### DHA Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Frequently Asked Questions

### Q: How do DHA topics differ from other SBIR/STTR medical technology funding opportunities?

A: SBIR/STTR topics enable the Defense Health Agency to spark the next generation of medical technologies for the future battlespace. These programs support U.S. small businesses developing high-risk, high-impact medical materiel technologies with the potential for wider commercialization. DHA topics focus on innovations in the following general categories:

- 1) Combat casualty care, including medical simulation to support medic training;
- 2) Military infectious diseases; and
- 3) Military operational medicine

### Q: We are new at this. How can I find assistance for my proposal writing process?

A: Proposal writing takes practice. Evaluators will rate the scientific and commercialization potential of your innovation, and are not focused on whether your proposal reads like a professional publication. Ensuring that your technical and cost proposal sections are written as clearly as possible will help you to convey your plan accurately. State or regional proposal writing assistance may be available. Be assured that DHA SBIR/STTR often funds first time proposals from small businesses.

#### Resources:

- 1) During the Pre-Release period of the Broad Agency Announcement (BAA) cycle, subject matter experts can answer technical questions concerning published topics. After the BAA officially opens, these subject matter experts are no longer able to speak to you directly. However, after the official open date, you can publish public FAQ-style questions on the Topic Q&A board here: <a href="https://www.dodsbirsttr.mil/topics-app/">https://www.dodsbirsttr.mil/topics-app/</a>
- 2) If you run into technical issues with the submission of your proposal on the Defense SBIR/STTR Innovation Portal (DSIP) site, job aids for each proposal section may be found here:

  https://www.dodsbirsttr.mil/submissions/learning-support/training-

- <u>materials</u>. If these job aids do not address your submission issue, contact the DOD SBIR/STTR Help Desk at <u>DoDSBIRSupport@reisystems.com</u>, with available hours of 9:00 a.m. 5:00 p.m. (ET). The DSIP Help Desk does not host a telephone interface.
- 3) If you need general SBIR/STTR proposal writing assistance, you will find great resources on the Small Business Administration (SBA) <a href="https://www.sbir.gov">www.sbir.gov</a> portal. Scroll down to the "Find Local Assistance" area to see listings of proposal assistance organizations in your state. Depending on your state's funding, many of these services may be offered at no charge. The <a href="https://www.sbir.gov">www.sbir.gov</a> site also houses training materials and event recordings.
- 4) If you need help understanding budgeting calculations for DOD contracting, you can locate your local Procurement Technical Assistance Center; <a href="https://www.dla.mil/SmallBusiness/PTAP/PTAC/">https://www.dla.mil/SmallBusiness/PTAP/PTAC/</a>

### Q: How do DHA Phase II proposal timelines differ from other SBIR/STTR programs?

A: DHA SBIR/STTR Phase II proposals run on an expedited evaluation schedule in order to shorten the funding gap between Phase I and Phase II. For this reason, you will generally receive a proposal notification timeline during the fifth month of your contract.

### Q: Can you list some best practices for DHA SBIR/STTR proposers?

A: Experienced proposers develop structured habits that make the most of their writing time and drive down process and goal uncertainty:

- 1) Read topics carefully to make sure you understand the capability gap and any fielding constraints described, such as conformance to size, weight, and power restrictions. Here's an added hint: affordability is critical even if it isn't explicitly mentioned. Reviewers will expect you to propose a better, faster, and cheaper item than currently fielded solutions.
- 2) Ask technical questions during the BAA Pre-Release period when you can communicate directly with topic authors. DHA topic authors prefer contact by email.
- 3) Check that your budget is compliant with the cap shown in the solicitation, and that percentages for subcontracting and partnerships meet prescribed ceilings for SBIR or STTR funding opportunities.

- Remember that contractors and consultants do not count as employees of your small business.
- 4) Ensure that the PI has demonstrably adequate technical expertise to manage the overall project. Could the SBIR PI be legally considered as a full time employee at another organization, such as a university?
- 5) Your work plan is important, and sometimes small businesses don't realize that the way the work is planned is a useful indicator of their potential technical success for reviewers. Spend the time and space you need on showing how the project will be specifically structured.

