

HOW TO WORK WITH MTEC



Stacey Lindbergh
Executive Director, MTEC

execdirect@mtec-sc.org
843-760-3566

Table of Contents

OVERVIEW	3
MEDICAL TECHNOLOGY SUPPORT CENTER	3
USAMRMC Program Office	3
MTEC Officers and Staff	4
HOW TO GET INVOLVED WITH MTEC	4
HOW SOLICITATIONS AND PROJECTS ARE PROCESSED WITH MTEC	4
MTSC pOTA PROJECT PROPOSAL FORM	6
RESOURCES & TOOLS	7
QUICK REFERENCE GUIDE	8

OVERVIEW

The Medical Enterprise Technology Consortium (MTEC) is a tax-exempt, nonprofit corporation consisting of industry, academia and nonprofit organizations committed to supporting the U.S. Army Medical Research and Materiel Command (USAMRMC) in developing biomedical technologies for the benefit of our warfighters, veterans, and the wider civilian community. The MTEC Board of Directors is chaired by a former USAMRMC Commanding General, Major General (Ret.) Lester Martinez, MD MPH, and is comprised of academic leaders and corporate executives with deep experience in medical technology development. Business and management services are provided by Advanced Technology International (ATI), a nonprofit corporation whose core competency is building and leading complex collaborations. Membership includes the top biomedical R&D organizations from across the nation, and from international organizations.

Through this unique enterprise, the DoD realizes increased efficiencies in the acquisition process through new and expanded collaborations. The ability to leverage resources, facilities, programs and people provides a high return on investment and information sharing, and allows the focus to remain on biomedicine in the areas of:

- Prevention, diagnosis, and treatment of infectious diseases;
- Care of combat casualties;
- Military operational medicine;
- Clinical and rehabilitative medicine;
- Medical training and health information science; and
- Advanced medical technologies.

MTEC is different. Other non-profit organizations are doing wonderful work in providing a means for wounded warriors to cope with their functional losses, but MTEC is working to treat these injuries in a way that can make the wounded whole again.

MTEC is goal oriented. The focus is on building teams to solve problems and getting technologies to those in need. Research priorities are purposeful and outcomes-driven. The reach of the team ensures that research outcomes and new technologies will be applied across the entire medical infrastructure for the benefit of all citizens.

MTEC cuts through red tape. MTEC operates under an Other Transaction Agreement partnership model. This model relieves some of the contractual burdens typically associated with federally –funded research, which allows the government to acquire new technology and prototypes more quickly. Organizations that deliver positive outcomes may be eligible to receive additional funding for work toward FDA approval and manufacturing without the need to repeat the proposal cycle.

MTEC has a wide resource aperture. While the initial funds creating MTEC come from the Department of Defense, over the long term, all sources of government and private sector resources can be allocated to these research and technology initiatives. This will widen the scope and scale of solution providers involved in military and civilian medical needs.

MTEC is efficient. ATI’s experience leading technology-based collaborations has created a broad-reaching national network of pre-existing business relationships, a rapid ramp-up capability based upon significant first-hand experience with sophisticated public-private partnerships, and a deep reservoir of earned trust and respect through years of capable program execution in support of public and private industry research sponsors.

MTEC is open and comprehensive. MTEC boasts a nationally dispersed membership drawn from industry, academia and the nonprofit sector. Open membership policies and low barriers to entry enable MTEC to add new members. With broad insight into research activities that otherwise would be conducted in silos, MTEC can foster integrated research partnerships and speed the availability of solutions to the military, veterans and the civilian population.

MTEC employs blended funding streams. Initial operating funds for MTEC and research award funds are being provided by USAMRMC. Within two years, MTEC’s operations will be sustained through consortium membership fees, project award assessments for necessary contracting and support services, and private and corporate philanthropy. Funds for research projects will flow from USAMRMC, other Federal agencies, corporate partnerships, venture capital, and/or private philanthropy.

