

Request for Project Proposals



Solicitation Number: MTEC 19-03-VML
“Volumetric muscle loss (VML) repair following extremity trauma”

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

Request Issue Date: October 11, 2018

Proposal Due Date: November 13, 2018
Noon Eastern Daylight Time

White Papers Are NOT Required

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1 Executive Summary

1.1 The Medical Technology Enterprise Consortium

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.

*Note: Pending successful completion of the VML effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 USC 2371b section f.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “nontraditional” 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.

1.2 Purpose

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). The award(s) will be managed by the Combat Trauma and Acute Rehabilitation Project Management Office (CTAR PMO) in support of the Extremity Injury Repair – Muscle (EIR-M) effort at USAMMDA. The EIR-M Integrated Product Team (IPT) will provide consultative input into the project as needed, and conduct annual in-progress reviews with the Milestone Decision Authority, as well as interim reviews if needed more frequently.

The goal of this research is to develop an off-the-shelf biologic prototype capable of preventing, mitigating or treating traumatic large-volume muscle loss (VML) injuries of the extremities. While such injuries are devastating, irreversible, and uniformly associated with long term disability, recent advances in regenerative medicine have made new approaches possible. The Government seeks to assess the potential for repurposing products* already commercially available or in clinical development for related indications, such as critical limb ischemia,

iatrogenic muscle injuries, Duchene's muscular dystrophy, compartment syndrome, and severe sports medicine injuries. Products capable of regenerating or repairing multiple tissue types or creating a therapeutic wound environment will also be considered.

*NOTE: The repurposed product must be an existing product with demonstrated clinical benefit for at least one related skeletal muscle disorder indication. At least one successful FDA-regulated Phase 2 clinical trial should have been completed (TRL 7). In addition, the product should have a plausible mechanism for benefit in VML injuries.

2 Administrative Overview

2.1 Request for 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 prototype Other Transaction Agreement (pOTA) or other stand-alone OTAs as necessary to meet mission requirements.

2.2 Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar approximately 1-2 weeks after the release of the RPP. Further instructions will be forthcoming via email.

2.3 Funding Availability, Period of Performance, and Type of Funding Instrument Issued

The U.S. Government (USG) currently has available approximately \$2 million (M) for Fiscal Years (FY), FY18, FY19, and FY20 to fund Phase 1 (as described in Section 4.2). It is possible that additional funds of at least \$2.5M for Fiscal Years 21 and 22 may become available for the continuation of this project through later implementation phases (e.g., Phase 2 described in Section 4.2).

The Period of Performance (POP) is not to exceed 24 months for Phase 1, and up to an additional 36 months for Phase 2 if the milestones/deliverables of Phase 1 are achieved.

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.

It is expected that MTEC will make one award to a qualified team to accomplish all tasks. If a single proposal is unable to sufficiently address the entire scope of this RPP's technology objectives (outlined in section 4), several Offerors may be asked to work together in a collaborative manner. 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.

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement (pOTA) 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 pOTA 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 MTEC Members-Only 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 Proposal 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.

2.4 Proprietary Information

The MTEC CM will oversee submission of Proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary 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 entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Directors granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these

MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or 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.

2.5 Offeror Eligibility

Offerors must be MTEC Members in good standing.

2.6 Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

Proposals that do not include Nontraditional Defense Contractor or Nonprofit Research Institution 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 criterion during the Compliance Screening. Please see the MTEC PPG and RPP (Section 5) for additional details.

2.7 Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

2.8 Requirements

If the Offeror asserts either:

(1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.

(2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.

(3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

The Offeror must submit Warranties and Representations (see Attachment 2 of the PPG) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor or nonprofit research institution. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional

defense contractor's or nonprofit research institution's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant contribution* includes:

1. Supplying a key technology or products
2. Accomplishing a significant amount of the effort
3. Use of unique skilled personnel, facilities and/or equipment
4. Causing a material reduction in cost or schedule, and/or Improvement in performance

2.9 Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). 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.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

Cash Contribution

Cash Contribution means the Consortium and/or the Research Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Research Project. The cash contribution may be derived from the Consortium's or Research Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Research Project or specific tasks identified within the SOW of a Research Project. Prior IR&D funds will not be considered as part of the Offeror's cash.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Research Project, and restocking the parts and material consumed.

