

Request for Project Proposals



Solicitation Number: MTEC-17-05 - Permanent Vascular Repair (PVR)

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
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Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

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***Proposal Due Date: May 10, 2017
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White Papers Are Not Required

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1 Executive Summary

1.1 Purpose

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

- (a) biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) deployment of intellectual property (IP) and follow-on production.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “non-traditional” government contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the Proposal Preparation Guide (PPG) and MTEC website.

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the U.S. Army Medical Materiel Development Activity (USAMMDA) technology objectives. Military relevance is a critical component of proposal submission. Strategic oversight for the award(s) supported by this RPP will be provided by the Extremity Vascular Injury Repair Integrated Product Team (IPT) and the Tissue Injury and Regenerative Medicine (TIRM) Program Management Office at USAMMDA.

Vascular trauma to the extremities remains a major cause of morbidity and mortality among US and allied warfighters, and has increased proportionately in recent conflicts. At the peak of recent conflicts, Improvised Explosive Devices (IEDs) caused more than 3,000 casualties per year, many involving extremity injury. Arterial damage, laceration and thrombosis can require vascular reconstruction to save tissues from ischemia, necrosis, and further amputation. The current standards of care for vascular reconstruction - harvesting of autologous vein and synthetic grafts (e.g., Teflon/Dacron) - both have important limitations. Autologous grafting is limited in patients with multiple extremity injuries, and vein harvest can lead to chronic venous insufficiency at the donor site, as well as limit future vascular surgery options in young patients (i.e., heart bypass grafting). Currently available synthetic grafts are generally considered a 2nd line option due to contraindications to use in contaminated battlefield wounds.

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The overall objective of this RPP is to advance the development of an off-the-shelf tissue-engineered vascular graft capable of permanently repairing small and medium sized vessels of the extremities. The outcome from this initiative is to result in a commercial product that is approved by the U.S. Food and Drug Administration (FDA) to treat traumatic injuries in wounded personnel as close to the point of injury as feasible to maximize rates of limb salvage.

The initial period of performance will be 12 months, with potential to pursue follow-on clinical prototype maturation. Overall costs (direct and indirect) for an initial award may range from \$350,000-\$650,000.

1.2 Request for Project Proposals

Each MTEC research project proposal submitted must contain both a Technical and Cost Proposal Volume as described in Section 3 of this request and must be in accordance with the mandatory format provided in the MTEC PPG, which is available on the Members-Only MTEC website at www.mtec-sc.org. ***White papers are not required for this RPP.*** The Government reserves the right to award proposals received from this RPP on a follow-on Other Transaction Agreement (OTA) or other stand-alone OTAs as necessary to meet mission requirements.

1.3 Funding Availability and Type of Funding Instrument Issued

The U.S. Government (USG) will negotiate funding amounts for Fiscal Year (FY) 2017 (FY17) up to a total of \$650,000. Any potential follow-on funding would be negotiated based on FDA feedback, partner matching, and estimates for additional study completion in FY18 through FY23.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

Award funding will be structured incrementally and based upon completion of milestones.

MTEC anticipates that a single award will be made to a qualified team composed of multiple investigators/institutions responsible for partnering with the USG to accomplish all tasks. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks. Any potential follow-on work will most likely be a non-competitive follow-on to this project awardee.

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement (OTA) Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the OTA between the USG and MTEC. Subsequently, any proposal that is selected for award will be funded

through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the Members-Only MTEC website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their proposals that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

Offerors are advised to check the MTEC website periodically during the proposal preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

1.4 Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's proposal and the subsequent agreement administration if the proposal is selected for award. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CM responsibilities. Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private foundations that award grants for research and operate in research areas that are aligned with those of MTEC. These private foundations may be interested in reviewing proposals within their program areas, allowing for opportunities to attract supplemental funding sources. On your proposal Cover Page, please indicate your willingness to allow MTEC Officers access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit research project proposals, nor receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

1.5 Offeror Eligibility

Offerors must be MTEC Members in good standing.

1.6 Inclusion of Non-traditional Defense Contractors

Proposals that do not include Non-traditional Defense Contractor participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award. This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criteria during the Compliance Screening. Please see the MTEC PPG (Section 3.3.2) and RPP (Section 4), for additional details.