#### Q: What are the keys to a successful budget?

A: Budgets should be commensurate with work proposed, be compliant with worksheet instructions, and make rationales clear. DHA SBIR/STTR does not approve the use of Phase I/II SBIR/STTR funds for any marketing purposes, to include conference travel, expo booth costs, or public relations/advertising costs. Your budget should ordinarily not include any work performed outside the U.S. or by a DOD organization.

#### Q: How important are letters of support, and who should write them?

A: Letters of support can benefit your proposal if they indicate direct commercial interest from a supply chain partner or investor. Additionally, letters can indicate partnership commitments. DHA SBIR/STTR projects often begin at early Technology Readiness Levels, so we realize that not all projects will start out with written indications of customer validation at Phase I.

### Q: Can I answer a Phase I topic with a Direct to Phase II Proposal?

A: DHA SBIR Direct to Phase II topics are written differently than Phase I topics. Only Phase I proposals will be accepted for Phase I topics, and only Direct to Phase II proposals will be accepted for Direct to Phase II topics. Because Direct to Phase IIs are part of a pilot program, DHA SBIR Direct to Phase II topics are always issued in a separate BAA section from Phase I topics.

# Q: I met a service member subject matter expert at a conference who was interested in our technology. Should I include them in my proposal as a consultant?

A: DOD personnel should not be listed within Phase I and Phase II proposals as contributors. If you are awarded a Phase I or Phase II from DHA, your Technical Assistance Advocate can reach out to service member stakeholders if you feel they could assist with your commercialization efforts as the project progresses.

### Q: Can I provide an in-person demo as part of my Phase I plan, and would this demo impact my Phase II proposal?

A: Phase I budget ceilings may not allow in-person demos to be prioritized unless they are specified in a topic. However, if a demo is arranged with your Contracting Officer's Representative (COR), please be aware that the results of this demo will not be considered in your Phase II evaluation process. Only the submitted written proposal may be considered for evaluation. You may be asked to schedule demos after your Phase II proposal has been submitted, given DHA's expedited Phase II proposal process, which may begin as early as your fifth contracting month.

### Q: Does DHA SBIR/STTR fund pre-clinical (animal studies) or clinical trial work?

A: DHA SBIR/STTR Phase I instructions strongly discourage the use of animals in Phase I R&D, particularly since approval timelines could delay awards past funding eligibility. For Phase II or Phase II Enhancement projects, there is no bar to this type of expenditure; however, if partner organizations are utilized, related work must remain under the specified percentage for subcontractors. Phase III funding, if subsequently received from a sponsor organization, is not restricted by this percentage rule. Note that DHA Phase I SBIR/STTR topics are intended to fund the early stages of an innovation, and not an existing R&D effort ready for testing.

Though not related to the SBIR/STTR programs, the Congressionally Directed Medical Research Programs (CDMRP) <a href="https://cdmrp.army.mil/">https://cdmrp.army.mil/</a> can sometimes fund clinical trial work.

### Q: Are there certain definitions or standards for animal or human testing that companies should be aware of?

A: We recommend reviewing the resource links of the U.S. Army Medical Research and Development Command Office of Research Protections. These policies will directly impact your DHA SBIR/STTR contracting process: <a href="https://mrdc.amedd.army.mil/index.cfm/collaborate/research\_protections">https://mrdc.amedd.army.mil/index.cfm/collaborate/research\_protections</a>

# Q: What are DHA Phase II Enhancements, and which Phase II contracts are eligible for enhancement?

A: Up to \$550,000 may be added to active DHA Phase II SBIR/STTR projects as 1:1 match for qualified Phase III funding received. The DHA SBIR/STTR Technical Assistance Advocate (TAA) works with performers and Contracting Officer Representatives to assemble Phase II Enhancement packages for approval. Phase II Enhancements are funded when funding is available.

## Q: How should small business performers think about follow-on military medical funding?

A: DHA SBIR/STTR performers should prioritize dual-use commercialization opportunities, as DOD Research, Development, Testing, and Evaluation (RDT&E) funding is highly constrained. Small businesses should never assume that the DOD will be their first or only customer. A commercial version of a product for the general marketplace may be more beneficial to create, allowing for a military version to follow.

### Q: Does DHA provide Technical and Business Assistance (TABA) funding to awardees?

A: DHA SBIR/STTR does not participate in TABA at this time. DHA provides technical and business assistance by assigning a Technical Assistance Advocate (TAA) subject matter expert to each contract.