



**MTEC**  
Medical Technology  
Enterprise Consortium

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Newsletter**

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## MTEC Solicitation Process

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My name is Polly Graham, and I am the MTEC Program Manager. At the 2nd Annual Membership meeting, I provided an overview of the MTEC Solicitation process to describe what MTEC members may expect when submitting a response to a research opportunity. The following narrative summarizes the Annual meeting presentation, and adds in

a few additional areas that have developed since the members convened on March 30th, 2017.

The specific statutory language which allows for medical technology technologies to be developed under Other Transaction Authority's (OTA's) is included in Section 815 of the 2016 National Defense Authorization Act with the inclusion of "enhancing the mission effectiveness of military personnel". Prior to this language, prototype projects were primarily authorized for DOD weapon systems, platforms and components. There are two "must have" pre-requisites for a potential sponsor to leverage the OT acquisition vehicle: 1) the requirement the sponsor desires to solicit must fall within the six key technology domains of the OT agreement, and 2) the requirement must meet the definition of a prototype project. The MTEC scope includes six key technology domains further defined on the [MTEC website](#).

### Prototype Projects

The research project requirement must meet the definition of a prototype project. The DoD publishes an OT Guide<sup>1</sup> to provide some direction for the boundaries an OT award may operate within. While there is no statutory definition for a prototype, there are guidelines provided. Projects may include: 1) Systems or Subsystems; 2) Components or Materials; 3) Methodology or Processes; 4) Technology. A prototype project may be a preliminary pilot, test, evaluation, demonstration or agile development activity. A prototype project may be used to evaluate the feasibility of a particular: Technology; Process; Concept; End item; Effect, or other discrete feature. Projects may involve: Proof of concept; Pilot; Novel application of a commercial technology for a defense application; a creation, design, development, demonstration of technical or operational utility as related to

a prototype. Prototype project quantities are limited to the amount needed to prove technical or manufacturing feasibility or military utility. For medical R&D a prototype, examples may include a clinical trial to establish drug efficacy; designing and prototyping a medical device; developing a manufacturing procedure; establishing quality control standards for a manufacturing process. Prototype projects are not: basic research, services, maintenance, production (including low rate initial production) and construction. MTEC provides further recommendations that in general it is recommended that projects be: 1) at a stage to conduct studies required for a regulatory filing to the Food and Drug Administration (FDA); 2) prototype design is near final; 3) proof-of-concept has been demonstrated in a large animal model (if applicable); 4) the project team includes a committed industrial partner; and 5) the starting Technology Readiness Level (TRL) is within the 4 – 6 range, typically. TRL definitions as they apply to military medical technology are posted on the MTEC website. If there are any questions regarding where the prototype line is drawn, the Government's Agreements Officer will make that determination.

### Nontraditional Defense Contractors

One of the following four conditions are required in a proposal submission for a member to receive an award through the OT acquisition vehicle:

- (A) There is at least one nontraditional defense contractor (NDC) participating to a significant extent in the prototype project.
- (B) All significant participants in the transaction other than the Federal Government are small businesses or NDCs.
- (C) At least one third of the total cost of the prototype project is to be paid out of funds provided by parties to the transaction other than the Federal Government. (Cost share)
- (D) The senior procurement executive for the agency determines in writing that exceptional circumstances exist. (This is highly uncommon.)

An NDC is a business unit that has not, for a period of at least one year prior to the issue date of the Request for Project Proposals, entered into or performed on: any contract or sub-contract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the

Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section. If you are not sure if your organization qualifies as a NDC, we recommend verifying with your Accounting and Finance group.

The NDC does not have to be the MTEC member submitting the proposal. The NDC may be any member of a proposed team (the prime level, team members, subcontractors, lower tier vendors, or “intra-company” business units). The critical point is that the NDC is making a significant contribution to the prototype initiative (i.e., is a key participant).

The DOD Other Transaction Guide does not include a statutory definition of significant participation. According to the DoD OT Guide, rationale to justify a significant contribution may include:

- Supplying a new key technology or products,
- Accomplishing a significant amount of the effort,
- Causing a material reduction in cost or schedule, and/or
- A contribution that will cause an increase in performance.

If a proposal includes a nontraditional contractor then the proposal submission will be required to include Warranties and Representations. This section will provide a description/rationale of the significant participation for a proposed nontraditional team member. The Warranties and Representations are used along with statement of work and proposal to ensure the project meets OTA statutory authority, specifically addressing the whether the criteria regarding non-traditional participation to a significant extent has been met. Proposers need to use this venue for stating their case regarding the significance of the contributions of partner NDC are significant. In all cases, more detail and specificity is better than less.

## Cost Share

If a proposing team does not include significant participation of a nontraditional defense contractor, a project can still be awarded under the OTA, if 1/3 of the total project cost is provided as cost share. Cost share includes any project or program costs that not borne by the Federal Government. Offerors must explain how they derived the cost share value.

Types of Cost Share may include:

- Cash or outlays of funds to perform the research project tasks. Cash includes labor, materials, and relevant subcontractor efforts. Sources include new Independent Research & Development (IR&D) funds, profit or fee from another contract, overhead or capital equipment expense pool.
- In-Kind: Reasonable value of in-place equipment, materials or other property used in performance of the Research Project Award.

All cost share proposed must be part of the project scope and would otherwise be an allowable project cost. All proposed cost share will be subject to review to cost reasonableness review and must be concurrent with the proposed period of performance. Proposals that contain cost share cannot include fee and may only be proposed on cost type agreements. All project awardees will be required to provide financial reporting with appropriate visibility into expenditures for both Government funds and cost share funds.

## Intellectual Property (IP)

MTEC’s Intellectual Property (IP) Guidance document is located on the MTEC website. IP rights for MTEC research project awards are defined in the terms of an awardee’s Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the individual performers during the entire award period. Each Offeror will select either the MTEC Additional Assessment Fee or the Royalty Agreement (available on the MTEC members only website), not both, and submit a signed copy with the proposal.

Per Section 3.5.1, Royalty Payments, of the Consortium Member Agreement, Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the research project award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

Per Section 3.5.2, Additional Research Project Award Assessment, of the Consortium Member Agreement, In lieu of providing the royalty payment described in Section 3.5.1 above, members receiving research project awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4. This additional assessment applies to all research project awards, whether the award is Government funded or privately funded.

Payments shall be due no later than 90 days after the research project award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.

## Solicitation Development

The solicitation process will ideally begin with MTEC capturing current market demands as well as industry and research capabilities for any given technology area. These technology and market assessments combined with the sponsors requirements may then be rolled together to develop a robust set of requirements to develop the solicitation document. The sponsors will determine if whitepapers are needed, or if the process can start directly with soliciting full proposals. A Request for Project Information (RPI) is an important way for sponsors to determine current capabilities within any given technology area. RPI submissions will be used to develop upcoming research project solicitations. Project information papers will be reviewed by the Sponsor and used in a manner that shapes a future MTEC solicitation that requests full project proposals. The results of the project information paper submission will serve as a means to assess the development landscape and potentially focus the proposal effort that will follow. Project submissions may not contain proprietary information, and are accepted from both MTEC members and non-members.

## Solicitation Announcement

MTEC will email all members and the Government will post a Special Notice to the Fed Biz Opps website which will contain the key Technology Objectives for the research needs. The email and special notice will have a link to the MTEC website where the Request for Project Proposal (RPP) will be posted. Communications are permitted between government sponsors

and proposers, right up until the submission deadline. Thus far, MTEC has been receiving and responding to submitted questions via the MTEC inbox (mtec-sc@ati.org). All Frequently Asked Questions (FAQs) are posted to the members-only website for all members to access.