1.7 Cost Sharing

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *The extent of cost sharing is a Factor in the evaluation of proposals (RPP Section 4.1).* If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).

See the MTEC PPG for additional details. If the offer contains multiple team members, this information shall be provided for each team member providing cost share.

For additional information regarding Non-traditional Defense Contractors and Cost Sharing, please see the Cost Share Guidance document available on the Members-Only portion of the MTEC website www.mtec-sc.org.

1.8 Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

Each offeror will select either the MTEC Additional Assessment Fee or the Royalty Agreement (available on the MTEC members only website), not both and submit a signed copy with the proposal. Summary explanations of each are provided below.

Consortium Member Agreement (CMA)

- Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the performing Member from licensing/commercialization of the technology, capped at 200% of funding provided. MTEC members receiving MTEC funding agreements for research projects will be required to execute an MTEC Royalty Agreement outlining the terms in more detail, to pay an additional 2% assessment fee on the award. (Per Section 11.17 Intellectual Property).

Royalty Agreement

- The awardee will be subject to a 10% royalty on all Net Revenues received from licensing/commercialization of the technology developed under the Research Project Award, capped at 200% of funding provided (Per Section 3.5 of the CMA).

Additional Assessment Fee

- Member agrees to pay an additional assessment fee of 2% to satisfy its obligations under Section 3.5 of the CMA. This is in addition to the 1% assessment fee for all Research Project Awards. Per Section 3.4 of the CMA, each recipient of a research project award under the MTEC OTA shall pay MTEC an amount equal to 1% of the total funded value of each research project award. Such deposits shall be due no later than 90 days after the research project award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.

1.9 Expected Award Date

Offeror should plan on the period of performance beginning August 15, 2017 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

1.10 Anticipated Proposal Selection Notification

As the basis of selections are completed, the Government will forward their selections to MTEC CM to notify Offerors.

2 Full Proposal

2.1 Full Proposals

Full Proposals in response to this RPP, must be received by the date on the cover page of this RPP. Proposals received after the time and date specified will not be evaluated.

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format provided in the MTEC PPG is mandatory. MTEC will post any general questions received and corresponding answers (without including questioner's proprietary data) on the Members-Only MTEC website.

2.2 Proposal Submission

Offerors must submit proposals via email to mtec-sc@ati.org.

2.2.1 Submission Format

Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt, .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

- **Full technical proposal submission:** one Word (.docx or .doc) or PDF file. Separately, a Word (.docx or .doc) version of the SOW (Appendix A of the proposal) and a Word (.docx or .doc) or PDF file of Regulatory Correspondence (Appendix C of the proposal) are required.
- **Full cost proposal submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (Appendix B) required. Separately, Section II: Cost Proposal Formats either in Excel (.xlsx or .xls) or PDF format is required.
- **Warranties and Representations:** If Nontraditional Defense Contractor participation is proposed, Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

MTEC will email receipt confirmations to Offerors upon submission of proposals. Offerors may submit proposals in advance of the deadline.

3 Proposal Preparation Instructions

3.1 General Instructions

The Technical Proposal and Cost Proposal must be submitted in two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. The proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (MTEC-17-05-PVR).

Offerors are encouraged to contact the POC identified herein up until the proposal submission date/time to clarify requirements. Offerors are to propose a Milestone Payment Schedule which should include all significant event/accomplishments that are intended to be accomplished as part of the project, a planned completion date (based on months post award), the expected research funding expended towards completing that milestone, and any cost share, if applicable. The Milestones and associated accomplishments proposed should, in general, be commensurate in number to the size and duration of the project. A milestone is not necessarily a physical deliverable; it is typically a significant R&D event. Quarterly and final technical reports may be considered deliverables, but they are not milestones. Please include quarterly and final technical reports as part of the Milestone Payment Schedule, without an associated cost.

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the Government Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Research Project Awards as result of this RPP.