MEDICAL TECHNOLOGY SUPPORT CENTER

USAMRMC Program Office

J.B. Phillips, PhD	Office of the Principal Assistant	james.b.phillips10.civ@mail.mil	301-619-4595
Sara Langdon	Office of the Principal Assistant	sara.b.langdon.ctr@mail.mil	301-619-4591
Jonathan Miller, PhD	Office of the Principal	jonathan.s.miller26.civ@mail.mil	301-619-7367

MTEC Officers and Staff

Stacey Lindbergh	Executive Director	execdirect@mtec-sc.org	843-760-3566
Kathy Zolman	Program Manager	kathy.zolman@ati.org	843-760-4349
Rebecca Harmon	Contracts Administrator	rebecca.harmon@ati.org	843-760-3358
Bill Howell	Chief Operating Officer	william.howell@officer.mtec-sc.org	843-345-3686
Lauren Palestrini, PhD	Director of Research	lauren.palestrini@officer.mtec-sc.org	718-619-7570
Rick Satcher	Director of Commercialization	rick.satcher@officer.mtec-sc.org	919-541-7418

HOW TO GET INVOLVED WITH MTEC

“What steps would we need to take?”

As a first step in the process, potential sponsors should contact MTSC using the point of contact information provided above. MTSC will provide you with the pOTA Project Proposal Form. The form will ask you to define the prototype, requirements, funding plan, project management plan, sponsor office technical representative (SOTR), evaluation plan, and end game.

You should state the specific capabilities your command is interested in sponsoring, and identify your funding and shared funding sources. MTSC will evaluate your

information to determine if the focus of the proposed project fits within the scope of the pOTA and the consortium. The project must be awarded competitively and address R&D activities associated with maturity levels in the late 6.2 through 6.3 and 6.4 funding categories.

“Who evaluates what projects are eligible for MTEC?”

MTSC outlines the evaluation process requiring a pOTA Project Proposal form. The form must be approved by the USAMRMC Principal Assistant for Acquisition, the Principal Assistant for Research and Technology, and the USAMRMC contracting and legal team.

Need a Faster Option?

There are three ways to get involved with currently available funding.

Incrementally Fund an Existing Initiative

There may be an open initiative for a similar requirement that can be worked collaboratively. Work can be initiated in less than 45 days. Contact MTSC to determine what active initiatives may meet your needs.

Award a Basket Proposal

Determine if there are any proposals in the basket that meet your requirement (60-90 days award time). Contact MTSC to access the current basket list.

Out-of-Cycle Request

Please contact the MTSC Office to discuss out-of-cycle requests.

HOW SOLICITATIONS AND PROJECTS ARE PROCESSED WITH MTEC

The solicitation process ideally will begin with MTEC capturing current market demands as well as industry and research capabilities for any given technology area. These technology and market assessments then can be combined with the sponsor's requirements to develop a robust set of requirements for inclusion in the solicitation document. The sponsors will determine if white papers are needed, or if the process can start directly with soliciting full proposals.

Two key documents are then developed: 1) the Request for Project Proposal (RPP); and 2) the Proposal Preparation Guide (PPG). The RPP will include all required technology objectives, any commercialization plan requirements, and other unique requirements. The RPP also will clearly state the evaluation criteria and adjectival merit rating descriptions so the proposers may understand the

evaluator's significant priorities during the technical review process. The PPG will include all technical, clinical, and cost formatting requirements. This document also will describe the potential award types and the compliance screening process.

USAMRAA will post a special notice to the Federal Business Opportunities website, on behalf of MTEC, which will contain the key Technology Objectives for the research needs. The special notice also will have a link to the MTEC website, where the RPP will be available on the public MTEC website. The PPG will be available to MTEC members on the members-only website.

Communications **are permitted** between government sponsors and proposers during the RPP preparation time, as well as after the RPP is posted, until the deadline for

proposal submission. Thus far, Advanced Technology International (ATI), MTEC's Consortium Manager, has been receiving and responding to proposer-submitted questions via an MTEC inbox. MTEC's Consortium Manager responds to all questions via email, and then posts Frequently Asked Questions to the members-only website for all members to access.

