

Request for Project Proposals



Solicitation Number: MTEC-17-02-Prototype Acceleration (PA)

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

Request Issue Date: April 26, 2017

Amendment No. 01

***Proposal Due Date: May 26, 2017
12:00PM Eastern Daylight Time***

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 with the goal of facilitating biomedical research and development (R&D) activities. In cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) and other Government agencies, MTEC supports R&D to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

1. biomedical research and prototyping;
2. exploration of private sector technology opportunities;
3. technology transfer; and
4. deployment of intellectual property (IP) and follow-on production.

MTEC is 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 MTEC Members-Only website at www.mtec-sc.org.

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), is a Request for Project Proposals (RPP) with USAMRMC 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 USAMRMC.

The USAMRMC is establishing the Prototype Acceleration Award (PAA) mechanism to be offered exclusively to MTEC members. The PAA mechanism focuses on advancing novel prototype technologies into the next major stage of development or next major milestone dependent upon their current maturity. Examples of the next major stage of development/milestone include, but are not limited to: late animal testing and regulatory filing; manufacturing; next clinical trial; regulatory approval; etc.

To be eligible, prototypes must fulfill a recognized research need/capability gap as described in Section 3.2 and must be (at a minimum) at a technology readiness level (TRL) 4. Technology Readiness Level definitions can be found at: <https://mtec-sc.org/documents-library/>. The research proposed should have an end goal of advancing the technology to the next major stage of development/next major milestone within a 12-month period of performance. Total costs for an award (direct and indirect) may range from \$150,000 - \$300,000.

1.2 Request for Project Proposals

Each submitted MTEC research proposal must contain a Technical Proposal, Cost Proposal and Statement of Work as described in Section 3 of this request. Proposals must be submitted in the format provided in the MTEC Small Project Guide (SPG), which is available on the MTEC Members-Only 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) currently has approximately \$2M in funding available for this effort. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program. 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 the PAA. The funding estimated for this RPP is approximate and subject to realignment.

Due to the anticipated budget and period of performance, the MTEC expects to use a firm fixed price type award. The MTEC reserves the right to request costing data sufficient to ensure a fair and equitable price.

Funding of any projects is dependent on scientific merit and availability of funds. The Government-selected Research Project Awards will be funded under the Other Transaction Agreement (OTA) Number W81XWH-15-9-0001 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 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 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 the submission, compliance review, and cost analysis of the 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 MTEC CM responsibilities. As part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g. foundations, organizations, individuals) that awards grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities (e.g., Bill and Melinda Gate Foundation) 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 access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers granted access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements. These MTEC Officers represent organizations that currently are not MTEC members. As a result their parent organizations are not eligible to submit research 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.

1.5 Offeror Eligibility

Offerors must be MTEC Members in good standing.

1.6 Inclusion of Nontraditional Defense Contractors

Proposals that do not include Nontraditional 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 SPG 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 SPG 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 Nontraditional 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 pick 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. See the MTEC SPG for additional details.

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, or 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 using 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

Offerors should plan on the period of performance beginning September 1, 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 bases 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 SPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format provided in the MTEC SPG 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 by noon Eastern Daylight Time on **May 26, 2017** 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 (5-page limit):** One Word (.docx or .doc) or PDF file is required. Refer to the SPG and PAA Proposal Template (see Attachment A) for details related to the preparation of the technical proposal.
- **Cost data:** One Excel (.xlsx or .xls) or PDF file is required. Refer to the MTEC SPG for details related to the preparation of the cost data.
- **Statement of Work (SOW) submission (1-page limit):** One Word (.docx or .doc) file is required. Refer to the MTEC SPG for details related to the preparation of the SOW.
- **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. Refer to the MTEC SPG for details.

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

3 Proposal Preparation Instructions

3.1 General Instructions

The Technical Proposal and SOW must be submitted as separate documents, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. The format provided in the MTEC SPG is mandatory. The PAA Proposal Template provided in Attachment A by MTEC must be used to prepare the Technical Proposal. Proposals shall reference this RPP number (MTEC-17-02-PA). Offerors are encouraged to contact the point of contact (POC) identified herein up until the proposal submission date/time to clarify requirements.

Offerors are to propose a Milestone Payment Schedule that 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. 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

The overall technology objective is to significantly advance the readiness of prototype technologies (currently at a minimum of TRL 4) into the next major stage of development/to the next major milestone within a 12 month period of performance. Examples of the next major stage of development/milestone include, but are not limited to: late animal testing and regulatory filing, manufacturing, next clinical trial, regulatory approval, etc. Proposed efforts must be based on logical reasoning and sound scientific rationale. Projects must eventually result in deliverables that transition medical solutions to government and/or industry partners.

The PAA mechanism is not intended to support basic research or research involving human subjects. Technology must be at least a Technology Readiness Level (TRL) 4. Preliminary data is required. TRL definitions can be found at: <https://mtec-sc.org/documents-library/>.

Current technical focus areas for the PAA include:

- **Wound Care/Anti-infectives to include point of injury wound care**
 - Novel platforms for the delivery of wound care anti-infectives, with a special emphasis on treatments that are integrated into dressings/bandages
 - Novel anti-infective therapies that have the ability to prevent the development of infections post-injury
 - Novel anti-infective therapies that reduce inflammation and pain sensation
 - Therapies to fight antimicrobial resistance
 - Novel treatments for skin/wound infection

Offerors of proposed wound care/anti-infective technologies must show results that exceed fielded solutions. Proposed technologies must not pose an increased burden on current logistical requirements. Proposed technologies must not require special shipping or storage conditions.

