

**Request for Project Proposals**



**Solicitation Number: MTEC-E22-05-PA  
“MTEC Prototype Acceleration Funding”**

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: January 5, 2022***

***Solution Brief Due Date: March 1, 2022  
Noon Eastern Time Zone***

***White Papers Are NOT Required***

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## 1 Executive Summary

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### 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 Department of Defense (DoD) U.S. Army Medical Research and Development Command (USAMRDC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

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

MTEC is a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “nontraditional” defense contractors (refer to the MTEC Proposal Preparation Guide (PPG), Section 3 for definition), academic research institutions, and not-for-profit organizations; for more information on the MTEC mission, see the MTEC website ([www.mtec-sc.org](http://www.mtec-sc.org)).

### 1.2. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for the new MTEC Prototype Acceleration Funding mechanism (See Section 3 for more details), to be funded with MTEC consortium funding:

- **Objective** – To “de-risk” technology advancement toward a military application to a point that allows the MTEC member to secure follow-on funding
- **Funding Available** – \$1,000,000 total, up to \$250,000 per award
- **Award Type** - Grant
- **Scope of Work** – Tasks technical in nature
- **Solicitation Process** – Stage 1: Solution Brief, Stage 2: Solution Brief Pitch, Stage 3: Cost Proposal

## 2 Administrative Overview

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### 2.1. Solicitation Process

This **MTEC Prototype Acceleration Funding** RPP will be conducted using a multi-staged approach.

- **Stage 1 [Solution Brief]:** Current MTEC members are invited to submit Solution Briefs using the mandatory format contained in this RPP (see Section 9 of this RPP). The MTEC

staff will evaluate Solution Briefs submitted and will select the Solution Briefs that best meet the criteria in Section 5 of this RPP. Offerors whose proposed work is selected for further consideration based on the Solution Brief evaluation will be invited to submit a Solution Brief “pitch” in Stage 2.

- **Stage 2 [Solution Brief Pitch]:** Offerors will participate in a virtual judging round [deep dive/pitch], from which Awardees will be selected. The evaluation panel may be comprised of MTEC professional staff, representatives from private funders, military representatives, and independent subject matter experts (under confidentiality agreements) to help evaluate the technical and commercial merits of the applicant. Offerors whose proposed work is selected for award based on the pitch will be invited to submit a “cost proposal” in Stage 3.
- **Stage 3 [Cost Proposal]:** Offerors recommended for funding will be required to submit a full cost proposal, which will be used for award negotiations and execution of the Research Project Award.

## 2.2. Proposers Conference

The Proposers Conference is a virtual webinar format that provides potential Offerors the opportunity to interact directly with MTEC related to this specific funding opportunity. The flow of the Proposers Conference is as follows. First, MTEC will provide an overview of the solicitation. Then, all attendees are invited to anonymously type in questions into the webinar’s chat function, which are answered verbally and live by the appropriate presenter from MTEC. We highly encourage anyone interested in this funding opportunity to listen in and/or ask questions. Please register for the MTEC E22-05-PA Proposers Conference to be held on **January 21, 2022 at 1:00 PM ET** at: <https://attendee.gotowebinar.com/register/7815953593165142288>

Th Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

## 2.3. Funding Availability and Type of Funding Instrument Issued

MTEC currently has available a total of \$1,000,000 for this program. The maximum request for funding for each Solution Brief should not exceed \$250,000. MTEC anticipates that at least four awards will be made to qualified Offerors. *[NOTE: MTEC will be the sole funder of the awards resulting from this RPP. Therefore, awarded projects will be technically and financially managed by MTEC professional staff. The Government will **not** provide funding in support of this RPP.]*

The Period of Performance (POP) is not to exceed 24 months; however, faster timelines are highly encouraged.

Awards may be structured as cost reimbursable milestone payment method or firm fixed price milestone payment method (refer to the MTEC Proposal Preparation Guide (PPG) Section 2.12 for more information).

#### **2.4. Proprietary Information**

The MTEC CM will oversee submission of Solution Briefs 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 Solution Brief and the subsequent agreement administration if the Solution Brief is selected for award. In accordance with the PPG, please mark all Confidential or Proprietary Information as such. An Offeror's submission of a Solution Brief 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 organizations. MTEC Officers and Directors granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and a conflict of interest document.