If the sponsor chooses to include a white paper phase, the overall process could allow for approximately 2-3 months to prepare, review and provide feedback to the Offerors. Following the white paper phase, or directly after RPP release if white papers will not be requested, Offerors will submit full proposals. The government sponsor will provide all technical evaluations and determinations. Following the technical evaluations and project determinations, the sponsor will notify ATI regarding project selections. ATI then conducts a full cost analysis. USAMRAA will review the cost summary, conduct an internal Determination and Findings, and once approved, the Agreements Officer will advise ATI that the research projects may be awarded.

Generally, ATI is able to execute this process in approximately 8 months without white papers and expects to take about 10 months when including a white paper phase.

Prototype Other Transactions Agreement (pOTA) is the term commonly used to refer to the 10 U.S.C. § 2371b authority to enter into transactions other than contracts, grants or cooperative agreements. pOTA's for prototype initiatives are acquisition instruments that generally, are not subject to the federal laws and regulations governing procurement (FAR based) contracts. As such, they are not required to comply with the Federal Acquisition Regulation (FAR), its supplements (i.e., DFARS) or laws that are limited in applicability to procurement contracts.

MTEC operates under prototype Other Transaction Agreements (pOTA) between the Government and the Medical Technology Enterprise Consortium (MTEC). The MTEC Consortium Manager (CM), Advanced Technology International (ATI), administers the efforts of the pOTA and issues Research Project Awards to the MTEC members.

The MTEC base agreement includes the terms and conditions from the MTEC Prototype Other Transaction Agreement (pOTA). A sample base agreement is available for review on the MTEC members-only website. Once a base agreement is in place, ATI will issue a Research Project Award under the base agreement for selected projects. Research Project Awards will include the funding, period of performance, and Statement of Work as well as the required project deliverables and milestone payment schedules. If funding is not available from the original sponsor at the time of source selection, that sponsor has the option of placing a source-selection-approved proposal

in an electronic "basket" with the option of funding it within two years of the date of the original solicitation. In this way, the approved projects can be "shopped" to other federal sponsors and/or private sponsors who may have a similar interest in the technology area that is addressed in the approved project. Should a funding sponsor be identified, that sponsor can require both the technical and cost proposals be updated (depending on how long the proposal has been residing in the basket), and then send that proposal forward for a full cost analysis.

Once the projects are awarded, MTEC and ATI will provide monthly invoices and technical deliverables for each project to the MTSC and sponsoring agency for approvals.

Key Sequential Steps in the MTEC Solicitation Process**

1. Conduct Technology and Market Assessments in key research areas as approved by MRMC MTSC (MTEC)
2. Gather Government agency requirements and private sector interests, and develop the draft solicitation (ATI + MRMC MTSC)
3. Review and approve the draft solicitation (MRMC MTSC + potential private sponsors)
4. Publish the solicitation / invite white papers (ATI)
5. Submit white papers (MTEC Members)
6. Review white papers for teaming opportunities; "shop" concepts to potential private sector sponsors to assess interest; prepare comments/recommendations for discussion with MRMC MTSC (MTEC)
7. Evaluate white papers (MRMC MTSC with MTEC participation)
8. Provide white paper feedback to Offerors (ATI)
9. Prepare and submit technical and cost proposals (MTEC Members)
10. Evaluate technical proposals (MRMC MTSC or MRMC MTSC + other funding sponsors; MTEC observes)
11. Conduct full cost analysis on all proposals recommended for funding by the Technical Evaluation Panel (ATI)
12. Proposals updated and reviewed by Sponsor(s) (MTEC Members + MRMC MTSC + other sponsors)
13. Execute source selection decisions (USAMRAA)
14. Award Research Projects (ATI)
15. Shop / Update / Review / Award Basket Projects (MTEC + basket project funding sponsor)

** For those solicitation cycles where a white paper phase will not be included, steps 5 through 8 are omitted, and step 4 invites submission of full proposals.