3.2 Technical Proposal

3.2.1 Technology Objectives

Background: Extremity trauma is one of the most common battlefield injuries. Through advances in early field intervention and resuscitation, such injuries have become increasingly survivable. Despite progress, extremity injuries can be devastating with complex injuries to the vasculature, bone, connective tissues, muscle, and nerves. Approximately 50% of patients with complex extremity injuries have severely impaired limb function. These injuries are commonly associated with long term complications and poor functional recovery. In fact, at the same age, military personnel have doubled the rate of post-traumatic osteoarthritis compared to individuals in the civilian population. Severe extremity trauma with initial limb salvage leads to delayed amputation in approximately 14% of patients, typically following many months of repeated surgeries and attempts at rehabilitation. Only 20% of wounded military personnel who experience severe extremity trauma are ultimately able to return to service.

The field of reconstructive surgery following extremity trauma is largely characterized at present by the need for multiple, staged reconstructive procedures, and the use of often scarce autologous tissue with frequently suboptimal results, and low rates of return to duty. In many cases, the best that can be hoped for is to prepare the damaged limb for prosthetic attachment. Optimal solutions would not only provide more durable repairs, but reduce the need autologous tissue and number of surgical procedures.

Objective: This MTEC RPP seeks proposals focused on the clinical, prototyping, and manufacturing needs of entities developing prototypes that can serve as permanent arterial and/or venous grafts for reconstruction and repair of traumatic injuries. The prototype must be intended for permanent vascular repair – serve as a permanent vascular graft to repair and reconstruct extremity injuries. It is recognized that products intended for other indications could be repurposed; in other words, an expanded indication for an existing FDA-approved product may serve as a prototype.

Several factors should be considered for preparation of a proposal in response to this RPP:

- **Dual-use markets:** The ultimate goal is to develop and commercialize a dual-use product for both civilian and military markets. The limited commercial viability of a product intended solely for the trauma market makes funding a product with potential ‘dual use’ for other more common applications attractive. The potential market for a successfully licensed product would include primary indications in other vascular surgery treatment areas, such as hemodialysis access and/or the treatment of peripheral arterial disease. This would allow the Government to support the development of an appropriately licensed product with a greatly reduced, targeted investment by supporting the trauma-related indications, while the commercial partner(s) seeks a commercially viable primary indication.

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- **Later stage projects would be most relevant to this solicitation:** Later stage projects have a far greater need for manufacturing scale up and standardization to support the project development plan. At a minimum, MTEC expects that Offerors have already had formal communication with the FDA (e.g., pre- Investigational New Drug (IND) meeting) regarding the product, and have data sufficient to file an IND. It is expected that the products are at a minimum of Technology Readiness Level (TRL) 5 and either seeking funding to: i) obtain Investigational New Drug (IND) / Investigational Device Exemption (IDE) for Center for Devices and Radiological Health submissions (IND/IDE) approval to proceed into clinical trials within the first 12 months of the period of performance, or ii) advance development beyond Phase 1 or feasibility clinical trials. It is expected that projects will manufacture or be able to procure products with sufficient clinical safety data to support proceeding into clinical trials.
- **The trauma patient population:** Through MTEC's consortium model, it is expected that Offerors will have access to resources that can help overcome potential challenges of studying the prototype in trauma patients. Difficulties in conducting regulated studies in trauma patients include the lack of consent in severely injured patients, and significant variability in the nature and severity of injuries and the overall health status of patients. Partnerships between industry and academia are likely to overcome these challenges. Proposals should focus on developing a product that can be used to treat the trauma patient population.
- **Industrial partner:** The eventual goal is to transition a product that provides permanent vascular repair to industry for FDA approval. MTEC, therefore, encourages that proposals be led by an industrial partner committed to bringing this product to market. At a minimum, all proposals must include an industrial partner with commercialization experience.
- **Military relevance:** Relevance to the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries are a key feature of this award. Prototypes must demonstrate the potential to fill an identified capability gap in permanent vascular repair beginning at forward echelons of medical care.
- **Cost share:** The funds provided for this initiative are to prime the pump for efforts focused on the trauma patient population, but are not anticipated to be the sole funding resource for the efforts. It is anticipated that the Government funds would provide incentive for industry funding to join the project. Offerors are strongly encouraged to discuss outside funding potential prior to submitting proposals.