#### **2.5. Expected Award Date**

Offeror should plan on the period of performance beginning September 2022 (subject to change). MTEC 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.

#### **2.6. Anticipated Solutions Brief Selection Notification**

As the basis of selections is completed, the MTEC CM will notify Offerors.

### **3 Technical Requirements**

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#### **3.1. Background**

MTEC is launching this new "Prototype Acceleration Funding" opportunity to de-risk medical technology development by MTEC members in order to advance their readiness to secure follow-on funding. In other words, the Prototype Acceleration awards will provide funding by MTEC to "bridge" the technology maturation to a point where the MTEC member is able to secure follow-on funding. Follow-on funding is broadly defined to include both private and public sources of funding received at least 6 months after initiation of the work funded by the Prototype Acceleration award. Candidates for MTEC Prototype Acceleration awards must focus on technologies with military relevance. Offerors must be either a small business (as defined by the

[Small Business Administration](#)) or a current MTEC awardee facing funding challenges in need of bridge funding.

Awardees may receive up to \$250,000 to achieve a technical milestone(s) that helps them secure follow-on funding. Requested budget must align with the complexity of the proposed scope of work. Offerors may request less than \$250,000. MTEC will be the sole funder of the Prototype Acceleration awards (the Government will not provide funding in support of the awards resulting from this RPP).

### **3.2. Minimum Requirements for Submission of a Solution Brief**

Solution Briefs submitted in response to this RPP shall meet the following minimum requirements for submission of a Solution Brief:

1. MTEC Membership Status: The prime contractor of the proposed project must be an MTEC member of good standing at the time of proposal submission.
2. MTEC Member Eligibility: The prime contractor of the proposed project must be either:
  - A small business (as defined by the [Small Business Administration](#)); or
  - A current MTEC awardee.
3. IP/Freedom-to-Operate: Offeror shall have an appropriate license(s) to IP and freedom-to-operate in place to commercialize its technology.
4. Fit the prototype definition: Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. The definition of a “prototype” is as follows: a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project.
5. Minimum Technology Readiness Level (TRL): The expected TRL **at the time of submission of the Solution Brief** is at least TRL 4. Offerors have achieved TRL 4 if:
  - **Pharmaceutical (Drugs)**: Offeror has demonstrated proof-of-concept and safety of candidate drug formulation(s) in defined laboratory/animal model(s).
  - **Pharmaceutical (Biologics, Vaccines)**: Offeror has demonstrated proof-of-concept and safety of candidate biologic/vaccine constructs in defined laboratory/animal model(s).
  - **Medical Devices**: Offeror has demonstrated proof-of-concept and safety of candidate devices/systems in defined laboratory/animal models.
  - **Medical Information Management/Information Technology & Medical Informatics**: Medical Informatics data and knowledge representation models are instantiated with representative data or knowledge from applicable domains.

\*NOTE: Full definitions of TRLs can be found [here](#).

6. **Follow-on Funding:** This solicitation is intended to “bridge” the technology maturation to a point where the MTEC member is able to secure follow-on funding. Follow-on funding is broadly defined to include both private and public sources of funding received at least 6 months after initiation of the work funded by this Prototype Acceleration Funding mechanism. The Offeror is required to provide a well-defined strategy for acquisition of follow-on funding. Letters of support from potential follow-on funders are highly encouraged.

### 3.3. Scope of Work

In multi-domain operations (MDO), today’s operating force will be overwhelmed with casualties, the ability to evacuate will be limited, first responders and medics will struggle with limited resources and ability to achieve the “Golden Day,” resulting in operational units and commanders rapidly losing freedom of maneuver and combat effectiveness. Therefore, medical assets must be highly mobile and more dispersed (e.g., smaller, more modular medical units), Warfighters will require greater self-sufficiency and autonomy (e.g., may have more limited medical-related communications and re-supply), and there will be an increased cognitive and physical stress on Warfighters (they will need ways to maximize lethality and return to the fight quickly).