In-Kind Contribution

In Kind Contribution means the Offeror's non-financial resources expended by the Consortium Members to perform a Research Project such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Research Project, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Research Project.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on a Consortium Member's cost sharing portion.

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.

2.10 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.

Per Section 3.4 of the Consortium Member Agreement (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. Additionally, MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards:

Royalty Payment Agreements

Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the Research Project Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving Research Project Awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4 of the CMA. This additional assessment applies to all research project awards, whether the award is Government funded or privately funded.

2.11 Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government purpose data rights or unlimited data rights. If this is not the intent, then the Proposal should discuss data rights associated with each item,** and possible approaches for the Government to gain Government purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each

Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

2.12 Expected Award Date

Offeror should plan on the period of performance beginning February 15, 2019 (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.

2.13 Anticipated Proposal Selection Notification

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

3 Proposal

3.1 Proposal

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 outlined in Section 4.3 is mandatory. MTEC will post any general questions received and corresponding answers (without including questioners' proprietary data) on the Members-Only MTEC website. The Government will evaluate Proposals submitted and will select Proposals that best meet their current technology priorities using the criteria in Section 6.

3.2 Proposal Submission

Instructions on how to submit are included in the RPP version that is posted on MTEC Members Only Site.

MTEC membership is required for the submission of a Proposal. Offerors must be MTEC Members in good standing. Offerors submitting Proposals as the prime contractor must be MTEC members of good standing by **November 8, 2018**.

Do not submit any classified information in the proposal submission.

3.3 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.

MTEC will email receipt confirmations to Offerors upon submission. Offerors may submit in advance of the deadline. **Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces with MTEC's submission form. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted.**

4 Proposal Preparation Instructions

4.1 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 this MTEC RPP is mandatory and shall reference this RPP number (MTEC-19-03-VML). 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. 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.

4.2 Technical Requirements

Technical Background:

The exact incidence of VML following combat trauma is unknown and has not been rigorously assessed. Estimates from civilian trauma indicate that ~250,000 open fractures occur per year in the US, and these commonly involve a component of VML injury. In the military, a study of battlefield injuries in 14,500 Service members evacuated from OEF/OIF from 2001-2013 suggests high VML incidence. Approximately 77% had musculoskeletal injuries and many had open soft tissue extremity wounds. Roughly 8% of all medically evacuated patients received a disability

rating specifically for VML injury. The estimated life-time disability cost per patient is \$340,000-440,000 in addition to medical costs and lost wages.

Recovery is uniformly poor, leading to significant long term disability, and leading to increased rates of delayed amputation of technically salvageable, but functionally deficient limbs. There is no agreed upon standard of care for this condition, and no clinically available therapy that can address the loss of function for this condition. The current standard of care for VML involves the use of free muscle transfer (i.e., muscle flaps) for bone coverage followed by extensive physical rehabilitation. However, most muscle flap procedures are not intended to restore muscle function except in limited circumstances. Functional muscle transfer including vasculature and innervation have been shown to improve strength to an injured muscle group. However, such procedures require a level of surgical expertise available only in limited, specialized centers.

It is unlikely that there will be a single solution for VML repair. Interventions will likely be required along the continuum of care, beginning close to the point of injury or during initial damage control surgery. In the course of market research, multiple products have been identified which may potentially prevent additional muscle loss and stimulate a repair response early in the course of injury. Such products may be highly valuable in a prolonged field care situation. Such interventions may offer significant improvements over currently limited treatment options.

Work Plan:

The focus of this RPP is to develop an advanced prototype of an off-the-shelf biologic capable of preventing, mitigating or treating traumatic large-volume muscle loss (VML) injuries along the continuum of care. The prototype must be able to repair injured muscle tissue to a degree suitable for extremity repair and reconstruction.

The work is expected to be conducted in two phases over a 5 year period of performance as follows.

Potential Offerors are expected to propose in response to Phase 1, only. A brief description of Phase 2 is provided for informational purposes only.