Proposals must aim to demonstrate significant technology advancement toward regulatory approval for a vascular reconstruction indication. The goal of an MTEC award will be to develop

the prototype through to FDA approval/licensure for marketing. Examples of activities that could be proposed include but are not limited to:

- Funding subject matter expertise.
- Regulatory activities, such as consultation and funding to develop a regulatory strategy, meetings with the FDA regarding clinical trial design and manufacturing requirements, and the preparation of regulatory applications and filings
- Execution of studies (i.e., generation of data) needed for regulatory approval, such as biocompatibility, shelf-life, storage, etc.
- Improve the efficiency and reproducibility of the manufacturing process at scale, including the transfer of laboratory-based processes into scalable, production-ready, commercial manufacturing processes with defined acceptance criteria and reliably sourced biomaterials.
- Developing dynamic and innovative quality assurance strategies to ensure stable and reproducible grafts at scale, such as systems that can provide rapid batch testing for the evaluation of a production run, automated and non-destructive imaging systems for inspection and characterization of the product, and non-destructive in-process technologies that can monitor key parameters of the manufacturing process.
- Conduct clinical trials in trauma patients or related surrogate populations.

Period of Performance and Funding: The initial period of performance will be 12 months, with potential follow-on clinical prototype maturation. Overall costs (direct and indirect) for an initial award may range from \$350,000-\$650,000. The proposed efforts for the first 12-month period of performance must include FDA engagement regarding clinical and manufacturing activities, with follow-on efforts in subsequent years to be determined based on the feedback received from the FDA.

3.2.2 Preparation of the Technical Proposal

In accordance with the MTEC PPG, the technical proposal has a maximum limit of 10 pages and must include the following information:

1. **Description of the prototype:** Describe the prototype.
2. **Clinical Indications:** Describe all clinical indications already approved and planned for the product label.
3. **Technology Readiness Level (TRL):** Indicate the TRL stage in which the project will start. A table with the description of TRLs is included below:

| Technology Readiness Level | Description |
|----------------------------|--------------------------------------|
| TRL 1. | Basic scientific principles observed |

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| | |
|--------|---|
| TRL 2. | Preclinical research ideas and protocols developed |
| TRL 3. | Hypothesis testing and initial proof of concept (PoC) demonstrated in limited number of in vitro and in vivo models |
| TRL 4. | PoC and safety of candidate drug/biologic/device demonstrated in defined animal models |
| TRL 5. | Investigational New Drug (IND/IDE) filed, or at a minimum, sufficient preclinical studies including animal safety and toxicity to support and IND/IDE application |
| TRL 6. | Phase 1 clinical trials completed with data that supports proceeding to Phase 2 |
| TRL 7. | Phase 2 clinical trials completed and Phase 3 clinical study plan approved |
| TRL 8. | Phase 3 clinical trials completed and NDA/BLA/PMA/510k application approved |
| TRL 9. | Post-marketing studies/surveillance |

4. **Key Deliverable(s) at End of 12 months:** State the deliverable of the project at the end of the first 12 months of the period of performance.
5. **Key Deliverables Beyond Year 1:** If funding was made available to continue your project beyond 12 months, state the proposed key deliverables to the best of your ability for Years 2-5.
6. **IP:** Describe pertinent information about Intellectual Property
7. **Regulatory Pathway:** A description and justification of the anticipated regulatory pathway and current status in the U.S. and/or other countries, including completed and/or planned regulatory milestones.
8. **Plan of Development:** Discuss the key points of a plan appropriate for the Offeror's stage of development
9. **Status to Date:** Describe pertinent preliminary data and the status of the effort to date.

10. **Side effects:** Describe anticipated or known product side-effects
11. **Product Considerations:** Discuss product storage, temperature, shipping, and shelf-life considerations
12. **Timeline/Cost:** Estimate the product development timeline and costs through product deployment/launch
13. **Cost per Unit:** Estimate the cost per unit
14. **Commercialization Plan:** Discuss the commercial plans and manufacturing capability (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of this award
15. **Company Information:** Include information on the company's business size (based on the NAICS size standard) and status
16. **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the work.
17. **Previous Government Funding:** Include a listing of prior government awards supporting the prototype (if any).

Submitters should also include:

- Appendix A: Statement of Work (SOW) which includes proposed work and milestones
- Appendix B: Cost Proposal Narrative, and
- Appendix C: Regulatory Correspondence which includes all pertinent correspondence with the U.S. FDA or other credible international regulatory agency (e.g., pre-IND meeting minutes, IND approval, etc.) to support the current status of your proposed product.