Therefore, proposed projects shall focus on providing medical solutions to support readiness and care in future battlefield scenarios in support of the following areas:

- **Prolonged Field Care (PFC):** Because battlefield conditions impose severe constraints on available manpower, equipment, and medical supplies available for casualty care, there is a need for medical interventions that can be used within the battle area or as close to it as possible, before or during medical evacuation. Preferred medical techniques and materiel that can be used by combat medics must be easily transportable (i.e., small, lightweight, and durable in extreme environments and handling), easy to use and require low maintenance. Additionally, wound infection in a PFC<sup>1</sup> environment poses a significant threat to operational readiness and effectiveness. It is anticipated that future battlefield scenarios will necessitate the need for medical techniques, knowledge products, and materiel<sup>2</sup> to manage wound infections in theater.
- **Medical Readiness:** This area focuses on developing technologies that maximize medical readiness and provide mobile health solution sets for the modern Warfighter. Efforts may include diagnostics, treatments, AI-based advanced telehealth technologies, and training

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<sup>1</sup> Prolonged field care is defined as field medical care, applied beyond “doctrinal planning timelines” by a North Atlantic Treaty Organization (NATO) Special Operations Combat Medic (NSOCM) or higher, in order to decrease patient mortality and morbidity. PFC utilizes limited resources and is sustained until the patient arrives at an appropriate level of care. Rasmussen TE, Baer DG, Cap AP, et al. 2015. Ahead of the Curve. *J Trauma Acute Care Surg* 79: S61-64.

<sup>2</sup> Materiel is defined as equipment and supplies of a military force.

solutions to prevent or reduce injury and improve physiological and psychological health and resilience. This objective includes environmental health and protection including the assessment and sustainment of health and the operational effectiveness of Service members exposed to harsh operational environments including altitude, cold, heat, and exposure to environmental health. This focus area also includes medical readiness in response to infectious diseases encountered by Service members during deployment and those that can significantly impact performance.

- **Maximizing Human Potential:** This area aims to develop effective countermeasures against military-relevant stressors and to prevent physical and psychological injuries during training and operations in order to maximize the human potential, in support of the Army Human Performance Optimization and Enhancement, MDO, and the DoD Total Force Fitness concepts.

**It is encouraged that potential Offerors reach out to the MTEC Director of Research listed in Section 6 of this RPP to determine whether your proposed technology has military relevance, aligns with the mission of MTEC, and is within scope for this RPP.**

The proposed scope of work should focus on tasks relevant to advance the prototype to the next major milestone that helps secure follow-on funding. Project scope should be proposed based on the prototype's maturity at the time of submission. **Examples** of the work that could be included in the scope of work are **(but not limited to)**:

- Prototype refinement/maturation progressing towards clinical product
- Prototype delivery for military-relevant testing
  - Ruggedization for operation in military environments
  - Testing of prototypes
  - System prototype demonstration in a relevant or operational environment (live or simulated)
- Stability and shelf-life studies
- Nonclinical and preclinical studies required for the technical data package for a regulatory application
- Preparation of regulatory packages (e.g., Investigational New Drug application, Investigational Device Exemption application), including regulatory consultant costs.
- Clinical feasibility studies (as needed) to support regulatory approval/clearance
- Clinical pivotal studies (as needed) to support regulatory approval/clearance
- Establish robust quality system
- Improve efficiency and reproducibility of manufacturing process for scale up
- Establish Good Manufacturing Practice (GMP) manufacturing for clinical trials and for market release
- Work towards clearance/ approval by the U.S. Food and Drug Administration (FDA)



- Integration of medical informatics system components and system is evaluated in a simulated environment/ Develop interfaces to supporting systems
- Initial production runs; first article testing, etc.
- Low-rate initial product runs

### **3.5. Restrictions on Animal and Human Subjects**

Proposals must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, and continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually). Offerors shall include IACUC and IRB review and approval in the Statement of Work (SOW)/Milestone Payment Schedule submitted with the Solution Brief Pitch. Approvals **MUST** be in place prior to the initiation of work using animal or human subjects.

## **4 Solution Brief Preparation and Process**

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### **4.1. Solution Brief Submission**

Solution Briefs shall be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the **MTEC-E22-05-PA Solicitation Number** on each Solution Brief submitted. See Attachment 7 of the PPG for further information regarding BIDS registration and submission.

