

MTEC
Medical Technology
Enterprise Consortium

2018
ANNUAL REPORT



*Protecting
and Healing
Those Who Serve*

MTEC at a Glance

The Medical Technology Enterprise Consortium (MTEC) is a 501(c)(3) nonprofit organization designed to accelerate the translation of medical technologies into solutions that prevent and treat injuries and restore the health of United States military personnel and veterans.

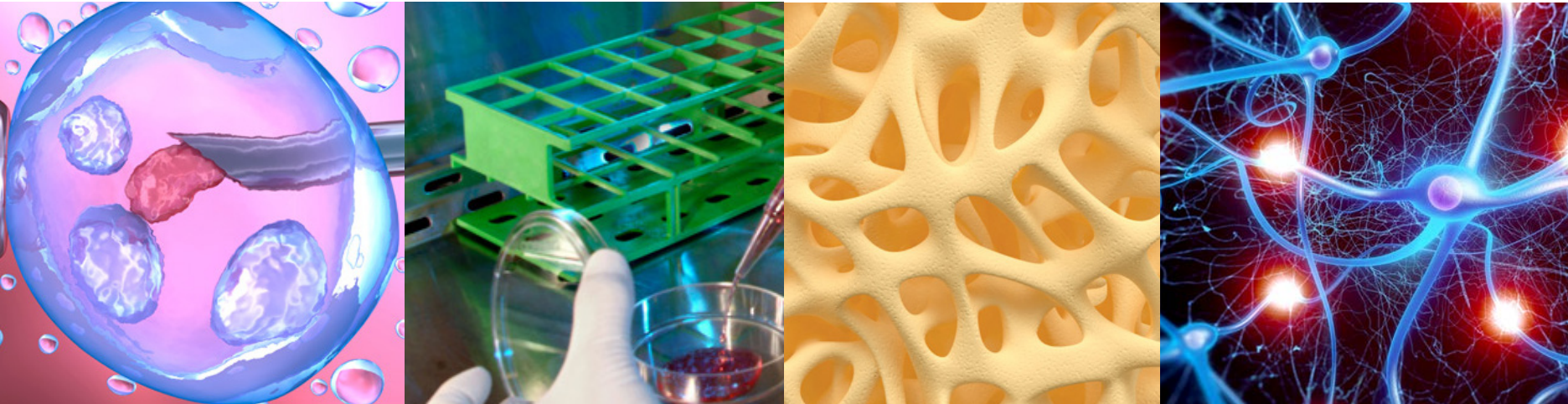
MTEC represents a public – private collaboration among the US federal government (primarily DoD organizations) with academic institutions, private industry and non-profit organizations (MTEC consortium members). This public-private collaboration uses a simplified contracting vehicle (the Other Transactions Agreement (OTA)), which enables federal sponsors to quickly partner with MTEC members in a more open, transparent, and discursive manner. The OTA tears down the walls that traditionally restrict such open transactions to enable rapid and repeated interaction among the Government, private technology developers, and funding partners.

The consortium membership includes academic research centers, independent research and development institutes, small technology companies, and large biomedical organizations from around the world. Members offer to the federal government technology opportunities that can prevent injury and restore the wounded back to health.

Our goal, our passion, is to bring medical technologies forward with faster transition from the laboratory to the patient, either on the battlefield or at the bedside, and then onward to the global civilian community.

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Welcome

Our past year of operation brought a dramatic growth in research opportunities. It is now evident that our partnership with the U.S. Army Medical Research and Materiel Command (USAMRMC) is solid. We also expanded our partnership to include the Department of the Navy, and are hopeful that it will extend to other organizations within the U.S. Department of Defense (DoD) and throughout the federal government.