The government may request additional information from potential offerors to verify information provided in the technical proposals.

3.2.3 Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use

Technical proposals must comply with important restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, human cadavers, or laboratory animals. For a complete description of these mandatory requirements and restrictions and others, Offerors must refer to the accompanying MTEC PPG, Section 6.11 Additional Requirements.

These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.

For example, the clinical studies under this RPP shall not begin until the USAMRMC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRMC ORP is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving

human subjects. Offerors must allow at least 30 days in their schedule for the ORP review and authorization process.

3.3 Cost Proposal

MTEC will make cost proposal formats available on the Members-Only MTEC website. **The proposal formats provided in the MTEC PPG is mandatory.** Refer to the MTEC PPG for additional details.

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

3.3.1 Proposal Preparation Cost

The cost of preparing proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

4 Selection

As described in Section 3.3.2 of the Proposal Preparation Guide, the CM will conduct a preliminary screening of received proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested. One of the primary reasons for non-compliance and elimination during this initial screening is that the proposal does not offer significant nontraditional defense contractor participation or cost share (see RPP Section 1.6). The Cost Sharing/Non-traditional Contractor determination will be made as shown in Table 1:

| TABLE 1- COST SHARING/NON-TRADITIONAL CONTRACTOR ASSESSMENTS | |
|--|--|
| RATING | DESCRIPTION |
| PASS | <p>Offeror proposing an MTEC research project meets at least ONE of the following:</p> <ul style="list-style-type: none"> • Offeror is a Non-traditional Defense Contractor • Offeror's proposal has at least one Non-traditional Defense Contractor participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share |
| FAIL | <p>Offeror proposing an MTEC research project does NOT meet any of the following:</p> <ul style="list-style-type: none"> • Offeror is a Non-traditional Defense Contractor |

| | |
|--|---|
| | <ul style="list-style-type: none">• Offeror's proposal has at least one Non-traditional Defense Contractor participating to a significant extent• Offeror provides at least one third of the total project cost as acceptable cost share |
|--|---|

Following the preliminary screening, the Government sponsor will undertake proposal source selection. The proposal source selection will be conducted in accordance with the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

- a) *Select the proposal (or some portion of the proposal) for award*
- b) *Place the proposal in the Basket if funding currently is unavailable; or*
- c) *Reject the proposal (will not be placed in the Basket)*

4.1 Proposal Evaluation Process

Qualified applications will be evaluated by a panel of subject matter experts that will make recommendations for funding to the Source Selection Authority appointed by the Commanding General, USAMRMC based on Factors, Sub-factors and criteria described below.

The RPP review and award process may involve the use of contractors as subject-matter-experts or reviewers; where appropriate, the USG will employ non-disclosure-agreements to protect information contained in the RPP as outlined in Section 1.4.

Evaluation of proposals offered in response to this RPP shall be based on an independent, comprehensive review and assessment against all source selection criteria and evaluation factors, as further described. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet the requirements. Mere acknowledgement or restatement of a requirement or task is not acceptable.

Offerors submitting the best value proposals that meet the following Factors and evaluation criteria will be selected for award negotiations:

1. Technical Approach
2. Management, Schedule, Resources and Personnel
3. Potential for Transition and Commercialization
4. Cost/Price

Factors are listed in descending order of importance. The Technical Approach factor, Management, Schedule, Resources and Personnel factor, and Potential for Transition and Commercialization factor, when combined, are significantly more important than the Cost/Price

factor; however, Cost/Price will contribute substantially to the selection decision. As the collective non-cost factors begin to reach equality in the technical evaluation ratings, cost becomes a more important factor in the trade off analysis.

Table 2 explains the adjectival merit ratings that will be used for the non-cost factors.

| TABLE 2- GENERAL MERIT RATING ASSESSMENTS | |
|---|---|
| RATING | DESCRIPTION |
| OUTSTANDING | Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low. |
| GOOD | Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low. |
| ACCEPTABLE | Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate. |
| MARGINAL | Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high. |
| UNACCEPTABLE | Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable. |

4.1.1 Factor 1. Technical Approach

(1) Ratings. The Technical Approach factor will be evaluated using the merit rating as shown in Table 2.