An automated BIDS receipt confirmation will be provided by email. 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. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

### **4.2. Instructions for the Preparation of the Stage 1 Solution Brief**

Offerors submitting Solution Briefs in response to this RPP will be required to submit using the following steps outlined below:

#### ***Stage 1: Solution Brief***

#### **Required Submission Documents (3): Submitted via BIDS**

- 1. Solution Brief:** One PDF document 5MB or lower [Required template is provided in Section 9 of RPP]
- 2. Appendix 1 – Pitch Deck:** One PDF document 5MB or lower [Required template is provided in Section 10 of RPP]

- 3. Appendix 2 – Letter(s) of Support:** One Word or PDF document 5MB or lower. If submitting multiple letters of support, then please consolidate all into one document.

Solution Briefs must be prepared **according to the mandatory format provided in Section 9** of this RPP. The Solution Brief is **limited to five pages**. The Appendices are **excluded** from the page limitation. Formatting requirements include 12 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. **Solution Briefs exceeding the page limit may not be accepted.**

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.

**Do not submit any classified information in the Solution Brief submission.**

Upon review of the Solution Briefs, Offerors may be invited into Stage 2 of the Solution Brief process. Offerors who are not invited to proceed into Stage 2 (Solution Brief Pitch) will be provided feedback.

### ***Stage 2: Solution Brief Pitch***

#### **Required Submission Documents (4): Submitted via BIDS**

- 1. Solution Brief Pitch:** One PDF document 5MB or lower.
- 2. Statement of Work:** One Microsoft Word document 5MB or lower. [Required template is provided in Attachment 4 of PPG]
- 3. Cost Realism Table:** One PDF document 5MB or lower. [Required template is provided on page 28 of the PPG]
- 4. Current and Pending Support:** One PDF document 5MB or lower. [Required template is provided in Attachment 5 of PPG]

In Stage 2, the Offeror(s) will provide a virtual “pitch” of the proposed project during a meeting with the Judging Panel. The solution brief pitch should provide more details about the technical and business viability of the proposed work outlined in Stage 1 (Solution Brief). The information discussed during the pitch provides a means for the Judging Panel to engage in a discussion with the Offeror to gain a greater understanding of the proposal and the Offeror’s capabilities. The pitch should be restricted to **a maximum of 30 minutes for the presentation by the Offeror with a total time of one hour** to include questions from the Judging Panel. Any materials that will be presented during the pitch or included as supplementary material must be provided in advance

of the meeting date. Briefing slides or documents or a combination thereof can be used to support this effort.

1) The Solution Brief Pitch should include the following:

- **Technology Description and Approach:** A more robust description of the technology, approach and emphasize why this approach is expected to result in a successful outcome. This discussion should include relevance to the military and civilians (as relevant).
- **Competitive Advantage:** A clearly defined competitive advantage of the proposed technology over already existing solutions and other solutions in development by others in the field.
- **Technical Maturity Advancement:** The Offeror will describe the proposed scope of work, milestones provided with objective, quantifiable/measurable metrics that will be used to measure progress during the POP/delivery schedule and describe the oversight managerial methods that will be employed to maintain a quality and timely performance. This approach should follow the SOW provided with the pitch. This discussion shall include an explanation of how the proposed work will advance the technical maturity of the technology.
- **Financial Maturity Advancement:** The Offeror will describe how the proposed technical advancement in maturity supports the potential for follow-on funding. The Offeror should clearly articulate their strategy to secure follow-on funding, which is the end goal of the E22-05-PA funding mechanism.
- **Market and Business Model:** Clear articulation of value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.
- **Development Strategy (including timing and regulatory):** Feasibility of the Offeror's product development strategy, including regulatory and FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances.
- **Relevant Experience:** The Offeror will convey details related to key personnel and past performance(s) that demonstrate relevance to the scope of the proposed work and build confidence in the team's capabilities.
- **Effectiveness (Opportunity and Risk):** The Offeror will identify, assess, evaluate, and clearly convey items for opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project measure, and the mitigation plan for each identified risk item.