2018 Highlights

- Increased funding sponsors to five USAMRMC Joint Planning Committees (JPCs) plus three DoD service laboratories representing all research and technology focus areas within MTEC's scope
- Grew membership to 270 organizations
- Built a co-investment circle of multiple venture capitalists (8) and medical foundations (20).
- Executed multi-topic awards for both immediate funding and basket
- Presented USAMRMC with another 150 new project ideas from an open concepts request
- Introduced the MedTech Innovator and military pitch day to identify new device companies and technologies
- Established a relationship with BIO to increase MTEC's exposure within the community of biologics and drug companies

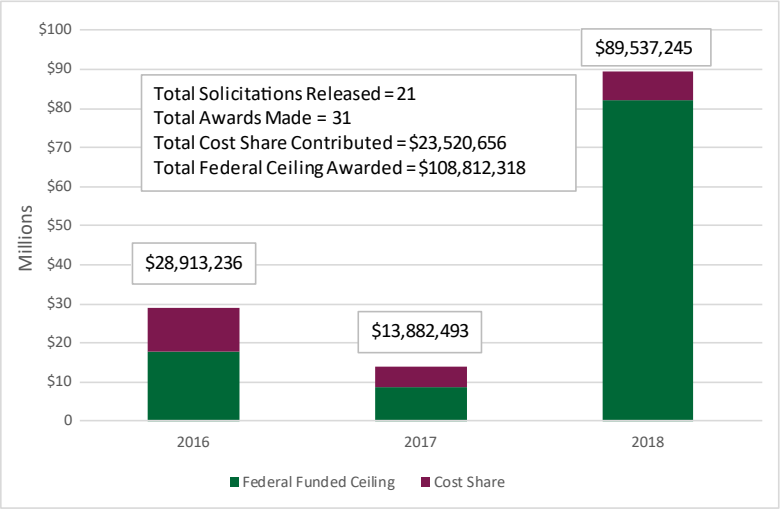
We must acknowledge two communities that are key to our work: (1) the military which is placing its trust and funds into our hands to provide cutting edge solutions, and (2) the MTEC membership - a growing and evolving network of university, industry, and government entities - that work hard to advance technologies and capabilities that meet military and civilian needs. We are grateful for their active participation in MTEC.



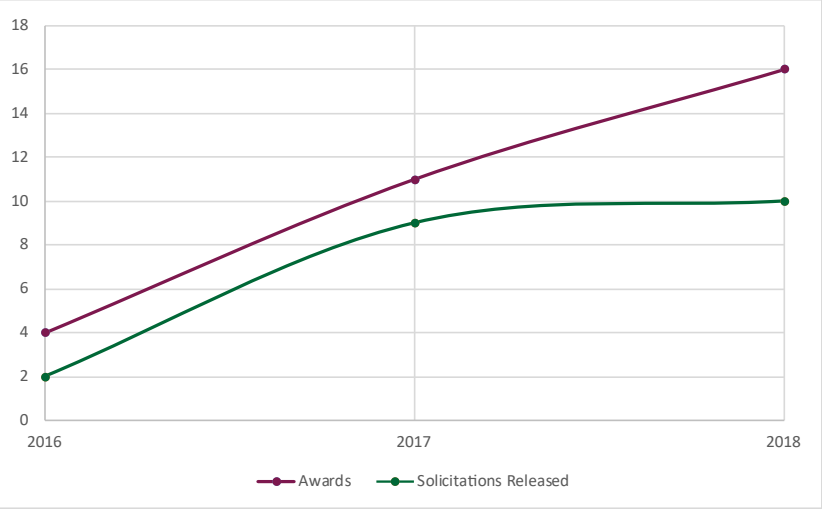
My Best Regards,
Dr. Lester Martinez Lopez, MD, MPH,
Major General (Retired), U.S. Army
President & Chairman of the MTEC Board