Phase 1 (up to 2 years): An existing FDA-regulated commercial or clinical investigational product (*see note below) will be tested in one or more well-controlled animal bridging studies. Studies will progress logically based on outcomes through go/no-go decisions after each study has achieved appropriate objectives. Product(s) will first be tested in a small proof of concept study in a rodent model. If successful, a large animal model will be used for confirmation. The optimal timing of the intervention may also be evaluated in one or more appropriate models.

Phase 2 *Optional Follow-on work* (up to 3 years): If preclinical development studies are successful, the Awardee may be offered an optional extension to conduct a small proof-of-concept clinical

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trial in VML-injured patients. Further negotiations will be conducted between the Awardee, MTEC, and the Government if proceeding to a clinical trial becomes feasible.

*NOTE: The government seeks to repurpose an existing product with demonstrated clinical benefit for at least one related skeletal muscle disorder indication. This RPP seeks prototype development **by repurposing products already commercially available or in clinical development for related indications**, such as critical limb ischemia, iatrogenic muscle injuries, Duchene's muscular dystrophy, compartment syndrome, and severe sports medicine injuries. Products capable of regenerating or repairing multiple tissue types or creating a therapeutic wound environment will also be considered. The following parameters will be considered most desirable when evaluating candidate products to be repurposed and tested in this project:

- Currently in FDA-regulated clinical development with approved INDs for at least one indication related to VML. Products should have demonstrated benefit for a skeletal muscle disorder in at least one FDA-regulated clinical trial (TRL 7). In addition, the product should have a plausible mechanism for benefit in VML injuries.
- Has the potential for FDA-approval for use in skeletal muscle repair.
- Be maximally restorative of natural form and function, improving return to duty rates. In addition, it would have broad application to heal complex injuries, independent of regional anatomy. The ideal product would reduce scar formation and pathologic fibrosis which currently limits rehabilitation outcomes and endogenous regeneration.
- Speed functional recovery. Solutions that speed the rate of recovery in addition to the degree of recovery will be of greater advantage in improving clinical rehabilitation outcomes.
- Cost effective, improving affordability for patients and medical systems, increasing efficiency along the continuum of care of the VML patient and reducing the overall costs of care. It is unlikely that there will be a single material solution for VML. Optimal solutions are likely to intervene in the disease process along the continuum of care, starting as close to the point of injury as possible through acute reconstruction and rehabilitation. Ideal solutions will be capable of repairing or restoring multiple tissue types including the microvasculature, nerves, soft tissues and underlying bone. Ideal solutions will also be usable in the setting of co-morbidities. Solutions will reduce the need to harvest healthy native tissue to include muscle autograft and/or flap construction. Optimal products will also be simple in design, application and requirement for ongoing technical or medical support and follow-up.
- Versatile, being capable of repairing multiple tissue types (e.g., nerve, microvasculature, bone, myotendinous junction).

- Safe, lowering the risks of infection, immunologic rejection, and harmful side effects of any associated therapies that may be required, lowering the risks of long term complications.
- Well tolerated, by reducing pain and the amount of rehabilitative therapy required.
- Highly accepted and sought after by patients.

Project Deliverables

The goal of an MTEC award will be to develop the prototype through proof of concept for VML treatment, with an option to continue product development to relevant supplemental FDA marketing approval/licensure. Support may include subject matter expertise, consultation and funding to develop regulatory strategy, conduct animal bridging studies, clinical trials and/or improve efficiency and reproducibility of the manufacturing process at scale to support the desired military indication.

4.3 Preparation of the Proposal

The proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (MTEC-19-03-VML). 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. Offerors are encouraged to contact MTEC with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following:

- **Technical Proposal submission:** one signed Technical Proposal (.pdf, .doc or .docx). The Technical Proposal is limited to 10 pages. The page limitation excludes the following (see PPG for details): Technical Proposal Cover Page, MTEC Member Organization Information Sheet, Table of Contents, List of Figures and Tables, Bibliography, and Appendices. The Technical Proposal must be in 12 point type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. The Technical Approach section of the Technical Proposal **must include only** the requested information indicated below:
 - **Title:** [Insert descriptive title of project]
 - **Principal Investigator:** [Insert name, organization, email address, phone number]
 - **Re-purposed Prototype Description:**
 - Describe the re-purposed prototype including potential relevance to the desired VML indication
 - Indicate anticipated or known product side-effects
 - Describe all indications currently being sought
 - **Technical Strategy:** [Outline the proposed methodology to meet the requirements of Phase 1 in sufficient detail to show a clear course of action.]