## MTEC Small Projects

MTEC Small Projects fall within the following description:

- Proposals must have an overarching objective that demonstrates significant technology advancement within a 12-month period of performance.
- Overall costs for an award may range from \$150,000 – \$300,000.

These proposal submissions will follow a 5-page template as described in the Small Project Guide (SPG), accessible on the members-only website. All other NDC and assessment fee requirements remain the same as with larger projects.

## Commercial Solutions Opening

MTEC may choose to use a streamlined, interactive approach for acquisitions called the Commercial Solutions Opening. Due to the nature of the requirements set forth in certain RPPs, this streamlined, interactive approach is often a better means to highlight company methodologies and skills that should allow the Government to gain a fuller appreciation of the work required to be completed. It provides more freedom and initiative to the Offeror to describe how the Offeror would approach and solve such an action. The full description of this contracting approach will be posted to the MTEC website, but the following sections describe the formats and requirements of the contract methodology.

The Commercial Solutions Opening is a streamlined, interactive approach that follows three steps:

1. Solution Brief Content - The Offeror will submit a Solution Brief, which is a “pseudo white paper”. The Solution Brief is limited to five pages and evaluated by the Sponsor. Offerors may be invited into Step 2. Offerors who are not invited to proceed into Step 2 will be provided feedback.
2. Solution In-Person Briefing - In Step 2, the Offeror(s) will provide a “pitch” of the proposed project during an in-person meeting. The pitch should be restricted to a maximum of 1 hour with a total time of 2 hours to include questions from the Government and discussion. Offerors who are not selected for award will be provided feedback.
3. Full Proposal - The Offeror’s invited to submit a full proposal are encouraged to contact the MTEC and/or Government with any questions so that all aspects are clearly understood by both parties.

The full proposal will be required to include the following:

- Full technical proposal submission
- Full cost proposal submission
- Warranties and Representation

## Request for Project Proposal

The Request for Project Proposal serves as the Request for

Proposal and will include:

- All required technology objectives
- Commercialization plan requirements
- Any unique requirements
- The evaluation criteria and adjectival merit rating descriptions so the Offerors may understand the evaluator’s significant priorities

Project proposals will only be accepted from MTEC members in good standing. The Proposal Preparation Guide (PPG) will be available to MTEC members on the members-only website and will include all technical, and cost formatting requirements. The PPG will also describe the potential award types and the compliance screening process.

## Research Project Awards

The Base Agreement will include all terms and conditions from MTEC Other Transaction Agreement. Sample base agreements are currently available for review on the MTEC members-only website. All projects approved for funding will have base agreements executed. Task Order Awards are added to each Base Agreement and will include the Statement of Work as well as the Deliverables and Milestone payment schedules.

## Basket Provision

The Basket provision is unique in that it allows projects that meet the required technical criteria, but may not have received funding yet, to reside in a holding place (called a “basket”) for a period of 2 years from initial solicitation release. 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.

Should funds subsequently become available, the original proposal may receive funding by:

- The same funding sponsor at a later time when additional funds become available (up to 2 years from original solicitation);
- A different federal funding sponsor;
- A private sector funding sponsor (philanthropic, foundation, venture, etc.)

In this way, the approved projects may be shopped to other federal sponsors and/or private sponsors.

## Annual Cycle

MTEC future goals include the ability to gather all sponsors requirements into a single comprehensive annual cycle, this will allow for economies of scale. Ideally, MTEC will be able to align the timeline for a given fiscal year so the sponsors will know their requirements to have them embedded in the FY project call the year prior to when needing the research initiated.

MTEC encourages questions and discussion with potential Offerors about our funding opportunities, so please contact me at polly.graham@ati.org with any inquiries or concerns regarding the MTEC solicitation process.

# Active and Upcoming Funding Opportunities

Dr. Lauren Palestrini, *Director of Research Programs*



My name is Lauren Palestrini, PhD, and I am the Director of Research at MTEC. At the Annual MTEC membership meeting, I provided an overview of the active and upcoming funding opportunities currently planned for 2017. MTEC's funding opportunities are intended to support the advancement of projects that are based on logical reasoning and sound scientific rationale. They should not be exploratory in nature and do require a foundation of preliminary data. MTEC-sponsored projects must result in "prototype" research deliverables that ultimately transition medical solutions to practice. These projects should be at a minimum of Technology Readiness Level (TRL) 4 – at a stage ready to conduct studies required for a regulatory filing to the Food and Drug Administration (FDA), which suggests that the prototype design is near frozen, proof-of-concept has been demonstrated in a large animal model (if applicable), and a committed industrial partner is involved. For TRL descriptions: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>

MTEC encourages discussion with Potential Offerors about our funding opportunities, so please contact me at [Lauren.Palestrini@officer.mtec-sc.org](mailto:Lauren.Palestrini@officer.mtec-sc.org) if you would like to discuss

whether your technology aligns with the intent of a particular opportunity. This interaction will hopefully provide a better understanding of the metrics for the technology areas to be funded, thereby resulting in a higher quality proposal. In some cases, we will also schedule virtual information sessions, which will provide opportunities for direct communication between potential Offerors and the Government technical or programmatic leads of particular funding opportunities.

In addition to MTEC's topic-specific funding opportunities, we will be releasing a Broad Topic Request for Project Information in May 2017. The U.S. Government specifically requested that MTEC garner project information papers so that these can be used to influence their Fiscal Year 2018 decisions for funding and selection of project focus areas. This is a critical opportunity for both MTEC members and non-members to showcase prototype technologies that could be used as a basis for upcoming Requests for Project Proposals (RPPs). The Government is interested in receiving papers related to all of their technology domains (described below). In addition, the Government has provided specific areas of interest within their technology domains that seem to have a higher likelihood of funding in Fiscal Year 2018 due to current DHA or Army strategic priorities.

Table 1 summarizes MTEC's active and upcoming funding opportunities, as of March 31, 2017. A more in-depth description of each opportunity is included following Table 1.

**Table 1.** MTEC's active and upcoming funding opportunities.

Topic	Request for Project Information (RPI)	White Paper	Full Proposal	Estimated Release Date
1. Combating Antibiotic-Resistant Bacteria	X			Active
2. Extracorporeal Life Support Device			X	Active
3. Permanent Vascular Repair			X	Active
4. Prototype Acceleration Award			X	Late April 2017
5. Operational Architectures to Support Military Medical Training Simulations			X	Late April 2017
6. Cellular Therapies for the Treatment of Hemorrhagic Shock			X	May 2017
7. Broad Topic	X			May 2017
8. Regenerative Medicine		X		Summer 2017
9. Systems Biology Approach to Infectious Disease		X		TBD

## 1. Combating Antibiotic-Resistant Bacteria (CARB)

### Request for Project Information (RPI)

Due: May 12, 2017

The use of antibiotics saves millions of lives each year around the world. Unfortunately indiscriminate use and lack of compliance with treatment guidelines have led to conditions for accumulation of mutations in bacteria that have caused drug resistance, resulting in a significant decrease in the number of available drugs effective to treat both rare and common bacterial infections. The rise in antibiotic resistance threatens various aspects of life, including both human and animal health, the agriculture industry, the economy, and the treatment of post-surgical infection from elective and life-saving medical procedures. Therefore, there is a critical need to develop novel antibiotics, other therapeutics, and, vaccines to combat infection by antibiotic-resistant bacteria and improve medical surveillance and diagnostic tests for the identification and characterization of antibiotic-resistant bacteria. Advancement in these areas will hopefully make a major impact by strengthening national and international healthcare for humans and animals, public health, agriculture practices, food safety, and research, development and manufacturing.