Quick Historical Data Points

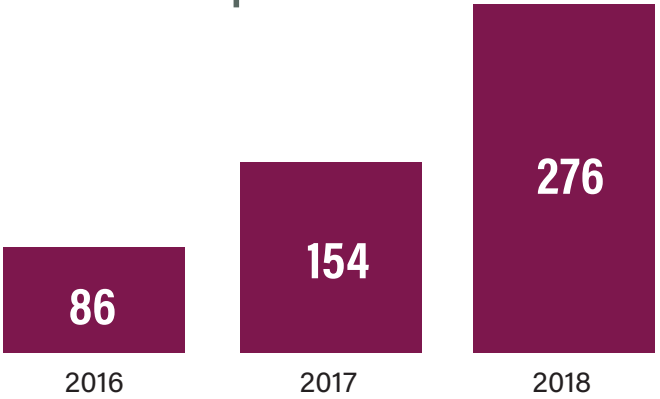
Awarded Ceiling with Cost Share



Number of Awards and Solicitations



Membership Growth



These graphics demonstrate significant growth in 2018. This trend is expected to continue into 2019 with approximately \$70 million already identified for execution.

Infectious Disease Research Program

The Military Infectious Disease Research Program (MIDRP) has the unique goal of developing and fielding medical products (i.e., vaccines, therapeutics, diagnostics, etc.) to prevent U.S. service members from becoming ill from naturally occurring infectious diseases they may be exposed to while they’re deployed far from home. Unlike other federal agencies such as the National Institute of Health (NIH), the military needs are slightly different, often more prophylactic rather than therapeutic and within austere environments rather than hospital settings. The MIDRP also develops preventive medicine products such as improved repellents suitable for the military

operational environment, bednets and other products for preventive medicine officers that reduce insect and vector-borne disease transmission and enhance their ability to assess disease threats in the field. These diseases/illnesses include:

- Mosquito borne parasites such as malaria, dengue, zika
- Blood and fluid borne diseases such as ebola and HIV
- Diarrheal diseases from the water and food supply
- Novel therapeutics to combat the growing resistance to antibiotics, especially with infections present in combat wounds and surgical procedures

Recent Awards or Solicitations

Title	Awardee	Ceiling Value	Status
Dengue Human Challenge Model	SUNY & University of Maryland	\$ 3 M	Awarded
Bacteriophage Anti-bacterial Therapeutic	Multi-topic	\$ 7 M	In cost discussions for award
Combating Antimicrobial Resistant Bacteria	Single solicitation for WRAIR	\$ 1 M	Closed and being evaluated

Case Study: Dengue Human Challenge Model

This truly teamed effort has as an objective to develop a human challenge model for mosquito borne dengue fever that will alleviate the need to conduct field Phase 2 trials. The Walter Reed Army Institute of Research (WRAIR) developed dengue serum extracted from infected mosquitoes that provides a consistent dosage of virus that can be admitted through inoculation to subjects. The State University of New York (SUNY) was awarded the task of developing candidate vaccines for the four dengue serotypes which will be used to test the model. SUNY in conjunction with the University of Maryland will conduct the clinical trials that will challenge human subjects and determine both the efficacy of the vaccine candidates but more importantly the consistency of the challenge serum as a means to express the disease. If the model is found acceptable by the FDA, this will accelerate candidate vaccines and therapeutics considerably by allowing stateside laboratory and clinical settings to be used with far fewer human subjects at risk than the traditional field studies with hundreds to thousands of subjects. It will also drive the costs well below current field standards.



The success of this program could lead to fewer humans at risk in further candidate testing, quicker study periods and overall development times, and significantly lower costs.

