## **Request for Project Proposals**



# Solicitation Number: MTEC-E22-06-Commercialization "MTEC Commercialization Grants"

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 13, 2022

Amendment No. 01 Issue Date: February 15, 2022

Due Date: March 11, 2022 Noon Eastern Time Zone

Amendment No. 01 does the following: Extends the due date from February 23, 2022 to March 11, 2022.

All other terms and conditions remain unchanged.

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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 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).

## 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 Commercialization Grant" mechanism (See Section 3 for more details), to be funded with MTEC consortium funding:

- Objective To provide non-dilutive MTEC awards that fund M-Corps partner engagement for the purpose of providing members professional services that advance commercialization readiness
- Funding Available \$600,000 total, up to \$50,000 per award
- Award Type Grant
- Scope of Work Business, technical and strategic planning projects

#### 2 Administrative Overview

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

MTEC currently has available a total of \$600,000 for this program. The maximum request for funding for each application should not exceed \$50,000. MTEC anticipates that at least twelve 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 <u>not</u> provide funding in support of this RPP.]

The Period of Performance (POP) is not to exceed 12 months.

Awards will be issued as Grant Agreements to MTEC small business members who will subcontract to identified service providers. It is anticipated that 75% of funds will be provided at award and remaining 25% upon completion of the project with final report.

#### 2.2. Webinar

An overview of the MTEC Commercialization Grant program may be found at <a href="https://www.youtube.com/watch?v=YtDICAOavGI&t=597s.">https://www.youtube.com/watch?v=YtDICAOavGI&t=597s.</a> We will hold another overview and Q&A on January 26, 2022 at 1:00 PM ET. Please register at: <a href="https://ati.zoomgov.com/meeting/register/vJltcuqhqzwjEnRXKkBlaFRZJtepbPFcPwl">https://ati.zoomgov.com/meeting/register/vJltcuqhqzwjEnRXKkBlaFRZJtepbPFcPwl</a>

## 2.3. 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 application and the subsequent agreement administration if the application is selected for award. In accordance with the PPG, please mark all Confidential or Proprietary Information as such. An Offeror's submission of an application 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 your pitch deck within their program areas, allowing opportunities to attract supplemental funding sources. **On your pitch deck, 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 Evaluation Panel participants will agree to, and sign a nonproprietary information and a conflict of interest document.

## 2.4. Expected Award Date

Offeror should plan on the period of performance beginning March 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 Grant Agreement.

## 2.5. Anticipated Selection Notification

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

## **3** Requirements

### 3.1. Use of M-Corps partner network

The intent of this program is to help MTEC members advance their commercialization readiness of technologies with relevance to the military and the MTEC mission.

MTEC has recently established the M-Corps, a network of subject matter experts and service providers that provide resource support for business, technical, and regulatory services. The funds requested must be used to support a partnership with an M-Corps provider that helps the applicant address challenges associated with technology development and commercialization. See <a href="https://www.mtec-sc.org/m-corps/">https://www.mtec-sc.org/m-corps/</a> for a list of current partners. **Applicants are required to use the M-Corps network in selecting outsourced services.** Contact information for partners may be found on the members only site. Please email Rick Satcher, Director of Commercialization, rick.satcher@mtec-sc.org for assistance if needed.

M-Corps was initiated in the second half of 2020 and is growing rapidly. M-Corps partners must be MTEC members, and a simple teaming agreement is required to be part of the M-Corps network. We are adding new M-Corps partners daily. However, if a project requires an external service provider who is not an M-Corps partner (and hence not an MTEC member) at the time of submission, the service provider will be required to join MTEC and M-Corps before funds can be released to a winning applicant. Official quotes from service providers are required with the proposal submission.

### 3.2. Minimum Requirements for Proposal Submission

Proposals submitted in response to this RPP shall meet the following minimum requirements for submission of an application:

- MTEC Member Eligibility: The applicant of the proposed project must be a small business (as defined by the <u>Small Business Administration</u>) developing technology at TRL 4 or above (See requirement #5). Public companies are excluded.
- 2. <u>MTEC Membership Status:</u> The applicant must be an MTEC member of good standing at the time of proposal submission.
- 3. <u>MTEC M-Corps Status:</u> The service provider must be an MTEC member of good standing and an M-Corps partner at the time of award.

- 4. <u>IP/Freedom-to-Operate:</u> Offeror shall have an appropriate license(s) to IP and freedom-to-operate in place to commercialize its technology.
- 5. <u>Minimum Technology Readiness Level (TRL)</u>: The expected TRL **at the time of submission of the application** is at least TRL 4. Although the requested scope of work may not directly relate to a proposed technology, the Applicant must demonstrate to the Evaluation Panel that they are actively developing a technology at a minimum of a 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 <a href="here">here</a>.