### TECHNOLOGY FOCUS AREAS

This MTEC RPI is generally focused on the development of technologies (i.e., biosurveillance, diagnostic tests, antibiotics, vaccines, and other therapeutics) that combat antibiotic-resistance. Project information papers will be reviewed by the Sponsor and used in a manner that shapes a future MTEC solicitation that requests full project proposals. The results of the project information paper submission will serve as a means to assess the development landscape and potentially focus the proposal effort that will follow. The use of interdisciplinary approaches including systems biology and synthetic biology to advance prototype development efforts to combat antibiotic resistance are encouraged but not required. Examples of specific areas of interest include, but are not limited to:

- Disease surveillance to detect and control antibiotic-resistance
  - o National and global approaches to coordinate and integrate data across established medical surveillance systems, including laboratory response networks
  - o Robust laboratory platforms for testing resistance and genetic characterization of antibiotic-resistant bacteria
  - o Improved methods or approaches to monitor and control the spread of antibiotic-resistant bacteria in theaters of operation

- o Technologies or approaches tailored to leverage overseas laboratory assets and capabilities for medical surveillance of antibiotic-resistant bacteria
- o Enhance ongoing U.S. Department of Defense efforts to maintain a repository of resistant bacteria strains by developing novel advances in specimen collection, storage, and data analysis
- o Agile new technical or logistical approaches to augment the whole-genome sequencing methods of existing U.S. Department of Defense surveillance efforts, (e.g., the Multidrug-resistant organism Repository and Surveillance Network at Walter Reed Army Institute of Research and the Global Emerging Infectious Disease Surveillance and Response programs)

- Improved, affordable diagnostics that rapidly detect and/or characterize antibiotic-resistant bacteria

- o Point-of-need, rapid diagnostic methods that rapidly differentiate between bacterial and viral infections
- o Point-of-need, rapid diagnostic tests that identify patterns and/or mechanisms of antibiotic resistance to limit the use of antibiotics
- o Utilization of genetic material (e.g., whole genome sequencing or metagenomics) and/or bioinformatics to develop new diagnostics tests with an open-system architecture compatible with the widest possible range of military-relevant settings from austere point-of-use and mobile, deployed hospitals in theaters of operation through clinical use in fixed-facility military and civilian hospitals worldwide
- o Novel, culture-based methods that profile and characterize antibiotic resistance

- Development of novel antibiotic drugs or other non-traditional therapeutics for the treatment of infections caused by antibiotic-resistant bacteria

- o Novel antibiotics or therapeutic approaches include those that combat carbapenem resistance that is based on impermeability, efflux pump mechanisms, overexpression of broad-spectrum  $\beta$ -lactamases, and/or expression of  $\beta$ -lactamases and other carbapenemase enzymes

- Development of novel vaccines to prevent the spread of resistant bacteria

- Advancement of innovative therapeutic approaches to combat or circumvent antibiotic-resistance

Efforts to reduce the incidence of drug-resistant infections due to nearly a dozen types of bacteria are of particular interest, however, the submission of projects that target other drug-resistant bacteria with military relevance are also encouraged. For more information please see: <https://mtec-sc.org/wp-content/>

Project information papers must be submitted by 11:59 pm on May 12, 2017 via email to [mtec-sc@ati.org](mailto:mtec-sc@ati.org). Project information submissions should describe projects that are based on logical reasoning and sound scientific rationale. They should not be exploratory in nature and do require a foundation of preliminary data. Please note that MTEC-sponsored projects must result in “prototype” research deliverables that transition medical solutions to industry. Projects must be at a minimum of TRL 4.

For TRL descriptions: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>

Project information papers may be submitted by both MTEC members and non-members. Please note that MTEC membership is required for the submission of a full proposal in response to a future MTEC Request for Project Proposals (RPPs) for CARB. To join MTEC, please visit <http://mtec-sc.org/how-to-join/> The CARB RPP is expected to be released in late summer/early fall 2017.

## 2. Extracorporeal Life Support (ECLS) Device Request for Project Proposals (RPP) Due: April 28, 2017

The U.S. Army Medical Research and Materiel Command (USAMRMC) envisions potential future battlefield scenarios of prolonged field care, which will result in the presentation of critically ill patients with acute lung injury (ALI) and acute kidney injury (AKI) far-forward on the battlefield. The response to this scenario will include deploying lightweight, rugged, user-friendly extracorporeal life support (ECLS) devices to Field Hospitals (Role of Care 3) and to transport patients during fixed wing medical evacuation. MTEC’s RPP requests development concept papers to build ECLS devices that integrate the two functions of respiratory and renal support (including extracorporeal blood purification) into one platform. These devices will replace all or part of lung function for patients with acute respiratory distress syndrome or other types of pulmonary failure, and/or kidney function for patients with AKI. This combination device increases its practicality on the battlefield, where every ounce of weight and cubic foot of space is coveted. The ultimate objective is to produce a product that could reach FDA approval and improve battlefield trauma care and evacuation.

This MTEC ECLS Project will be executed in three phases that proceeds from development concept papers, to a down selected set of schematics, and finally to a prototype build that would undergo testing in an in vitro or in vivo model by a third party, military laboratory.

- **PHASE 1:** The first phase of the project is the submission of a development concept paper (proposal) that describes the prototype design, timeline for prototype

development, anticipated regulatory pathway, potential commercialization approach(es), and projected costs.

- **PHASE 2:** MTEC will provide \$50k to each awardee selected in Phase 1 to complete detailed engineering design ‘schematics’ that demonstrate an understanding of the request to develop a single ECLS device that can be used to treat both AKI and Acute Lung Injury (ALI). Awardees will have 45 days to prepare and submit their schematics. An outside panel of biomedical engineers and clinical specialists will evaluate the schematics for feasibility and completeness to address the intended clinical and operational goals. The MTEC will then select no more than 3 sets of schematics to progress to Phase III of the project. If desired, the Department of Defense (DOD) or MTEC will provide feedback on the schematics to be incorporated during Phase 3 of the project. If requested by the Offeror(s), the Department of Defense (DOD) or MTEC will provide feedback to the Offerors(s) on the rejected schematic(s).
- **PHASE 3:** The MTEC will provide approximately \$0.5 million dollars for the construction of up to 3 prototypes selected in Phase 2 (approximately \$170k per prototype). Though the prototypes may not be finalized in terms of form, fit, and function, they should provide an indication of their capability to meet clinical and operational requirements as listed hereafter. The awardees will have 180 days to construct these prototypes. Upon completion, each prototype will participate in a performance challenge either in vitro or in vivo conducted by a DOD intramural lab. The three awardees will be expected to attend the challenge to setup, operate, and breakdown their prototypes. The evaluation criteria for, and description of, the challenge will be provided as soon as it is available.

The intent of the Government is to develop and procure such an ECLS device for use within its deployed medical forces.

Development Concept Papers in PHASE I must address the following essential characteristics for the combined ECLS device:

1. Have a reasonable regulatory approach toward Food and Drug Administration (FDA) market authorized device for use in controlling CO<sub>2</sub> exchange in critically ill patients with ARDS and perform hemofiltration, hemodialysis and/or ultrafiltration in critically ill patients with AKI. The development concept papers must describe the methodology for the proposed approach and why they believe it will be successful.
2. Capable of various flow rates (150ml/min – 500 ml/min) and accommodate the use of a standard dialysis catheters (at least 13.5 F) and varying insertion lengths (15 and 24 cm).
3. Deliver a choice of therapies (including, but not limited to, continuous RRT and partial lung support) with the option of combined AKI and ARDS therapies being con-

ducted simultaneously.