Ability to address a specific Technology Objective area. The Offeror’s proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology of interest as defined in section 3.2 above. This likelihood of success will be determined by considering the soundness of the technical approach, including complete and clear processes to execute the effort. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan and objectives, and the suitability of the proposed statistical plan. The proposed road map and SOW should provide a feasible plan for addressing the project’s objectives. The plan will be evaluated for how well the rationale,

objectives, and specific aims support the research idea. The proposed effort will be assessed for the extent the solution is a technological breakthrough solution that is an innovative, novel approach, which is a brand new technology that currently is not readily available. A description of the proposed efforts demonstrated abilities to advance the technology maturity level and to demonstrate projected performance improvements will be assessed. Relevance to the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries and the extent to which the proposal offers a joint Service solution will be considered.

4.1.2 Factor 2. Management, Schedule, Resources and Personnel.

(1) Ratings. The Management, Schedule, Resources and Personnel factor will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposal will be considered for:

- Presentation of a sound management plan that demonstrates an ability to perform the proposed project in an orderly, timely manner.
- Degree to which the project team's expertise, key personnel, and corporate experience demonstrate ability to accomplish the SOW.
- Extent that facilities and resources are sufficiently identified and available to execute the effort as proposed.
- Clearly identified tangible technical benefits resulting from cost share resources above the required statutory minimum. This would include:
 - Any cost share proposed when it is not required by statute because your proposal includes a non-traditional defense contractor participating to a significant extent; or
 - Any cost share beyond the statutory 1/3 minimum requirement if your proposal does not include a non-traditional defense contractor.
- Detailed schedule with cost risks, and potential mitigation strategies identified.

4.2.3 Factor 3. Potential for Transition and Commercialization

(1) Ratings. The Potential for Transition and Commercialization factor will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposal will be assessed for:

- How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of research, development, or clinical testing.
- How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for military Service members and or their beneficiaries.
- How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
- How well the proposal identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if

applicable), and addresses any impact of intellectual property issues on product development.

- How well the regulatory strategy is described, if applicable.

4.1.4 Factor 4. Cost/Price

(1) Ratings. The Cost area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

(2) Factor 4 Evaluation Process. The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter (PUL), if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

(i) Realism. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

(ii) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving

and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website.

(iii) Completeness. The MTEC CM will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.

4.2 Best Value

The Government will conduct the source selection and MTEC CM will award the projects in Best Value sequence. If applicable, the Government will invoke a best value process to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. Based on the results of the Technical Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offeror's will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

Definition of General Terms Used in Evaluations:

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

Weakness - A flaw in the proposal that increases the risk of unsuccessful award performance.

Significant Strength - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful award performance.

Deficiency - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

5 Points-of-Contact

For inquiries, please direct your correspondence to the following contacts:

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Manager, Ms. Lisa Fisher, lisa.fisher@ati.org
- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- Questions concerning membership should be directed to Ms. Stacey Lindbergh, MTEC Executive Director., execdirect@officer.mtec-sc.org.
- All other questions should be directed to Ms. Polly Graham, MTEC Program Manager, polly.graham@ati.org

Once an Offeror has submitted a proposal, neither the Government nor the MTEC CM will discuss evaluation/proposal status until the source selection process is complete.

6 Acronyms/Abbreviations

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| ATI | Advanced Technology International |
| CM | Consortium Manager |
| CMA | Consortium Member Agreement |
| FAQ | Frequently Asked Questions |
| F&A | Facilities and Administrative Costs |
| FDA | Food and Drug Administration |
| FY | Fiscal Year |
| G&A | General and Administrative Expenses |
| IP | Intellectual Property (e.g., patents, copyrights, licensing, etc.) |
| M | Millions |
| NDA | Nondisclosure Agreement |
| OCI | Organizational Conflict of Interest |
| ODC | Other Direct Charges |
| ORP | Office of Research Protections, USAMRMC |
| OTA | Other Transaction Agreement |
| POC | Point-of-Contact |
| PPG | Proposal Preparation Guide |
| RPP | Request for Project Proposals |
| SOW | Statement of Work |
| TRL | Technology Readiness Level |
| USAMRMC | U.S. Army Medical Research and Materiel Command |
| USG | U.S. Government |