- **Military Transition:** Offeror will describe the pathway to developing this into a product that can be used by the military.
  - **Dual Use:** Offeror will describe opportunities for civilian use cases for the technology and how this will contribute to the sustainability of the company.
  - **Cost:** The Pitch must present summarized costs at the task level.
- 2) **Statement of Work (SOW):** Separately, one Microsoft Word document of the SOW is required. See Attachment 4 of the PPG for the template.
- 3) **Cost Realism Table:** Separately, one PDF document of the Cost Realism Table is required. See page 28 of the PPG for the template.
- 4) **Current and Pending Support:** Separately, one PDF document of the current and pending support. See Attachment 5 of the PPG for the template.

*FOR INFORMATION ONLY:* Additional attachments/appendices (henceforth referred to as supplemental information) to the Solution Brief Pitch submission may be requested after completion of the Stage 1 Solution Brief evaluation. The exact requirements of any such attachment/appendix are subject to change and will be provided at the time (or immediately following) the Stage 1 evaluation summary is provided.

At the conclusion of the Stage 2 evaluation, Offerors who are favorably evaluated will be invited to submit a final solution brief (which may be amended from the initial brief to incorporate discussion points from the interaction in Stage 2) and a cost proposal.

### ***Stage 3: Cost Proposal***

**Required Submission Documents (4):** Submit to [mtec-contracts@ati.org](mailto:mtec-contracts@ati.org).

1. **Solution Brief: One word or PDF document.**
2. **Section II: Cost Proposal Narrative as one word or PDF document.**
3. **Section II: Cost Proposal Formats as one excel or PDF document.**

For the preparation of the cost proposal, refer to the Section 7 of the PPG for direction. The Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC with any questions so that all aspects are clearly understood by both parties.

**Offerors are encouraged to use their own cost formats such that the necessary detail is provided.** MTEC will make cost proposal formats available on the Members-Only MTEC website. The Cost Proposal formats provided in the MTEC PPG are **NOT** 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.

#### **4.3. Solution Brief, Pitch and Cost Proposal Preparation Costs**

The cost of preparing Solution Briefs, Pitches and Cost Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

## **5 Selection**

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### **5.1. General Information**

Evaluations at all stages of the Solution Brief acquisition process shall be based on an independent, comprehensive review and assessment of the work proposed against stated 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 Solution Brief and/or the Solution Brief Pitch process may involve the use of contractors as subject matter experts (SME) consultants or reviewers. Where appropriate, MTEC will employ NDAs to protect information contained in submissions. The evaluation panels may be comprised of SMEs appointed by the MTEC CM and/or representatives from the U.S. military with relevant expertise.

MTEC reserves the right to negotiate with Offerors.

### **5.2. Solution Brief (Stage 1) - Selection and Evaluation Process**

The CM will conduct a preliminary screening of submitted Solution Briefs to ensure compliance with the RPP requirements. As part of the preliminary screening process, Solution Briefs that do not meet the following mandatory requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The following will be assessed as part of the Preliminary Screening process:

- **MTEC Membership Status:** The prime contractor of the proposed project must be an MTEC member of good standing at the time of proposal submission.
- **MTEC Member Eligibility:** The prime contractor of the proposed project must be either:
  - A small business (as defined by the [Small Business Administration](#)); or
  - A current MTEC awardee.
- **Formatting:** The Solution Brief and Appendices follow the required formatting and page limitations.

Qualified applications will then be evaluated by the MTEC evaluation panel (MEP). The MEP will make recommendations regarding invitation to Stage 2 (Solution Brief Pitch) and will involve several members of MTEC's professional staff, including but not limited to, the MTEC Director of Research, MTEC Director of Commercialization, MTEC Chief Operating Officer, and MTEC's Biomedical Research Associate. If deemed necessary, the MEP may involve the use of contractors and/or representatives from the U.S. military as SME consultants or reviewers. The MEP will be required to assess each Solution Brief according to the Evaluation Factors outlined in Section 5.3. The adjectival merit ratings that will be used for all evaluation factors are shown in Table 1. Feedback will be provided to the Offerors.