4. Lightweight (less than 45lbs) and rugged for battlefield use (withstand temperature extremes (hot & cold), drops/vibration, dust/rain/humidity as outlined in MIL-STD-810G). The device with its associated fluids and connections should be mountable onto a standard NATO litter system used to transport patients.
5. Operate on AC and DC power (11-28 Volt DC, 100/220 Volt AC 50/60Hz).
6. Operate using a rechargeable battery power source (battery life of a minimum of 8 hours when fully charged/hot swappable; objective is 12-24 hours).
7. User-friendly during initiation and maintenance of therapy, where target operators are Physician Assistants and/or General Physicians. Device should also be easy to maintain with the fielded equipment and the skills of biomedical equipment technician.
8. Should not require a large logistical footprint to use (supplies, fluids, minimal O2, etc.).
9. Capable of passing airworthiness requirements for fixed and rotary wing medical evacuation. Airworthiness testing is conducted by the US Army Aeromedical Research Laboratory at Fort Rucker, AL.
10. Easy to transport and secure in place upon aircraft and in a medical treatment facility.
11. Patient data generated from the device should be transferable via either a tethered or wireless means to computer or hand held devices and should follow Health Level 7-related standards as defined by the DoD Healthcare Management System Modernization.
12. A description of lifecycle considerations should be included in the Development Concept Paper, such as, additional research and development costs, FDA requirements, ease of production, environmental exposure, versatility, modularity, maximum utilization of off-the-shelf components, initial acquisition cost, maintenance and repair requirements, operating and support costs, training requirements, technical support and recycle/disposal.

**Caveat:** Although the critical specifications of the combined renal and lung support prototype device are outlined above, we encourage you to submit even if you cannot currently meet all the specifications within this time frame. Though we are hopeful that all parameters can be met in a first time run, it may become apparent that we have overestimated the ability of consortium members to respond in full. We would potentially consider lesser responses based upon what parameters were met and the approach to meeting the others over time. However, it is expected that an Offeror's approach to the prototype will demonstrate how to satisfy all of the critical

specifications at some point in time.

Development concept papers are due April 28, 2017 by 12:00pm EDT via email to [mtec-sc@ati.org](mailto:mtec-sc@ati.org). MTEC membership is required for the submission of a development concept paper in response to this RPP. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>

### *3. Permanent Vascular Repair Request for Project Proposals (RPP) Due: May 10, 2017*

This RPP is focused on Permanent Vascular Repair (PVR) – the development of products that can serve as permanent arterial and/or venous grafts for reconstruction and repair of traumatic injuries.

Extremity trauma is one of the most common battlefield injuries. Through advances in early field intervention and resuscitation, such injuries have become increasingly survivable. Despite progress, extremity injuries can be devastating with complex injuries to the vasculature, bone, connective tissues, muscle, and nerves. Approximately 50% of patients with complex extremity injuries have severely impaired limb function. These injuries are commonly associated with long term complications and poor functional recovery. In fact, at the same age, military personnel have doubled the rate of post-traumatic osteoarthritis compared to individuals in the civilian population. Severe extremity trauma with initial limb salvage leads to delayed amputation in approximately 14% of patients, typically following many months of repeated surgeries and attempts at rehabilitation. Only 20% of wounded military personnel who experience severe extremity trauma are ultimately able to return to service.

The field of reconstructive surgery following extremity trauma is largely characterized at present by the need for multiple, staged reconstructive procedures, and the use of often scarce autologous tissue with frequently suboptimal results, and low rates of return to duty. In many cases, the best that can be hoped for is to prepare the damaged limb for prosthetic attachment. Optimal solutions would not only provide more durable repairs, but reduce the need autologous tissue and number of surgical procedures.

This RPP seeks proposals from entities developing products that can serve as permanent arterial and/or venous grafts for reconstruction and repair of traumatic injuries. It is recognized that products intended for other indications could be repurposed. MTEC is seeking products near FDA approval or in development beyond Phase 1 or feasibility clinical trials (at a minimum of TRL 5, for TRL descriptions: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>). Prototypes must demonstrate the potential to fill an identified capability gap in permanent vascular repair beginning at forward echelons of medical care. At a minimum, it is expected that interested parties will either manufacture or be able to procure products with sufficient clinical safety data to support proceeding into clinical

trials. Proposals must aim to demonstrate significant technology advancement toward regulatory approval for a vascular reconstruction indication. Types of proposed activities that are of interest include, but are not limited to: regulatory filings, manufacturing, clinical trials in trauma patients or related surrogate populations, and data needed for regulatory approval.

The initial period of performance will be 12 months, with option years to pursue follow-on clinical prototype maturation. Overall costs for an initial award may range from \$350,000-\$650,000. Initial proposed efforts must include FDA engagement on clinical and manufacturing, with follow-on efforts to be determined based on feedback received (e.g., clinical trials in trauma patients or related surrogate populations). The initial award is not intended to support basic research or research involving human subjects, but follow-on awards may require clinical trials.

Full proposals are due May 10, 2017 by 12:00pm EDT via email to [mtec-sc@ati.org](mailto:mtec-sc@ati.org). MTEC membership is required for the submission of a proposal in response to this RPP. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>.

#### 4. Prototype Acceleration Award

##### Request for Project Proposals (RPP)

Expected Release Date: Late April 2017

The United States Army Medical Research and Materiel Command (USAMRMC) is establishing the Prototype Acceleration Award mechanism to be offered exclusively to MTEC members. The Prototype Acceleration Award mechanism focuses on advancing novel prototype technologies into the next major stage of development/milestone dependent upon their current maturity. Examples of the next major stage of development/milestone include, but are not limited to: late animal testing and regulatory filing, manufacturing, next clinical trial, regulatory approval, etc. Proposed efforts must be based on logical reasoning and sound scientific rationale. The Prototype Acceleration Award mechanism is not intended to support basic research or research involving human subjects. Preliminary data is required. Projects must eventually result in deliverables that transition medical solutions to industry.

To be eligible, prototypes must fulfill a recognized research need/capability gap as described below and must be (at a minimum) at TRL 4 - for TRL descriptions: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>. Proposals must have an overarching objective that demonstrates significant advancement in the readiness of the technology within a 12 month period of performance. Overall costs for an award (direct and indirect) may range from \$150,000 - \$300,000.

The U.S. Government currently has approximately \$2 million in funding available for this effort.

Current technical focus areas for the Prototype Acceleration Award mechanism include:

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

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

- Regenerative Medicine

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

#### 5. Operational Architectures to Support Military Medical Training Simulations

##### Request for Project Proposals (RPP)

Estimated Release Date: Late April 2017

This RPP is focused on Operational Architectures (system and technical) to Support Military Medical Training Simulations – the development of architecture models that will be used to guide the construction of integrated simulations and training modules for the Joint Evacuation and Transport Simulation (JETS) systems.

The military has a need to develop architecture models that will be used to guide the construction of integrated simulations and training modules for the JETS systems. The prototype Program/Systems architecture must be aligned with the most current Joint Capabilities Integration and Development System (JCIDS)

manual, Department of Defense Architecture Framework (DoDAF) and DoDAF Products Matrix. The prototype technical architectures will be used to guide the construction of an integrated System of Systems (SoS) training platform for DoD Global/Joint Patient Movement (GPM/JPM) training purposes.

