGRAM STRUCTURE

Q: How many awards are anticipated?
A: The number of awards will depend on the merits of the proposals received and funds available.

Q: Does DARPA intend to allow the performer to retain the prototype device at the end of the program, or is the device considered a Phase 2 deliverable to DARPA?
A: The final device is a deliverable to DARPA at the end of Phase 2 unless established otherwise in the contract.

TECHNICAL

Q: The BAA states that "engineering of single strain approaches are preferred because they will conceivably be more readily expandable to address additional/emerging needs." Does "single strain" in the statement refer to a single host organism, like E. coli, for instance or rather a single strain variant of a host organism, like E. coli?
A: As long as justification is provided, DARPA is accepting different approaches, including single strain variants of a given organism and/or multiple/different strains of a given organism.

Q: On page 8 there is a list of DoD-relevant protein-based therapeutics. By the end of Phase 2, does a proposed platform need to be able to synthesize 6 different proteins on this list or can variations of one protein count towards the 6? For example, interferon has several variations (alpha, beta, and gamma) that can function as therapeutics for different diseases.
A: As IFN alpha, beta and gamma are three different proteins (at their sequence level and structure) and they respond to different therapeutic uses, they can be considered as 3 of the 6 protein-based therapeutics requested by the BAA.

Q: Is it expected that the field operation of this technology will be de novo or will the expression strain for a particular protein drug be incorporated into the apparatus and activated on demand?
A: Denovo.

Q: Would the development of an integrated single-use, bio-manufacturing hardware platform that has a small footprint and is easily deployable- for making low cost biologics using mammalian and other expression system be of interest?
A: DARPA is open to proposals using mammalian cells lines. However, the proposer should make sure to read the BAA and comply with the short timeline requirements for production as mammalian cells typically need longer times than microbes. FDA issues must also be appropriately addressed. A compelling reason for using mammalian system should also be included (versus microbial).

Q: Is it expected that the biosimilarity of all the compounds in animal models for tox, PK/PD and immunogenicity is proven as part of the Bio-MOD program?
A: Yes, all manufactured compounds must comply with regulations and guidance on biosimilars from the FDA. This is the reason DARPA is requiring a strategic plan from all proposals on engagement with the FDA early in the program.

Q: Please provide some clarification as to what level of approval is required by the end of Phase 2 - i.e. 510(k), Premarket Approval (PMA), etc.
A: Please refer to the latest guidance on biosimilars from the FDA:

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm

Since the FDA guidance on biosimilars is fluid and constantly being updated, and approval requirements for the device, manufacturing process, and/or biosimilar product may or may not be different/necessary, DARPA encourages early engagement in the program with the FDA to help determine the timeline for the approval process as well as inform the requirements of the Bio-MOD device.

Q: Must all final release criteria assays be performed within the 24 hour target, including sterility and functional assays?
A: Yes, the 24-hour target includes end-to-end demonstration from protein synthesis to final formulated therapeutic with demonstrated potency, efficacy, and purity.