**Stage 1 - Solution Brief Evaluation Factors (of equal importance):**

- 1. Programmatic and Technical Relevance**
- 2. Commercialization Readiness**

**Evaluation Factor 1 – Programmatic and Technical Relevance:** The Offeror's proposal will be assessed for the extent at which the following are satisfied:

- **Military Relevance & Dual Use:** The degree to which the Offeror demonstrates a strong solution to a defined unmet military medical need consistent with Section 3 of the RPP, and the applicability of the technology to the civilian market for commercial sustainability.
- **Technical Merit:** The degree to which the Offeror presents a proprietary medical technology with strong supporting preliminary data and a competitive advantage.
- **Fits within the prototype definition:** The degree to which the proposal describes a prototype as described in Section 3.2 of this RPP.
- **TRL:** The Offeror's ability to clearly demonstrate that the proposed technology meets the minimum TRL requirement at the time of submission (TRL 4). Offerors will be assessed for how clearly they align their supporting data with the required data outlined in the TRL definitions document.
- **Proposed Use of Funds:** The degree to which the proposed scope of work and estimated budget is in alignment with this RPP.
- **Plan for Follow-On Funding:** The degree to which the Offeror demonstrates funding to-date, describes their current funding challenges, and demonstrates fundability going forward, particularly likelihood of receiving funding from follow-on funders if milestones proposed are achieved.

**Evaluation Factor 2 – Commercialization Readiness:** The Offeror's proposal will be assessed for its likelihood of achieving and advancing through the development milestones identified in its proposal, thus advancing the Offeror's commercialization readiness. Information that will be assessed (**if applicable to the proposed project**) includes, team, intellectual property, market opportunity, commercialization, reimbursement, and regulatory strategies, and the company's financials.

TABLE 1- 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.

**5.3. Solution Brief Pitch (Stage 2) - Selection and Evaluation Process**

Offerors invited to Stage 2 (Solution Brief Pitch) will then be evaluated by a judging panel. The judging panel will make recommendations for award and invitation to Stage 3 (Cost Proposal). The judging panel will involve some or all of the following:

- Several members of MTEC’s professional staff, such as the MTEC Director of Research, Director of Commercialization, and Chief Operating Officer
- Representative(s) from a private equity investor groups
- Subject matter expert(s) to provide input on the feasibility of the proposed scope of work
- Representative(s) from the military to provide input on alignment with military needs

The judging panel will be required to assess each Solution Brief Pitch according to the Evaluation Factors outlined in Section 5.5. The adjectival merit ratings that will be used for all evaluation factors are shown in Table 1. Based on the results of the evaluation of the Solution Brief Pitch, Offerors may be recommended for funding, placed into the basket, or not selected. Feedback will be provided back to the Offerors. Offerors who are recommended for funding will be invited to Stage 3 of the process – invitation to submit a cost proposal.

**Stage 2 - Solution Brief Pitch Evaluation Factors (listed in order of descending importance):**

1. **Management Team and Relevant Experience**
2. **Technical Feasibility**
3. **Commercialization Readiness Advancement**

**Evaluation Factor 1 – Management Team and Relevant Experience:** Strength of the organization and team, considering the qualifications of the personnel, facilities, equipment, supplies, services, and subcontractors. Project management plan will be considered as an aspect of this factor.

**Evaluation Factor 2 – Technical Feasibility:** Feasibility of the proposed solution and its alignment with the RPP’s topic area. The judging panel may consider the estimated budget as an aspect of overall technical feasibility.

**Evaluation Factor 3 – Commercialization Readiness Advancement:** Likelihood of achieving and advancing through the development milestones identified in its proposal, thus advancing the Offeror’s commercialization readiness. Examples of the information that may be assessed (**if applicable to the proposed project**):

- **Financial Maturity Advancement:** The degree to which the Offeror proposes to advance the technical maturity level during the performance of the project to a point that is likely to secure follow-on funding.
- **Market and Business Model:** Clear articulation of value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.
- **Development Strategy (including timing and regulatory):** Feasibility of the Offeror’s product development strategy, including regulatory and FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. If commercialization is not relevant to the proposed project, then feasibility of the plan to transition the technology to the government may be assessed.

#### **5.4. Cost Proposal (Stage 3) Evaluation**

Cost proposals submitted by invited Offerors will then be evaluated by the MTEC CM. 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.