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- Include a description of the animal bridging studies proposed, and the models to be employed to establish proof-of-concept in VML injury.]
- **Regulatory strategy:** [Describe the overall product regulatory strategy and current status in the U.S. or other countries. Include a summary of completed and/or planned regulatory milestones.]
 - **Transition and Commercialization Strategy:**
 - Estimate the product development timeline and costs through product deployment/launch for a primary commercial indication related to VML
 - Discuss commercial plans and manufacturing capability
 - Discuss product manufacturing, handling, and shelf-life considerations
 - Estimate cost per unit
 - Provide information on the company's business size (based on the NAICS size standard) and status
 - **Team:** [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the SOW]
 - **Previous Awards:** [List prior government awards supporting this prototype (if any)]
 - **Non-traditional defense contract, nonprofit research institution, or 1/3 cost sharing:** [Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution, or the ability to meet 1/3 cost sharing requirement.]
 - **Period of Performance:** [Indicate the proposed period of performance for Phase 1]
 - **Cost Share:** [It is anticipated that Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to discuss the ability to bring leveraged funding/cost share to complete the project goals.]
 - **Rough Order of Magnitude (ROM) Pricing for Phase 1:** [Indicate the proposed ROM (including indirect costs) for Phase 1 only. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project. Sufficient cost information to substantiate the proposed cost as realistic and reasonable for the proposed effort must be provided to ensure that a complete and fair evaluation of the cost or price can be conducted. **Use the table format below as an example to provide an initial ROM.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the “Subcontractor” section of the table. This information must be consistent with the Cost Proposal.]

Labor	<i>\$ 100,000.00</i>
Subcontractors	<i>\$ 50,000.00</i>

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Consultants	\$ 10,000.00
Material/Equipment	\$ 75,000.00
Other Direct Costs	\$ 1,000.00
Travel	\$ 5,000.00
Indirect costs	\$ 48,200.00
Total Cost	\$ 289,200.00
Fee (Not applicable if cost share is proposed)	\$ 0.00
Total Cost (plus Fee)	\$ 289,200.00
Cost Share (if cost share is proposed then fee is unallowable)	\$ 290,000.00
Total Project Cost	\$ 579,200.00

- **Statement of Work/Milestone Payment Schedule:** one Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the format provided herein (Attachment A). The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule. Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.
- **Cost Proposal for Phase 1 only by Task submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (see Attachment 1 of the PPG) required. Separately, Section II: Cost Proposal **by Task** Formats either in Excel (.xlsx or .xls) or PDF format is required.
- **Warranties and Representations:** one Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.
- **Royalty Payment Agreement or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Research Project Award Assessment Fee **or** the Royalty Payment Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.

Evaluation: The Government will evaluate and determine which proposals to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.4 Cost Proposal

MTEC will make cost proposal formats available on the Members-Only MTEC website. **The Cost by Task Proposal formats provided in the MTEC PPG are 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.

4.5 Proposal Preparation Costs

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

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

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, "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.

5 Selection

The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for elimination from further consideration is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, all small business participation, or cost share (see RPP Section 2.8). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	DESCRIPTION
PASS	Offeror proposing an MTEC research project meets at least ONE of the following: <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	Offeror proposing an MTEC research project does NOT meet any of the following: <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution 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 perform proposal source selection. This will be conducted using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

1. *Select the proposal (or some portion of the proposal) for award*
2. *Place the proposal in the Basket if funding currently is unavailable; or*
3. *Reject the proposal (will not be placed in the Basket)*

5.1 Proposal Evaluation Process

Qualified applications will be evaluated by a panel of subject matter experts (SMEs) who will make recommendations to a Source Selection Authority.

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure-agreements to protect information contained in the RPP as outlined in Section 2.3.

Evaluation of proposals shall be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors.

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 RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

The evaluation factors and evaluation criteria are described below.