The JETS SoS must support many access methods (e.g., computer, smart phone, hard-stand training centers, tablet, etc.). The intent is to integrate Training Centers with each other, and with Point of Demand (POD) training, within a medical Synthetic Training Environment (mSTE) that is connected through a DoD training portal. This enables access to training through integrated Live, Virtual, Constructive, Gaming (LVCG) training modalities, that provides value to the User and the DoD. The end-state is a platform delivering effective and integrated Training Center and POD capabilities. Together, they will (i) provide customized training to the User's when, where, and how they need to conduct training, on a global 24/7/365 basis, and (ii) address the training needs of the individual, team, squad, unit, and multi-units (e.g., mission planning, mission rehearsal, en-route care, patient movement control, logistics, patient hand-off, etc.). The system will provide training of GPM/JPM tasks (e.g., medic, corpsman, flight medic, Aeromedical nurse, Patient Control Cell member, etc.) by flowing simulated patient(s) through the replicated chain of evacuation from Role 1 to Role 4, and the ability to engage in training events with other Government agencies and Coalition Partners.

The development of the operational architectures will be structured into five Phases of work consisting of a base effort followed by four options to continue the system's maturation. The base effort and the first option are the basis for the upcoming award but we want to provide the full spectrum of work that may be follow on and therefore of interest to proposers.

- **Phase 1:** Develop prototype knowledge products that provide the Program/System Architecture views for the Joint Evacuation and Transport Simulation (JETS) Capabilities Development Document (CDD). Deliverables include integrated and synchronized System Architecture artifacts defined as required for a Capabilities Development Document (CDD), which include (but may not be limited to): AV-1; AV-2; OV-1; OV-2; OV-4; OV-5A; CV-2; CV-3; CV-6; SV-1; SV-2; SV-3; SV-7; SV-8.
- **Phase 2:** Deliverables include a prototype integrated and synchronized Operational and Technical Architectures for JETS Phase 1, which enables JETS Phase 2-4 capabilities and enables a positive Milestone B decision. Identification of current systems and development of integrated operational, system, and capability views into a functional operational architectural context.
- **Phase 3:** Deliverables include a prototype Capabilities Production Document (CPD) for JETS Phase 1, with aligned required and supporting documents according to the current JCIDS Manual, DoDAF and DoDAF Products Matrix.
- **Phase 4:** Deliverables include a prototype integrated

and synchronized Operational and Technical Architectures for JETS Phase 2, which enables JETS Phase 3-4 capabilities, and enables a positive Milestone B decision. Provide improvement to current capabilities to incorporate more interchange, interaction, and access modalities.

- **Phase 5:** Deliverables include a prototype Capabilities Production Document (CPD) for JETS Phase 2, with required aligned and supporting documents according to the current JCIDS manual and DoDAF. Increase through plug-ins the advent of new applications or technologies that enhance the overall breadth and depth of training. The five Phases of work will progress in a sequential manner over several years. The period of performance of each Phase is expected to range between 6-12 months.

The Government intends to solicit MTEC members/teams with expertise in the development of operational architectures and providing Information Technology solutions for military and/or health care systems. Proposals will be evaluated based on the technical and managerial soundness of the methodological approach to satisfy the documentation needs, and the Offeror's relevant past performance experience. This upcoming solicitation is the first Phase toward building a fully integrated training platform that will enhance warrior medic support with timely interjection of training specific to needs and the ability to continually educate and maintain professional skills. The U.S. Government currently has available approximately \$2 million for Fiscal Year 2017 and has planned additional dollars as necessary for the continuation of this project through all five phases.

## 6. Cellular Therapies for the Treatment of Hemorrhagic Shock (CTTHS)

*Request for Project Proposals (RPP)*

*Estimated Release Date: May 2017*

Trauma is the leading cause of death for individuals between the ages of 1–44 and the third leading cause of death in the U.S. overall, accounting for approximately 180,000 fatalities each year, of which up to 20% are potentially preventable. Seventy-five percent of traumatic deaths occur during the first 3 days after injury, and are primarily due to uncontrolled hemorrhage and traumatic brain injury (TBI). After 3 days, the remaining 25% of deaths accumulate at a low but steady rate and result from a complex interplay of inflammation, vascular compromise and dysfunctional coagulation associated with the initial tissue injury, shock and resuscitation. Clinical manifestations include acute kidney injury (AKI), acute respiratory distress syndrome (ARDS), venous thromboembolic disease (VTE), and MOF, and cerebral edema and ongoing cellular death after TBI. Current treatments for these inflammatory conditions are supportive and efficacy trials for new interventions have all failed. Consistent and

robust evidence supports the positive impact of rapid treatment for severe injuries including restoration of perfusion, oxygen delivery and wound coverage, however achieving rapid evacuation to damage control and definitive surgical treatment may prove impossible in future combat theaters. As a result the military requires therapies which can mitigate the potential impacts of severe injuries and delays to surgical interventions in order to prevent mortality from combat wounds.

Pre-clinical, and some limited clinical, data support the hypothesis that cellular therapies may be of use in mitigating the sequelae of severe injury. Numerous studies have documented improved organ function, reduced secondary organ (e.g. lung, kidney) injuries and improved survival with cellular therapy. In response to these and other findings of potential utility for cellular therapies, industry and academic institutions have developed prototype cellular therapy products which require further assessment in well-designed clinical studies to refine and advance the development of this prototype trauma therapeutics.

This RPP is focused on cell therapies that can be used to treat the inflammatory complications that arise after traumatic injury. (This request is not looking for cell therapies that can be used to achieve hemostasis.) The intent of this action is to support a Phase II clinical study to evaluate the safety and efficacy of cellular therapy in the treatment of hemorrhagic shock in severely injured patients. Therefore, the products being brought forth must be ready to enter the clinical stage within a short window and have all of the regulatory requirements for IND prepared for submission as a minimum. The focus of this effort is the actual clinical study and not the manufacturing of product, albeit the product must be made available under GMP standards to move forward. If manufacturing is required, that must be stated and the cost identified accordingly.

### Goals:

1. Produce clinical grade prototype cellular therapy agent in sufficient quantity to conduct a clinical assessment in a trauma patient population. Assessment needs to account for relevant regulations for prototypes to be administered to humans and ensure documentation of appropriate quality and process controls. The proposer will come forth with the appropriate protocol and surgical procedure that will serve as the basis for evaluation and supports labeling as a hemorrhagic shock therapeutic.
2. Develop a clinical study to assess mechanistic and outcome based patient responses to administration of cellular therapies with appropriate controls for administration of cellular therapy (placebo control, potential confounding treatments (e.g. inclusion/exclusion, hemostasis and blood transfusion) and outcomes assessment (blinding as to treatment). Relevant outcomes may include inflammation and/inflammatory complications, organ function/injury scores, and mortality. In addition, all safety data and indications need to be identified for capture and review.

3. Document sufficient patient population (number, severity, availability in the acute post injury phase, and ability to conduct exemption from informed consent) to ensure assessment of prototype cellular therapy is conducted in a timely manner.
4. Consider capacity for future assessment of cellular therapies from a variety of sources (e.g. industry, academic labs, and international partners) in a well described clinical population as a reimbursable service.

Later stage projects would be the most relevant to this request, such as those that are ready for human trials within 12 months. MTEC prefers that projects should be either entering formal FDA supportive clinical trials or preparing documentation for upcoming regulatory submission to the FDA. This is not meant to support pilot lot manufacturing for animal study purposes. The project information paper should include a clear description of the current status of the product.

It is expected that many of the actual cellular therapy projects may still be at the academic level, yet the manufacturing and clinical trial requirements demanded are most suited to industry. MTEC, therefore, considers that a teamed approach may have the greatest level of success, especially considering that the eventual goal is to transition products to industry for FDA approval. The project information paper should include a brief description of the team members and their roles in the execution of the project goals.