MEDICAL TECHNOLOGY SUPPORT CENTER (MTSC)



MTSC pOTA PROJECT PROPOSAL FORM

INSTRUCTIONS: This form must be completed by the sponsoring office for each technology/prototype need to be communicated to the MTEC. Submission and approval of a need are the first steps for a Sponsor considering solicitation of white papers or proposals from the MTEC to address a program objective. The purpose of this form is to provide information that allows a sufficient review of needs by the Agreements Officer and Medical Technology Support Center (MTSC) to ensure that it is allowable to pursue them under the MTEC and Other Transactions Authority for Prototype Projects. Sponsors will be notified of the approval status of their request.

This form also provides a mechanism to gather information for and facilitate early discussions between the MTSC and Sponsors considering the use of MTEC to meet their program goals.

Once a technology/prototype need has been approved, the next step is the development of either a Call for White Papers (CWP) or Request for Proposals (RFP). The MTSC will coordinate a call for topics and develop the Annual CWP. Sponsors are responsible for developing any out-of-cycle CWPs. Sponsors are responsible for developing RFPs.

TITLE: [Click here to enter text.](#)

SUBMITTER: [Click here to enter text.](#)

DATE: [Click here to enter a date.](#)

DEFINE THE PROTOTYPE*: [Click here to enter text.](#)

BENEFITS OF USING pOTA FOR THIS PROJECT: [Click here to enter text.](#)

BENEFITS OF USING MTEC (What collaborative efforts to do proposed, private funding and shared market interests, etc.): [Click here to enter text.](#)

DETAILED REQUIREMENTS (Specific criteria against which Offerors propose): [Click here to enter text.](#)

FUNDING PLAN (Include anticipated timeline from solicitation release to award, to include planned funding commitment and obligation; FY\$\$, Army or DHP RDT&E (GDF or CSI), Program Element): [Click here to enter text.](#)

PROJECT PERFORMANCE PLAN (to include Award Strategy, period of performance, phases, follow on contracting actions, etc.): [Click here to enter text.](#)

SPONSOR OFFICE TECHNICAL REPRESENTATIVE (SOTR, the program sponsor is required to staff a project manager to technically oversee the projects): [Click here to enter text.](#)

EVALUATION PLAN (Criteria and plan for whitepaper/proposal technical evaluation that may be done by a source selection team): [Click here to enter text.](#)

END GAME (what's your end goal with your requirement and MTEC? Any follow-on actions?): [Click here to enter text.](#)

*

RESOURCES & TOOLS

Advanced Technology International (ATI)

The Consortium Manager (CM) acting on behalf of MTEC to execute and administer the efforts under the MTEC Other Transaction.

Agreement

Refers to the Other Transaction Agreement between the Government and the Medical Technology Enterprise Consortium in care of (c/o) the Advanced Technology International (ATI).

Agreements Officer (AO)

The USAMRAA warranted Officer authorized to sign the Other Transaction Agreement Initiatives for the Government.

Agreements Officer Representative (AOR)

The individual designated by the Government on a per initiative basis to monitor all technical and programmatic aspects of the specific initiative.

Cash Contribution

A MTEC member organizations financial resources expended to conduct an initiative awarded under the MTEC Other Transaction Agreement. The cash contribution can be derived from MTEC member organization funds or outside sources, or also may come from non-federal contract or grant revenues or from profit or fee on a federal procurement contract. A MTEC member organization's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any subcontractor efforts expended on a MTEC Technology Initiative.

MTEC

The Medical Technology Enterprise Consortium (MTEC), which is made up of consortium members from industry, academia, non-profit organizations and not-for-profit organizations.

Consortium Manager (CM)

The organization acting on behalf of MTEC to execute and administer the efforts under the MTEC Other Transaction Agreement. MTEC entered into a Management Services Agreement with the Advanced Technology International (ATI) to perform this role.

Consortium Member Agreement (CMA)

The agreement governing the rights and obligations of the MTEC member organizations as they relate to the organization and operation of MTEC.

Determinations and Findings (D&F)

A form of written approval by an authorized acquisition official that is required by statute or regulation as a

prerequisite to awarding contract actions such as OTA initiatives.

