Request for Project Proposals



Solicitation Number: MTEC-E23-08-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)

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1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is a non-profit biomedical consortium sponsored by and working in support of the U. S. Department of Defense Army Medical Research and Development Command and other Government agencies in the biomedical sciences. MTEC's mission is to advance innovation related to drugs, biologics, vaccines, medical software, and medical devices for the purpose of protecting, treating, and optimizing the health and performance of U.S. military personnel ("Warfighter"). MTEC engages members from large businesses, small businesses, contract research organizations, "nontraditional" defense contractors, academic research institutions, and not-for-profit organizations to address 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.

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 2023 "MTEC Commercialization Grant" mechanism targeting the following:

- **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 \$500,000 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 \$500,000 for this program. The maximum request for funding for each application should not exceed \$50,000. MTEC anticipates that at least ten 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 will be held **Friday May 19, 2023 at 1:00 PM ET.** Further instructions will be forthcoming via email.

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 Proposal Preparation Guide (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.

2.4. Expected Award Date

Offeror should plan on the period of performance beginning **August 2023** (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. All Offerors will be notified by email from the MTEC CM of the results of the evaluation.

Offerors are hereby notified that once a Proposal has been submitted, the MTEC team will not discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

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 established the M-Corps, a network of subject matter experts and service providers that provide resource support for business, technical, and regulatory services. Ninety percent (90%) of the funds requested must be used to support a partnership with an M-Corps Partner. See https://www.mtec-sc.org/m-corps/ for a list of current partners. **Applicants are expected to use the M-Corps network for selection of outsourced services.** Contact information for partners may be found on the MTEC Members Only site (https://portal.ati.org).

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. Use of the current M-Corps network may receive preferential review.

Please email Rick Satcher, Director of Commercialization, at rick.satcher@mtec-sc.org for assistance if needed.

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 MTEC member and a small business developing technology at TRL 4 or above (See requirement #5 below). As defined in the Consortium Membership Agreement, a "small business" is a for profit organization that has 500 or less employees, including employees of Affiliates. Public companies are excluded. MTEC members that are recipients of a previous MTEC Award(s) or submitted a proposal that was placed in the basket in May 2021 or later may receive priority review.
- 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 at the time of proposal submission to substantiate their ability to commercialize the proposed 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 here.

3.3. Scope of Work

Current wartime operations assume that the United States and our allies will maintain air, land, maritime, space and cyber superiority. Future conflicts against peer and near-peer adversaries are expected to be layered stand-offs and fought across multiple domains. Mission success will be determined by our ability to compete to expand the competitive space, penetrate both strategically and operationally, disintegrate enemy's defenses, exploit enemy weaknesses, and recompete to consolidate gains. Medical capabilities play a critical role in each aspect of the future battlespace and must modernize rapidly to maintain Force readiness and increase soldier lethality.

Therefore, proposed projects shall focus on providing medical solutions to support readiness and care in future battlefield scenarios in support of the areas listed at https://mtecsc.org/whatwedo/.

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>, technical and strategic planning projects. 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 success. These grants are meant to help our small business members create and update a clear, concise strategy for their technology. **Examples** of the work that could be included in the scope of work are **(but not limited to)**:

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

<u>4</u> <u>Proposal Submission Process</u>

4.1. BIDS Submission

Applications 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-E23-08-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 (5): Submitted via BIDS

- 1. Executive Profile: One PDF document 5 MB or lower. [See Addendum 1 of this RPP]
- 2. Pitch Deck: One PDF document 5 MB or lower. Applicants are strongly encouraged to provide all information requested in a succinct pitch deck that is 12 slides or less. Addendum 3 of this RPP includes the required template for the Pitch Deck. An outline of recommended information to include in your pitch deck is provided in Addendum 2 of this RPP. Additional Back-up slides containing technical information with reference(s) to applicable peer reviewed publication(s) or patent(s) are recommended and can be included in your Pitch Deck. Back-up slides are excluded from the 12-slide limit.
- 3. **Budget Summary:** One Microsoft Excel document or PDF 5 MB or lower. [**See Addendum** 4 of this RPP]
- 4. Scope Statement and Milestone Summary: One PDF document 5 MB or lower. [See Addendum 5 of this RPP]
- 5. **Official Quote:** One PDF document 5 MB or lower representing an official quote from an M-Corps (or external) service provider.