#### **5.5. Best Value**

Projects will be awarded in Best Value sequence. If applicable, a best value process will be invoked to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. MTEC 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.

#### **5.6. 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 MTEC 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 MTEC 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 the 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**

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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, [mtec-contracts@ati.org](mailto:mtec-contracts@ati.org)
- Technical and membership questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., [lauren.palestrini@mtec-sc.org](mailto:lauren.palestrini@mtec-sc.org)
- All other questions should be directed to Ms. Kathy Zolman, MTEC Director of Program Operations, [kathy.zolman@ati.org](mailto:kathy.zolman@ati.org)

**Once an Offeror has submitted a Solution Brief, the MTEC CM will not discuss evaluation/status until the source selection process is complete.**

### **7 Acronyms/Abbreviations**

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ATI	Advanced Technology International
BIDS	System for Submission of the Solution Brief
CM	Consortium Manager
DoD	Department of Defense
FAQ	Frequently Asked Questions

F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act (FOIA)
G&A	General and Administrative Expenses
GMP	Good Manufacturing Practices
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
KRL	Knowledge Readiness Level
MDO	Multi-Domain Operations
MEP	MTEC Evaluation Panel
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
POC	Point-of-Contact
POP	Period of performance
PPG	Proposal Preparation Guide
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
Government	U.S. Government, specifically the DoD

## 8 Quick Reference Guide

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Statement of Work .....	PPG, Attachment 4
Cost Realism Table .....	PPG page 28
Cost Proposal Templates.....	Members-Only Website
Current and Pending Support Template.....	PPG, Attachment 5
BIDS Instructions.....	PPG, Attachment 7

## 9 Solution Brief Template

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**[NOTE: 5-page limit, see Section 4.1 of this RPP for more details]**

### **Contact Information**

- Organization Name
- Organization website
- In what city and state is your organization headquartered?
- PoC: first and last name
- PoC: email address
- PoC: LinkedIn url, professional website, or other link with bio

### **Member Eligibility [check all that apply]**

- Prime contractor is a small business (as defined by the [Small Business Administration](#))
- Prime contractor is a current MTEC awardee

### **Team**

- What is the most impressive thing that each key team member has done prior to his/her affiliation with the Offeror? [Any hacks, discoveries, creations, awards, or insights that you're particularly proud of?]
- What will each key team member contribute to this proposed effort?

### **Problem and Solution**

- Describe the clinical and market need.
- Describe the value proposition of your product.
- Describe the military relevance of your product.
- What stage is your product [early concept, pre-clinical, clinical, approval, or sales]?

- Describe the product in detail including relevant data and milestones/deliverables accomplished to date.
- Share a link to a demo of your product (if available).
- Include an image of your current prototype.

### ***Market Opportunity***

- Who are your intended customers?
- What is your target market (quantity and timing) for your technology?
- What unique insight or belief(s) do you have about this market?

### ***Competitive Advantage***

- What competitors currently exist in the market and what competition is emerging in the field?
- What is your competitive advantage?

### ***Business Model***

- Is freedom to operate in place for the applicant to commercialize its technology (indicate license(s) to relevant IP)?
- In a few sentences, what is your broader vision for your business as it grows and evolves over time?

### ***Follow-on Funding***

- Describe your current funding challenges and your need for this “bridge” funding.
- How much non-dilutive funding have you raised to date? Include the sources of funding.
- How much dilutive funding have you raised to date? Include the sources of funding.
- Demonstrate fundability going forward, particularly likelihood of receiving funding from third party investors if milestones proposed are achieved
  - If available and highly encouraged, provide a letter of support for potential follow-on funding by a third party (uploaded to BIDS as Appendix 2 of your submission)
  - Identify which investors you have spoken with. Include what those investors provided as feedback, in other words, briefly describe what they recommended should be done next

### ***The Ask***

- Total funding requested [maximum allowable request is \$250,000].
- Describe your proposed use of the requested funds.
  - What technical milestone(s) needs to be accomplished to position you for success with follow-on funding?
  - Describe the proposed work plan.

**10 Pitch Deck Template [Appendix 1 of Solution Brief Submission]**

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[See next page. Note: The \*.pptx version is available on the MTEC members-only website.]