In Kind Contribution

The MTEC member organization's nonfinancial resources expended by the MTEC member organization to conduct a MTEC project, such as wear and tear on in- place capital assets like machinery or the prorated value of space used for the conduct of a project, and the reasonable fair market value (appropriately prorated) of equipment, materials, and other property used in the conduct of a MTEC project.

Milestone

A scheduled event signifying the completion of a major deliverable or a set of related deliverables. A milestone that has been completed will be approved for payment to the MTEC member organization through the CM. This approved payable milestone will represent a predetermined dollar amount in relation to performance of a particular project under this Agreement.

Nontraditional Defense Contractor

Effective November 25, 2015, nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the Request for Proposal, any contract or subcontract for the Department of Defense that is subject to full coverage under the team members, subcontractors, lower tier vendors, or "intra- company" business units; provided the business unit makes a significant contribution to the prototype initiative (i.e., is a key participant). Examples of what might be considered a significant contribution include supplying new key technology or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance. Nontraditional defense contractors will be required to provide a DUNS number.

MTEC Board of Directors

The MTEC Board of Directors consists of the duly elected representatives from the general membership of the MTEC that governs the consortium.

MTEC Member Organization

The Nontraditional and Traditional Defense Contractors, including small and large businesses, for profit and not for profit entities, multi-member organizations, and Academic Research Institutions that are or become signatories to the Consortium Member Agreement.

MTEC Base Agreement

The agreement between the MTEC CM and the MTEC member entity or a team of MTEC member entities that serves as the baseline agreement for all project funding agreements and flows down applicable terms and

conditions from the Other Transactions Agreement between the government and MTEC.

Other Transactions Agreement (OTA)

The term commonly used to refer to the 10 USC 2371b authority to enter into transactions other than contracts, grants or cooperative agreements. The Department of Defense (DoD) currently has the authority to enter into such transactions that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting

platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. OTAs for prototype initiatives are acquisition instruments that generally are not subject to the federal laws and regulations governing procurement (FAR based) contracts. As such, they are not required to comply with the Federal Acquisition Regulation (FAR), its supplements (i.e., DFARS) or laws that are limited in applicability to procurement contracts.

QUICK REFERENCE GUIDE

Medical Technology Enterprise Consortium (MTEC)

A biomedical technology research and development consortium collaborating under a 10-year renewable Other Transaction Agreement (OTA) with the U.S. Army Medical Research and Materiel Command (USAMRMC).

MTEC Membership

MTEC Members are comprised of a broad and diverse membership that includes representatives from large business, small businesses, “non-traditional” government contractors, academic research institutions and not-for-profit organizations. Their capabilities are listed on the web site under the “Membership” tab. Organizations can join per instructions provided on the website, www.mtec-sc.org.

Public Web Site

www.mtec-sc.org

Please visit the public web site for additional information, to view or download documents, and join the consortium with step-by-step instructions.

Collaboration

MTEC is a consortium made up of world-class experts within the six technology areas. MTEC facilitates communication for increased collaboration as well as the formation of innovative partnerships. Collaboration is encouraged through the MTEC solicitation process up to the proposal submission due date and after source selection.

Technology Collaboration Events

Opportunity to provide industry/academia with greater visibility of program planning and roadmaps. Attend to network, collaborate with government/industry/academia and to discuss current technology gaps as well as future requirements.

Basket Provision

Source selection – approved but unfunded proposals are placed in the electronic basket and may be awarded anytime within two (2) years from the proposal submission close date (SOW and pricing updates may be necessary).

Statement of Work (SOW)

SOWs awarded through MTEC include research and development up to prototype demonstration. Government representatives may choose to accept the SOW as proposed by submitting a white paper.

Proposals

MTEC members make a business decision to submit full proposals following the requirements listed in the Proposal Preparation Guide (PPG).

Funding

Initiatives can be funded any time after an acceptable proposal is received and evaluated.

Other Transaction Initiative Awards

Typically made within 60-90 days from receipt of acceptable Government format SOW with funding.

Initiative Execution

The sponsoring/funding agency’s Agreement Officer Representative (AOR) is responsible for initiative oversight, management and approving completion of milestones.