5.2 Evaluation Factors

1. Technical Approach
2. Potential for Transition and Commercialization
3. Cost/Price

Evaluation factors are listed in descending order of importance.

Table 2 explains the adjectival merit ratings that will be used for the Technical Approach Factor, and Potential for Transition and Commercialization factor.

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.

5.2.1 Evaluation Factor 1. Technical Approach

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

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 4.2 above. The likelihood of success will be determined by considering the soundness and clarity of the technical approach. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan and the suitability of the proposed statistical plan. The SOW should provide a succinct approach for achieving the project's objectives. The SOW will be evaluated for how well the rationale, objectives, and specific aims support the proposed research. The effort will be assessed for the extent to which the solution is technologically innovative and how the proposed deliverable advances the TRL Military relevance is a critical component of proposal submission. This relevance includes 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. A description of the project team's expertise, key personnel, and corporate experience should demonstrate an ability to execute the SOW.

5.2.2 Evaluation factor 2: Potential for Transition and Commercialization

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:

- a) How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of research, development, or clinical testing.
- b) 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.
- c) 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.
- d) 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.
- e) How well the regulatory strategy is described, if applicable.

5.2.3 Evaluation Factor 3. Cost/Price

The Cost/Price area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

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, 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:

a) 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.

b) 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.

c) 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.

5.3 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 Approach 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.

5.4 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.

6 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 Administrator, Ms. Rebecca Harmon, mtec-contracts@ati.org

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- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org or MTEC Chief Operating Officer, Mr. Bill Howell, William.Howell@tunnellgov.com
- Questions concerning membership should be directed to the MTEC Executive Director, Ms. Stacey Lindbergh, execdirect@officer.mtec-sc.org
- All other questions should be directed to the MTEC Program Manager, Ms. Kathy Zolman, kathy.zolman@ati.org

Once an Offeror has submitted a Proposal the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

7 Acronyms/Abbreviations

ATI	Advanced Technology International
CAS	Contract Accounting System
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
HIPPA	Health Insurance Portability and Accountability Act
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IR&D	Independent Research and Development
MTEC	Medical Technology Enterprise Consortium
M	Millions
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
ORP	Office of Research Protections, USAMRMC
pOTA	Prototype Other Transaction Agreement
POC	Point-of-Contact
PPG	Proposal Preparation Guide
R&D	Research and Development
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TRL	Technology Readiness Level
USAMRMC	U.S. Army Medical Research and Materiel Command

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USG	U.S. Government
VML	Volumetric Muscle Loss

Attachment A: Statement of Work (SOW)

The SOW developed by the Lead MTEC member organization is intended to be incorporated into a binding agreement if the Solutions Brief is selected for award. If no SOW is submitted, there will be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Statement of Work

Submitted under Request for Project Proposal (*Insert current Request No.*)

(Proposed Project Title)

Introduction/Background (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

Scope/Project Objective (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

Requirements (*To be provided initially by the Offeror at the time of submission to be finalized by the Government based on negotiation of Scope/Project Objective*).

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the Cost Proposal. Subtasks need not be priced separately in the Cost Proposal.

Deliverables (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

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Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Milestone Payment Schedule *(To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding. The milestone schedule included should be in editable format (i.e., not a picture)*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

Milestone No.	SOW Task Number	Significant Event/Accomplishments/Deliverables	Due Date	Total Program Funds	Total Cost Chare	Total Project
1						
2						
3						
N						
Total						

Shipping Provisions *(The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)*

- The shipping address is:

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Classified Shipments:
Outer Packaging
Inner Packaging

Data Rights (see Section 2.10 for more information)

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded exclusively at private expense	Restricted	Organization XYZ	Milestones 1, 3, and 6
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	Government Purpose Rights	Organization XYZ	Milestone 2

Reporting (The following information, if applicable to the negotiated SOW, will be provided by the Government based on negotiation)

- Quarterly Reports – The MTEC research project awardee shall prepare a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. Quarterly Reports shall be submitted by the 25th calendar day following prior calendar quarter close based on the following schedule. (Required)

Report Months	Due Date
January – March	25 April
April - June	25 July
July - September	25 October
October - December	25 January

- Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)

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- Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)
 - Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)
-