- **Regenerative Medicine**
 - Biologic therapies for muscle regeneration with a special interest in the local delivery of therapeutics with biological activities (e.g., neuroprotective, neurotrophic) that promote muscle recovery post-trauma and slow muscle atrophy and degeneration
 - Novel platforms for regenerative medicine applications to include:
 - bone regeneration
 - bone grafting
 - rebuilding tissues or skin after injury (e.g., autologous skin regeneration following burn injury)

3.2.2 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.

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

3.3 Cost Proposal

MTEC will make cost proposal formats available on the Members-Only MTEC website. **The proposal formats provided in the MTEC SPG are mandatory.** Refer to the MTEC SPG for additional details. Equipment costs are not allowable for this solicitation.

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

The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. Proposals that do not meet these requirements may be eliminated from the competition or additional information may be requested. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation or cost share (see RPP Section 1.6). 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 • Offeror's proposal has at least one Nontraditional Defense Contractor 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 • Offeror's proposal has at least one Nontraditional 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 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)*

4.1 Proposal Evaluation Process

Qualified applications will be evaluated by a panel of subject matter experts G will make recommendations to a Source Selection Authority appointed by the Commanding General, USAMRMC.

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 1.4.

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.

4.1.1. Evaluation Factors

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

Evaluation factors are listed in descending order of importance. The Technical Approach 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 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.

4.1.1.1 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 3.2 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.

4.1.1.2. 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.

4.1.1.2. 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 SPG. 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 SPG.

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.

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 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.

4.3 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

All questions should be sent via email at mtec-sc@ati.org.

- 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@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

ATI	Advanced Technology International
CM	Consortium Manager
CMA	Consortium Member Agreement
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FY	Fiscal Year
G&A	General and Administrative Expenses
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
M	Millions
NDA	Nondisclosure Agreement
ODC	Other Direct Charges
OTA	Other Transaction Agreement
PAA	Prototype Acceleration Award
POC	Point-of-Contact
SPG	Small Project 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

Attachment A - PAA Proposal Template

[Note: Complete this template according to the detailed instructions provided within this document. 5 page limit. 11 point font (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type 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 0.5 inch.]

I. PROPOSAL OVERVIEW

- A. **Title:** [Insert descriptive title of project or product name]
- B. **PI:** [Insert Principal Investigator's name, Institution/Organization, email address, phone number]
- C. **Total funds requested:** [Insert total (direct + indirect) cost, cannot exceed \$300,000]
- D. **Clinical need, gap or requirement:** [State succinctly the operational or clinical need, gap or requirement that will be addressed or improved by your proposed prototype.]
- E. **Product Description:** [Describe the proposed prototype.]
- F. **Intended use for Military and Commercial Markets:** [Where is this prototype/capability in use within the DoD? (e.g., in a Medical Treatment Facility, in a research setting, not currently in use). Where is this product/capability in use and/or expected to be used within the civilian market?]
- G. **Technology Readiness Level (TRL):** [Indicate the TRL stage in which the project will start as well as anticipated TRL level at project completion. A document describing TRL definitions can be found here: <https://mtec-sc.org/documents-library/>.]
Estimated TRL at Project Start:
Estimated TRL and/or the next major deliverable milestone at Project End:

II. PROPOSAL BODY

- A. **Current Status of the Product:** [Describe the status of the effort to date.]
- B. **Next Major Stage of Development/Next Major Milestone:** [Describe the next major stage of development/next major milestone. How would funding be used to accelerate this effort to this point?]

- C. Research Strategy:** [Outline the proposed methodology in sufficient detail to show a clear course of action to achieve the next major stage of development/next major milestone. Include a description of controls and metrics to be used to measure success, as appropriate.]
- D. Projected Deliverable:** [Describe the anticipated outcome/deliverable of the proposed work.]
- E. Military Relevance and Impact Statement:** [Include the anticipated impacts of the deliverables/outcomes of the proposed work (e.g., ‘the results of this proposal will enable the *abc* devices to be used by deployed medics...,’ or ‘the knowledge gained will be used to update the clinical practice guidelines and checklists for *xyz*.’). Include the potential relevance of the proposed work to the military mission, health, medicine, and its impact on Service members, Veterans and their beneficiaries.]
- F. Timeline:** [Timeline may be presented in chart format or as a list of tasks for the proposed work with corresponding time frame.]
- G. Commercialization plan:** [State how you will transition the results of the work performed in the proposal to the next milestone and ultimately, to the commercial marketplace. Concisely convey:
- A description and justification of the anticipated regulatory pathway
 - The business opportunity enabled by the innovation
 - The compelling value proposition for the intended customer
 - The current as well as the anticipated commercial landscape
 - Pertinent information about Intellectual Property
 - The planned indication for the product label, if appropriate
 - Transition plan (including potential funding and resources) showing how the product will progress to the next developmental stage, clinical trial phase and/or delivery to the market after the successful completion of this award
 - Estimated timeline of technology development to projected market.
 - The vision for the enterprise and how the proposed innovation fits into the future market.]
- K. Principal Investigator and team expertise for this project:** [Briefly state the qualifications of the PI and key personnel to perform the work.]
- L. FDA-approved drugs, devices, and/or materials that will be tested or modified by this proposal and the indication for which they are approved:** [List all FDA-approved drugs, devices, and/or materials that will be tested or modified by this proposal and the indication for which they are approved.]
- Will a new FDA indication be required to use the drug, device, and/or material in the way applied in your proposal? YES NO