5 Selection

5.1. Proposal Evaluation

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 evaluation process may involve the use of contractors as subject matter experts (SME) consultants or reviewers. Where appropriate, MTEC will employ non-disclosure agreements (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 then will be evaluated and scored by the MTEC evaluation panel (MEP). The MEP will be comprised of MTEC's Director of Commercialization, MTEC's Chief Science Officer, MTEC's Chief Development Officer and may involve several members of MTEC's professional staff. 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 merit ratings that will be used for all evaluation factors are shown in Table 1. Feedback will be provided to the Offerors. The MEP also will be the deciding body for Commercialization Grant awards.

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
 - Ability to convey all information described in Addendum 2 of this RPP in a succinct pitch deck
- 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.
 - The impact that Commercialization Grant funding may have in advancing TRL and adding company value.

| 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 understanding of the requirements. Proposal contains strengths outweigh any weaknesses. Risk of unsuccessful performance is lo | | | |
| ACCEPTABLE | Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate. | | |
| MARGINAL | Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high. | | |
| UNACCEPTABLE | Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable. | | |

5.2. Modification

MTEC reserves the right to negotiate and request changes to any or all parts of the Proposal. Offeror will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

5.3. 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.

5.4. Definition of General Terms Used in Evaluations

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to 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, mtec-contracts@ati.org
- Proposal questions should be directed to the MTEC Director of Commercialization, Mr. Rick Satcher, rick.satcher@mtec-sc.org
- All other questions should be directed to Ms. Kathy Zolman, MTEC Chief of Consortium Operations, kathy.zolman@ati.org

7 Acronyms/Abbreviations

ATI Advanced Technology International
BIDS Online Platform for Proposal Submission

CM Consortium Manager

IP Intellectual Property (e.g., patents, copyrights, licensing, etc.)

MEP MTEC Evaluation Panel

MTEC Medical Technology Enterprise Consortium

NDA Nondisclosure Agreement
POP Period of Performance
PPG Proposal Preparation Guide
RPP Request for Project Proposals

SME Subject Matter Expert

TRL Technology Readiness Level

Government U.S. Government

Addendum 1 – Executive Summary Template

| Company logo | [Name of technology] [Primary field] | |
|--|---|--|
| Contact: [Name] [Title] [Email] | Technology [Brief description] | |
| Field • [List relevant fields] | Key Competitive Advantage [Brief description] | |
| Key Features • [List key features] • | Market [Brief description of market size, other points of interest] | |
| TRL Stage of Development | Ask [Describe how you will spend the \$50,000 and what impact it will have on your business strategy] | |
| Patents • [List patent numbers] | | |
| Relevant peer-reviewed publications • [List publications] | | |
| Funding to Date [List all funding awarded] | | |

Addendum 2 – Suggested Material to Include in Pitch Deck

- 1. General suggestions and considerations:
 - a. Use facts and figures to describe the problem and reasons why the problem is critical to the military and civilian markets **today**.
 - b. Describe the solution for the military and civilian problem and the potential impact.
 - c. On the military side
 - i. Which service and in what locations is the problem a problem? For example, ground patrols in theater and explosive devices (dismounted injuries) were a bigger problem for the Marines and the Army than the Air Force and Navy. The solution must fit the military problem and not be a solution looking for a problem.
 - ii. How would your technology be implemented by the military?
 - d. Why is now the best time for your technology to be implemented?
 - e. Provide a story of real Service Members and civilians how they are impacted by the problem and how their care and health will be better with your solution.