The government sponsor has limited funding to contribute (approximately \$2 million in Fiscal Year 2017 funds), therefore it is hoped that this topic will yield in-kind contributions and/or financial contributions from MTEC members for 100% matching funds. Innovative work in this area will also serve the interests of medical communities as lifesaving response to, military combat, civilian trauma or mass casualty events has direct applicability to civilian trauma patients with high acuity injury, long transport times/distances, and lack of access to organ support therapies to mitigate inflammatory injury secondary to trauma. Given DoD funding of trauma trials focused on similar patients, significant efficiency through the use of well-established and proven trauma clinical trial sites is expected. Similarly, the potential for civilian application and the large number of significant trauma injuries world-wide, significant efficiency from prior investment in cellular therapy prototypes is expected.

## 7. Broad Topic Request

### Request for Project Information (RPI)

Estimated Release Date: May 2017

The Government specifically requested that MTEC garner project information papers so that these can be used to influence their Fiscal Year 2018 (beginning in October 2017) decisions for funding and selection of project focus areas. This is your time to showcase your prototype technologies that could be used as a basis for upcoming RPPs. The Government is interested in receiving papers related to all of their technology domains (described below). In addition, the Government has provided specific areas of interest within their technology domains that seem to have a higher likelihood of funding in Fiscal Year 2018 due to current DHA or Army strategic priorities.

First, we recommend that you prioritize the submission of papers outlining your capabilities and technological solutions as they relate to the specific areas of interest outlined below. Second, we suggest that you submit additional papers that describe your technological solutions related to the greater technological domains as applicable. This does not mean that projects within the general six technology objectives will not be included in upcoming RPPs, but that the amount of funding may not be of the same magnitude. We highly encourage the submission of papers in response to both the general six technology objectives AND specific areas of interest to inform the Government of the plethora of potential projects that are available via MTEC. For example, lower priority projects that are mature often garner attention to “finish them off” over other projects that require more funding and extended time to complete (hence greater risk).

Project information papers may be submitted by both MTEC members and non-members. Papers must use the template provided in the RPI and should describe projects that are based on logical reasoning and sound scientific rationale. They should not be exploratory in nature and do require a foundation of preliminary data. Please note that MTEC-sponsored projects must result in “prototype” research deliverables that transition medical solutions to industry. At a minimum, these projects must be at a minimum of TRL 4 - a stage to conduct studies required for a regulatory filing to the FDA, which suggests that the prototype design is near frozen, proof-of-concept has been demonstrated in a large animal model (if applicable), and a committed industrial partner is involved.

### TECHNOLOGY FOCUS AREAS (subject to change):

- Prevention, Diagnosis and Treatment of Infectious Diseases: This technology area focuses on infectious diseases encountered by Service members during deployment and those that can significantly impact performance. Research and development efforts may include vaccines, anti-parasitic drugs, deployable field clinical

diagnostics (human and vector), prophylactics and novel therapeutics to prevent and treat multi-drug resistant bacteria and fungi in combat wound infections, and control measures for arthropod vectors that transmit infectious disease – pertinent to naturally occurring endemic diseases with demonstrated or potential capability to decrease military operational effectiveness. Specific areas of interest include, but are not limited to:

- o Technologies (i.e., biosurveillance, diagnostic tests, antibiotics, vaccines, and novel therapeutics) that combat antibiotic-resistant bacteria and fungi, especially infections that manifest as a result of injuries on the battlefield and subsequent evacuation
- o Approaches using systems biology that support the use of a single therapy for multiple clinical applications, such as those related to dysentery diseases or antibiotic resistance
- Care of Combat Casualties: This technology area focuses on the development of medical interventions that can be used on the battlefield to reduce morbidity and mortality. Research and development may include efforts to develop and evaluate drugs, biologics, and/or devices for hemorrhage control, resuscitation and blood products; diagnosis and treatment of traumatic brain injury (TBI) and spinal cord injury; treatments for extremity trauma, tissue injury, lung injury and burns; en route care and intensive critical care (including advanced monitoring and pre-hospital care). Specific areas of interest include, but are not limited to:
  - o Drugs or devices that assist in the diagnosis of TBI, in particular those that can:
    - ◇ Assess the degree of concussive damage and be used to assist in decision-making regarding whether to order patient evacuation or return to duty
    - ◇ Be applied at the time of injury to reduce the severity and progression of TBI
    - ◇ Repair or restore function within a hospital setting
    - ◇ Resuscitation agents/therapeutics for treatment of shock and TBI to prevent secondary brain injury
    - ◇ Evaluation of venous thrombosis chemoprophylaxis to prevent microthrombi and secondary brain injury in animal models of TBI
    - ◇ Miniaturization/militarization and evaluation of the EyeBox device for diagnosis of concussion
  - o Technologies that can provide prolonged care to injured patients in an austere battlefield environment, including:
    - ◇ Diagnostics with new modalities or

algorithms to assist in directed care for personnel

- ◇ Treatments for extremity injury in the prolonged field care environment
  - Polymers for emergency fracture fixation in austere environments
  - Therapeutic agents for the stabilization of extremity injury to extend the window of limb salvage
- ◇ Evaluation of hemostatic devices for junctional trauma
- ◇ Next generation (e.g., bioresorbable) hemostatic foam for use in non-compressible hemorrhage
- ◇ Devices and techniques to extend the time for application of REBOA
- ◇ Next generation wound dressing prototypes for prolonged field care
- ◇ Pharmacological-based stabilization approaches
  - Tranexamic acid for trauma in the pre-hospital environment, especially where prototype evaluation can leverage existing international efforts in the assessment of this agent.
  - Next generation oxygen delivery agent prototypes for use in trauma resuscitation
  - Intravenous hemostatic agents for treatment of non-compressible hemorrhage
- ◇ Telehealth technologies and tools that transform healthcare
  - Development and optimization of prototypes for just-in-time training for bystander (non-medical) trauma resuscitation
  - Next generation decision support prototypes for triage and treatment of burn casualties
  - Monitoring tools for prolonged field care goal directed therapy
- ◇ Devices that replace all or part of the function of the lungs for patients with acute respiratory distress syndrome or other types of pulmonary failure, and/or of the function of the kidneys for patients with acute kidney injury

- Clinical and Rehabilitative Medicine: This technology area focuses on innovation in definitive and rehabilitative care to reset wounded Service members in terms of duty, performance, and quality of life. Efforts may include developing medical technologies (drugs, biologics, and/or devices) and treatments/rehabilitation strategies (methods, guidelines, standards, and information) for

acute and chronic pain management, regenerative medicine and composite tissue engineering, neuromusculoskeletal (NMS) injuries (including advanced prosthetics and orthotics), and sensory systems (vision, hearing and balance restoration). Specific areas of interest include, but are not limited to:

- o Improvements to the manufacturing processes for regenerative medicine products (e.g., universal culture media, bioreactors, preservation, quality assurance, automation)
- o Vision restoration, in particular:
  - ◇ Visual prosthesis (i.e., developing a brain-machine interface)
  - ◇ Regeneration/restoration/preservation of the optic nerve
  - ◇ Retinal repair or regeneration to improve or regain vision lost as a result of disease or traumatic injury
- o Hearing restoration/repair technologies
- o Treatments of spinal cord injury that facilitate increased movement and control of muscles within extremities (arms and legs)
- o Novel implanted or external interfaces that can acquire high fidelity physiological signals to drive advanced prosthetics or provide sensory/proprioceptive input
- o Technologies to objectively assess NMS rehabilitation across the spectrum of care from initial injury through return to duty/reintegration
- o Decellularization/recellularization scaffolding strategies to regenerate or replace organs
- o 3D bioprinting and biofabrication of tissues and organs
- o Artificial organ replacement (e.g., internal support systems, external support systems and full organ replacement)
- o Systemic peripherally acting analgesics for severe acute pain
- Military Operational Medicine: This technology area focuses on developing effective countermeasures against stressors and to maximize health, performance, and fitness. Research and development efforts may include diagnostics, treatments, and training solutions to prevent or reduce injury and improve physiological and psychological health and resilience. This objective also 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 hazards. Specific areas of interest

include, but are not limited to, the development of:

- o A suite of wearable physiological and performance sensors to assess Warfighter thermal strain, energy expenditure, and cognitive and physical performance, which would provide small unit leaders with real-time, accurate, actionable information to prevent injuries and predict readiness (Health Readiness and Performance System)
- o An integrated experimental and computational platform to characterize host responses to environmental health hazards in terms of pathogenic and adaptive processes to prevent or mitigate health effects of exposures to toxic chemicals and/or airborne hazards
- o Methods to detect or assess risk of musculoskeletal injury, training strategies to reduce the risk of injury, and evidence-based physical fitness standards and return-to-duty criteria
- o Pharmaceutical interventions to prevent hearing loss from exposure to hazardous noise
- o Injury criteria and medical performance standards to protect against hearing loss, vestibular injury, and ocular facial injury from blast and directed energy threats
- o Novel pharmacological and non-pharmacological interventions to promote sleep, manage sleep/work cycles, maintain cognitive performance, and improve overall Service member readiness
- o Nutrition-based interventions to promote efficient and timely recovery from injury and maintain the overall health of Service members in garrison and during operations
- o Evidence-based tools that address a broad range of behavioral health issues, including suicide prevention, resilience, substance abuse, Family issues and high risk behaviors
- o Pharmacological- and/or behavioral-based methods to treat post-traumatic stress disorder and restore the psychological health of Warfighters
- Medical Simulation and Information Sciences: This technology area focuses on exploring the implications for the use of technology for medical training and for the provision, management, and support of health services in the military. Research and development efforts may include improving military medical training through medical simulation, educational gaming, and objective training metrics, and improving the use and sharing of health related data for better strategic planning, process development, and software applications. Specific areas of interest include, but are not limited to:
  - o Health Information Technology/Informatics
    - ◇ Best Practices and IT systems from private

industry that can be applied to Medical Logistics for shipping, inventory control and tracking and other global medical logistics capabilities

- ◇ Medical Device Interoperability – need to have closed loop systems whereby medical devices interact with one another and provide care autonomously to support theater/operational medicine
- ◇ Business practice driven automated applications that can improve clinical outcomes and be later assimilated into the Electronic Health Record as best practice/decision assist guidelines
- ◇ Precision medicine that uses genetic profiling or proteomics to identify improved clinical approaches for hospital-based care for both military and civilian medical needs
- o Medical Simulation and Modeling:
  - ◇ Open source integrated virtual models for education and training. Research, develop, and integrate multiple data-driven inputs to build open source/open architecture models to represent tissues, organs, systems, and the entire body for use within virtual/augmented/immersive reality training and education. Such data-driven inputs are (but does not exclude others): de-identified imaging sources (CT, MRI, ultrasound, etc.); de-identified tissue characterization data sources (stress/strain, stretch, cut, puncture, etc.); and accurate/appropriate physiological tissue, regional, and systemic algorithms within an open source/open architecture engine.
  - ◇ Program prototype architectures and data paths for programs within the Medical Simulation Enterprise, such as: Joint Evacuation and Transport Simulation (JETS), and Point of Injury Training System (POINTS); Theater Hospital Operations Replication (THOR); Warfighter Preparation, Resiliency and Protection (WarPREP).
  - ◇ Holographic technology software and hardware prototypes for medical training. Ruggedized holographic devices that are able to be utilized in the training environments of the JETS and POINTS programs replicating the operational military medical environment and situations. Operational capabilities must function in punishing training situations occurring outdoors and operate in all types of weather conditions, during day and night.
  - ◇ Medical Synthetic Training Environment prototype. Combines Live, Virtual, Constructive and Gaming training modalities into a single

integrated training environment. Allows any user within the environments to be connected in a training event/sequence/ scenario.

- Advanced Medical Technologies: This technology area focuses on developing initiatives and products that will increase medical mobility while ensuring access to essential medical expertise and support regardless of the operating environment. Efforts may include e-health, digital warrior, hospital of the future integrative medicine, advanced orthopedic devices and treatments, advanced medical imaging technologies, robotic technologies to treat and rescue battlefield casualties, nanotechnology and biomaterials for diagnosis and therapy, technologies for treating neurological injuries, and regenerative medicine.
- Advanced Medical Regulatory and Manufacturing Technologies: This technology area focuses on developing initiatives and manufacturing-related products to support the technology areas listed above to decrease the risk and time of product development advancing through the Food and Drug Administration regulatory process. This will impact accelerated access to medical products, reduce cost of goods manufactured, and steady the industrial base to support ongoing commercial availability of medical products most needed in surge situations.

- A State of the Science study will be conducted to identify key issues surrounding the potential use of system biology approaches to developing preventive, therapeutic, and diagnosis measures against infectious diseases of military relevance, both on the battlefield and during post injury combat casualty care. MTEC will analyze the recommendations from this study with the purpose of identifying likely candidate bacteria to research, validate, and translate to the commercial market.
- Create a portfolio of activities necessary to identify mechanisms of resistance, which as a whole, constitute the lion's share of resistance characteristics in bacteria, and focus on the underlying characteristics that elicit and sustain these mechanisms with a goal of identifying potential nullifying or counteracting strategies. This activity will require an expert panel to review and develop recommendations for a comprehensive set of mechanisms.
- The goal of the program is to design an integrated research and prototype development portfolio of resistance mechanism discovery, integrated validation, and potential translation.

More information on the specifics of this RPP will be posted when available.

## *8. Regenerative Medicine*

*Request for Project Proposals (RPP)*

*Estimated Release Date: Summer 2017*

MTEC is in the process of formulating a RPP focused on regenerative medicine. More information on the specifics of this RPP will be posted when available.

## *9. Systems Biology Approach to Infectious Disease*

*Request for Project Proposals (RPP)*

*Estimated Release Date: TBD*

MTEC is in the process of formulating a RPP focused on systems biology approaches to infectious disease. Since this RPP is very early in the planning process, very limited information is available at this time:

# MTEC Funding Initiatives

Dr. Lester Martinez Lopez, *President and Chairman*

Bill Howell, *Chief Operating Officer*

Dr. Susan Raymond, *Director of Strategic Funding*

MTEC has spent its first year aggressively building the capacity and relationships necessary to attract resources to its work. The growth of funds flowing to MTEC can be translated into more research dollars for members. Those present at the annual membership meeting in San Antonio had the opportunity to hear Dr Susan Raymond, Mr. Bill Howell, and Dr Lester Martinez talk about these initiatives to increase the pool of available research dollars. For those unable to join us, the below comments summarize our first year efforts and near term goals.

**1. Establishing the Base for Donations:** We have completed all infrastructure to solicit and accept donations to best-in-class standards of the nonprofit sector. This includes such actions as the design and implementation of the website, development and publication of topic specific need documents to resonate with the public, acceptance and establishment of a Customer Relations Module (CRM) to track donors and facilitate reach out discussions, and prospect lists of corporations and high net worth individuals whose community and philanthropic engagement are aligned with MTEC. The MTEC story has proved compelling. MTEC has never been turned down for a meeting from any entity to date, and that bodes well as we foster deeper relationship that could lead to funding. We have built relationships with several outside charitable institutions that are starting to pass the MTEC word. Besides continuation of these actions, we have targeted specific groups for collaboration in marketing in 2017, such as the Veterans of Foreign Wars (VFW), the American Legion, the New York State Health Foundation veterans subcommittee, and the Combined Federal Campaign.