## 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, Al-based advanced telehealth technologies, and training 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 Commercialization 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 will focus on <u>business</u>, <u>technical</u> and <u>strategic planning projects</u>. Scientific and product development proposals are out of scope. Defining the value proposition for your technology, fit with military and civilian markets, as well proper strategies for IP, clinical and regulatory, market entry and reimbursement, and exits are critical to the early success of start-ups. These grants are meant to help our small business members create and update a clear, concise strategy for their technology. <u>Examples</u> of the work that could be included in the scope of work are <u>(but not limited to)</u>:

- Competitive landscape analysis/ market research
- IP protection and valuation
- Regulatory and reimbursement strategy

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

- Partnering / business development strategy
- Engineering design and evaluation
- Clinical trial protocol development

## 3.5. Restrictions on Animal and Human Subjects

Awards resulting from this RPP are prohibited from using animal and human subjects.

## 4 Proposal Submission Process

#### 4.1. BIDS Submission

Applications shall be submitted by the date and time specified on the cover page using BIDS: <a href="https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm">https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm</a>. Include the MTEC-E22-06-Commercialization Solicitation Number on each application submitted. See Attachment 7 of the PPG found on the MTEC members-only website for further information regarding BIDS registration and submission. Note: In BIDS, the term "full proposal" is used interchangeably with the term "application" mentioned throughout this RPP.

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 an Application/Proposal

Offerors submitting applications will be required to submit the following documents via BIDS. Mandatory Templates for each document specified below are found on the MTEC members-only website.

## Required Submission Documents (6): Submitted via BIDS

- **1. Executive Profile:** One PDF document 5 MB or lower. [Required template is provided on the MTEC members-only website]
- **2. Pitch Deck:** One PDF document 5 MB or lower. [Required template is provided on the MTEC members-only website]
- **3. Proforma:** One Microsoft Excel document or PDF 5 MB or lower. [Required template is provided on the MTEC members-only website]
- **4. Budget Summary:** One Microsoft Excel document or PDF 5 MB or lower. [Required template is provided on the MTEC members-only website]
- **5. Scope Statement and Milestone Summary:** One PDF document 5 MB or lower. [Required template is provided on the MTEC members-only website]
- **6. Official Quote:** One PDF document 5 MB or lower representing an official quote from an M-Corps (or external) service provider

Link to members only website- <a href="https://private.mtec-sc.org/documents-library/solicitations">https://private.mtec-sc.org/documents-library/solicitations</a>.

### 5 Selection

#### 5.1. General Information

Evaluations 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 evaluation 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.

Qualified applications will then be evaluated by the MTEC evaluation panel (MEP). The MEP will make recommendations 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 application according to the Evaluation Factors outlined below. The adjectival merit ratings that will be used for all evaluation factors are shown in Table 1. Feedback will be provided to the Offerors.

The evaluation factors are listed below and are of equal importance.

#### 1. Evaluation Factor 1 – Strength of Team

- Business Experience within industry sector, P&L, investor relations, etc.
- Start-up Experience within management and/or advisory board
- Fundraising Experience investor relations track record; previously raised capital
- Reputable service partner if not M-Corps partner as of date of submission

## 2. Evaluation Factor 2 - Technology and Market Relevance

- Stage of Development TRL-4 or above
- IP Status protection (trade secrets, patents, etc.); freedom to operate (license
- Validation from third party; prototypes, partnerships, commercial sales, etc.
- TAM/SAM/SOM significant size and growth potential; clearly defined target market and end-user

- Path to Market channel to market clearly defined; key partners in place; channels secure
- Competitive Position differentiation from competitors

## 3. Evaluation Factor 3- Funding and Use of Funds

- Internal and External Funding to date
- Exit Opportunity identified exit opportunity with capital plan
- Clear Pathway to Future Funding
- Proposed use of funds achieves one or more critical milestones that advances commercialization readiness and will support the company in pursuing follow-on funding.
- Clear milestones and deliverables are outlined in the project plan.

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.	

### 5.5. 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

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, <a href="mailto:mtec-contracts@ati.org">mtec-contracts@ati.org</a>
- Proposal questions should be directed to the MTEC Director of Commercialization, Mr. Rick Satcher, <u>rick.satcher@mtec-sc.org</u>
- All other questions should be directed to Ms. Kathy Zolman, MTEC Director of Program Operations, kathy.zolman@ati.org

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

# 7 Acronyms/Abbreviations

ATI	Advanced Technology International
BIDS	System for Submission of the Application
CM	Consortium Manager
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
MEP	MTEC Evaluation Panel

## Request for Project Proposals MTEC-E22-06-Commercialization

MTEC Medical Technology Enterprise Consortium

NDA Nondisclosure Agreement

OCI Organizational Conflict of Interest

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

Executive Profile Template	Members-Only Website
Pitch Deck Template	Members-Only Website
Proforma Template	Members-Only Website
Budget Summary Template	Members-Only Website
Scope of Work and Milestone Summary Template	Members-Only Website
BIDS Instructions	PPG. Attachment 7