2. Market Opportunity

- a. What is your TAM, SAM, SOM for commercial and military market? See https://www.thebusinessplanshop.com/blog/en/entry/tam_sam_som and use the graphic.
- b. What is the CAGR and key drivers and barriers for growth in the market.
- c. How does the technology fit in the existing clinical practice in military and civilian markets?
- d. Who is your target customer?
 - i. What do they need to see to agree that you are the best solution for their patients?
 - ii. How has the market validated this solution? Feedback from end users?
- e. What competitors currently exist in the market, and how is your solution a better fit for consumers?

3. Business Strategy

- a. Describe your go-to market or exit strategy and estimated timing.
- b. Highlight any current or pending business development agreements and significant partnerships.
- c. What is the vision for the company? Describe anticipated revenue streams (licensing, product sales or other) associated with your commercialization plan.
- d. When do you anticipate first revenues from each stream?
- e. Describe an appropriate staged finance plan given the market opportunity. What levels of funding are required for each stage along the path to commercialization?
- f. What commitments do you have for follow-on funding?
- g. What are the assumptions made when developing your models? How have you validated these assumptions?

4. Team

a. Experience and expertise of senior leaders, scientific advisory board, board of directors.

5. Intellectual Property

- a. Issued patents owned or licensed by the company as well as patent applications.
- b. Highlight the IP protection strategy.
- c. Include any significant past and pending publications based on the technology.
- d. Do you have freedom to operate or are you tied to another company or university IP?
- e. Highlight any license agreement.

6. Competition

- a. Briefly describe competing technologies on the market and in development and the competitive advantages this technology has over all others.
- b. What is the existing standard of care?
- c. Why have other attempts to change the standard of care failed?
- d. How will you avoid those issues and succeed? Is your product a cost savings (with a positive ROI) or a care improvement versus the current solutions out there?

7. Regulatory Strategy

- Describe interactions and outcomes of discussions with the FDA, and if no discussions have occurred, indicate if there is a predicate for your pathway or if it is novel.
- b. Describe the milestones needed to meet anticipated regulatory approval.

8. Reimbursement Strategy

- a. What is your reimbursement strategy and who have you consulted with to define your strategy?
- b. Does your product fall under existing reimbursement codes? If so, what codes?
- c. If not, what is your strategy to go to market without reimbursement?

9. Significant Milestones / Roadmap

- a. Summarize important goals the company has reached and plans to achieve more.
 - i. Technical
 - ii. Financial
 - 1. How much in non-dilutive and dilutive funding have you raised and from whom?
 - 2. Have you calculated value inflection points based on development milestones? Please provide.
 - 3. What is your runway (how long till you run out of money?
 - 4. Are you currently fundraising? If so, how much and how will you use the proceeds?
 - iii. Regulatory
 - iv. Manufacturing

10. Use of Grant Funds

- a. Description of the work plan briefly describe the main components of the work plan for this funding opportunity.
- b. Milestones and timelines Outline the milestones and timelines for deliverables
- c. Describe the impact this funding will have in meeting the short terms goals of the company.
- d. Please highlight any contributing funds provided by the member to execute the stated deliverables.

| Addendum 3 – Pitch Deck Template |
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Request for Project Proposals MTEC-E23-08-Commercialization

| Request for Project Proposals MTEC-E23-08-Commercialization | | |
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| Addendum 4 – Budget Summary Template | | |
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Addendum 5 – Scope Statement and Milestone Summary Template

| Addendam 5 – Scope Statement and whiestone Summary Template | | |
|---|--|--|
| | | |
| Solicitation Number: | | |
| Organization: | | |
| Proposal Title: | | |
| | | |

Scope Statement:

Define the scope of the effort and clearly state the objectives of the project.

Milestone Payment Schedule (MPS):

The MPS should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable, if applicable. The MPS should include a Final Report submission.

| MTEC Milestone | Significant Event / Accomplishment | Due Date | Milestone Funds |
|----------------|------------------------------------|----------|-----------------|
| Number | | | |
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |
| 7 | | | |
| 8 | | | |
| 9 | Final Report Submission | | |