## From a point of zero philanthropic presence or capacity

- Establish all fundraising systems and processes
- Establish gift intake capacity functioning at industry standard
- Identify and prioritize top foundation, corporate, and individual prospects
- Establish and prioritize top partnership prospects in areas of MRMC funding
- Beta Test the MTEC approach of co-funding MRMC areas and attracting funding to best-in-class ideas not funded through partnership pairing.

**2. Foundation Collaborations:** Philanthropy of all types is about relationships. We are building several relationships with charitable foundations with the goal of pooling dollars to gain greater impact on the research needs of the soldier and

veterans. These include several foundations that are market leaders within their work space and whose grant portfolios area aligned with MTEC's support for vision, ALS and spinal cord, hearing, regenerative medicine, and trauma related research. We have also been invited to attend and speak to the foundation funders of veteran causes at the annual meeting of the Council of Foundations in April.

**3. Venture Capital Engagement:** We are exploring the potential to establish a Co-Investment Circle of venture capitalists who would be located regionally throughout the US. The intent is to support start-up companies who can leverage their MTEC awards for additional dollars to mature the awarded technologies farther and strengthen the company toward eventual commerciality. We are in the process of building the legal structure for such a Circle, and are test marketing it with several venture capital leaders.

**4. Federal Agency Participation:** MTEC now has 10 research topics in active consideration, compared with two the first year, and several more in the process of intake. Just as our increasing breadth has provided more space in which to discuss private funding partnerships, we have actively engaging other federal agencies to broaden the potential users of the MTEC vehicle and increase research resources. Over the past several months, we have had discussions with every entity of the USAMRMC, the Defense Health Agency, the Navy's Office of Naval Research, and USAF medical research offices at Wright Patterson AFB. Results have been positive, and we continue to pursue opportunities. Additionally, we have met with the National Institutes of Health and the Department of Homeland Security, and have started discussions with the Defense Advanced Research Projects Agency (DARPA). All are interested in this model of contracting. We believe that the Federal future promises a wider set of agency engagements and deeper project topics and funding.

**5. MTEC Board Growth:** The MTEC Board has been expanded to include two new members with expertise and networks with the financial and philanthropic areas. These individuals are being sought now and the goal is to have them join the board by the next meeting in August. Their wisdom, experience and network of individuals and organizations should help posture the MTEC to attract more outside funding opportunities.

Progress to date, and the receptivity of organizations whom we have approached, provides a firm platform for 2017 efforts. Relationships take time, but we are optimistic that resources will expand as we redouble our outreach. With one and only one resource goal: increasing the chance to heal our nation's warriors.

## Year One Fundraising Performance Metrics (March 2016 - February 2017)

- Systems up and processing at industry standards
- CRM prospect management system in place
- 85 prospects identified and prioritized
- 4 private foundations actively in play
- 2 foundations reviewing research project “basket” proposals
- 3 corporations looking for alignment
- 4 partners interested in optic nerve funding if alignment can be found
- 3 organizations interested in co-convening
- 14 individual gifts received
- Venture capital/venture philanthropy conversations beginning

## 2017 Fundraising Priorities

Broaden the research domains to support broader range of prospect conversations. Funders have pre-existing interests; we need to be able to meet them where they are.

Bring at least three partnerships to fruition to generate outright grants, co-funding and visibility at scale, and do so more quickly than we can do on our own.

Double the number of partnerships in play.

Build out web and social media presence to drive traffic to the MTEC website in general, and especially to the donations functions.

Triple the number of individual gifts.

[Make an Online Donation!](#)



Stacey Lindbergh, MHA, MTEC Executive Director and Dr. Lester Martinez Lopez, MPH, Major General (Ret), U.S. Army, MTEC President and Chairman at the recent MTEC Members Meeting held at SwRI.



MTEC Members touring The Center for Intrepid, a rehabilitation facility providing state-of-the-art amputee care, assisting United States servicemen and women as they return to the highest levels of physical, psychological and emotional function.



MTEC members receiving a tour of the Southwest Research Institute (SwRI), MTEC member and host of the 2nd Annual Membership meeting.

## MTEC Webinars Coming Up!

On Tuesday, June 6th at 11AM EDT, MTEC is hosting a "Speed Networking" online meeting for our members to provide a two minute overview of their research capabilities. We would like to invite you to listen-in to gain an understanding of the capabilities of our membership. Registration is limited to the first 1000 participants. Use the link below to get more information and register for this event.

### Register for 6/6 Speed Networking Webinar

On Wednesday, June 7th from 2–3PM EDT, MTEC will host a webinar to help Department of Defense and other federal agency personnel understand more about MTEC and how MTEC may work for other federal departments or agencies as a creative way of doing business for advanced research and development. For more information and how to register, please click the button below.

### Register for 6/7 "How to Work with MTEC" Webinar

MTEC membership will provide an organization multiple benefits beyond the opportunity to submit proposals. Join Polly Graham, MTEC Program Manager and Stacey Lindbergh, MTEC Executive Director for this information packed webinar that will ensure MTEC members are taking advantage of all the benefits afforded to them through their involvement with one of the world's premier biomedical research and development consortia. Government and non-members are welcome to listen-in. Click below to get more information and/or to register.

### Register for 6/14 "How to Maximize Your MTEC Membership" Webinar

## MTEC Board Nomination Period Closing!

### Nomination Policy & Election Procedure

The MTEC Board of Directors voted to increase the size of the Board to include expertise in finance and fundraising/philanthropy. Nominations will be accepted from MTEC members through May 16th, 2017.

Please complete a [Director Nomination Form](#) (includes Nomination Policy & Election Procedure) and submit to: Stacey Lindbergh, MTEC Executive Director at [execdirect@mtec-sc.org](mailto:execdirect@mtec-sc.org).

The Nomination Committee will compile the nominations received and develop a slate of no more than 5 nominees for each seat which will be voted on by the MTEC Board of Directors. The newly elected Board members will take their seats at the MTEC Board of Directors meeting on August 27th, 2017 at the Military Health System Research Symposium.

## MTEC Events

Come visit MTEC at [BIO2017](#) on June 19th - 22nd. We'll be in booths #723 and with the [U.S. Army Medical Research & Materiel Command in booth #517](#).

MTEC will also be exhibiting and meeting with members at MHSRS from August 27th - 30th at the Gaylord Palm Resort & Convention Center in Kissimmee, FL.



**Optimizing the Health  
and Performance of  
Our Nation's Warfighters**

## **What is MTEC?**

The Medical Enterprise Technology Consortium (MTEC) is a new, tax-exempt, nonprofit corporation consisting of industry, academia and nonprofit organizations committed to realizing USAMRMC's vision. MTEC's main focus is to develop medical tools that better manage, treat, and rehabilitate those suffering from traumatic injury on the battlefield. The MTEC Board of Directors is chaired by Major General Lester Martinez-Lopez, MD MPH (Ret.), 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.

MTEC's initial focus will be the development of technologies that can improve or restore lost vision - the fourth leading result of combat actions - and on regenerative technology for tissue destroyed by trauma and burns.

## **MTEC's Technology Focus Areas**

- Prevention, Diagnosis, and Treatment of Infectious Diseases
- Care of Combat Casualties
- Support for Military Operational Medicine
- Support for Clinical and Rehabilitative Medicine
- Support for Advanced Medical Technologies

**For information and assistance with making a donation or forming a partnership with MTEC, please contact:**

**Stacey Lindbergh, MTEC Executive Director**  
**stacey.lindbergh@ati.org**  
**843-760-3566**