Combat Casualty Care Research Program

The mission of the Combat Casualty Care Research Program is to reduce the mortality and morbidity associated with major combat related trauma across the spectrum of care from battle-field to CONUS based hospitals. Specific emphasis is on point of care trauma care and life sustaining technologies over ex-tended periods of time awaiting evacuation. The new battlefield is driving a lower military personnel footprint without losing the ability to care for the wounded. Major areas of research include:

- Early intervention in life threatening battle injuries and prolonged care awaiting evacuation
- Enhanced self and buddy aid (tactical care)
- Improved basic and advanced life support
- Hard/soft tissue wounds; orthopedic and maxillofacial trauma repair
- Prevention/mitigation of wound infection and disease
- Remote triage, monitoring, and management
- TBI related injury therapeutics and diagnostics from battlefield to recuperative care

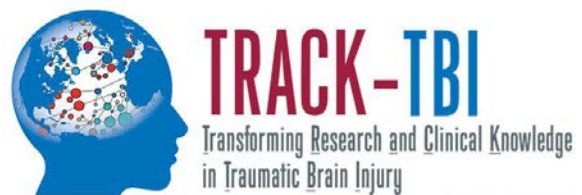
Recent Awards or Solicitations

Title	Awardee	Ceiling Value	Status
Cellular Therapeutic for Treatment of Hemorrhagic Shock	University of Texas Medical Center	\$ 2 M	Awarded
Drug Treatment for TBI	University of California-San Francisco	\$ 25 M	Awarded
Anti-Scar Treatment for Burns		\$ 2.4 M	In Evaluation

Case Study: Drug Treatment for Traumatic Brain Injury (TBI)

TBI has been one of the signature injuries of the current war. Thousands of warfighters have been diagnosed with mild to severe TBI. The objective of this large awarded project is two-fold: first, to establish a multi-site clinical trial network that has the capability, experience, and population to perform phase 2/3 clinical studies; second, to conduct actual testing of candidate TBI therapeutics through this network to provide a consistent means of comparison. The desire is to have a ready infrastruc-ture to conduct the studies that will allow for effective and effi-cient studies and provide data at the conclusion that will best represent the candidates’ therapeutics effects. The therapeutics will be oriented toward immediate TBI severity reduction in the battlefield and then longer term care upon evacuation stateside.

TRACK-TBI NET, led by Dr. Geoffrey Manley at the University of California, San Francisco, was awarded \$25 million to test drug Treatments for TBI in Phase 2 clinical trials. The network builds on a well-established infrastructure, which has enrolled over 3,000 patients and controls at 18 level 1 trauma centers across the country over the past 5 years.



The ability to reduce the severity of TBI on the battlefield and then restore health upon rehabilitative care provides a significant improvement to a soldier’s quality of life, and has ready translation into the civilian population of sports concussive and vehicular accident victims.

Operational Medicine Research Program

The Operational Medicine Research Program develops countermeasures against military-relevant stressors and prevents physical and psychological injuries during training and operations in order to maximize health, readiness, and performance.

- Environmental health and protection
- Injury prevention and reduction (blast, blunt trauma, neurosensory injury, musculoskeletal injury)
- Physiological health and performance (nutrition, weight balance optimization, restorative sleep)
- Psychological health and resilience (post-traumatic stress disorder [PTSD], suicide prevention, resilience, substance abuse prevention, and violence prevention)



Recent Awards and Solicitations

Title	Ceiling Value	Status
Health Readiness & Performance System (Wearable Sensors)	\$ 2.4 M	Post selection cost analysis and final proposal discussion
Tele-Sleep Decision Assist	\$ 4 M	Pending award

Case Study: Tele-Sleep Decision Assist Tool

Sleep management is a high priority of the military to optimize warfighter performance, remain safe, and potentially, reduce the likelihood of psychological issues downstream. The MTEC “Tele-Sleep Decision Assist Tool” Program aims to transition evidenced-based behavioral sleep interventions to address the limitations of current practices, such as an insufficient number of clinicians and sleep clinics specializing in behavioral sleep interventions, a large number of patients seeking treatment (high demand, low supply), and a current practice that relies on multiple visits of face-to-face sessions with the clinician to reach an acceptable patient outcome. Two awards are anticipated in the spring of 2019 that provide scalable behavioral sleep intervention methods and evaluation using human patients.

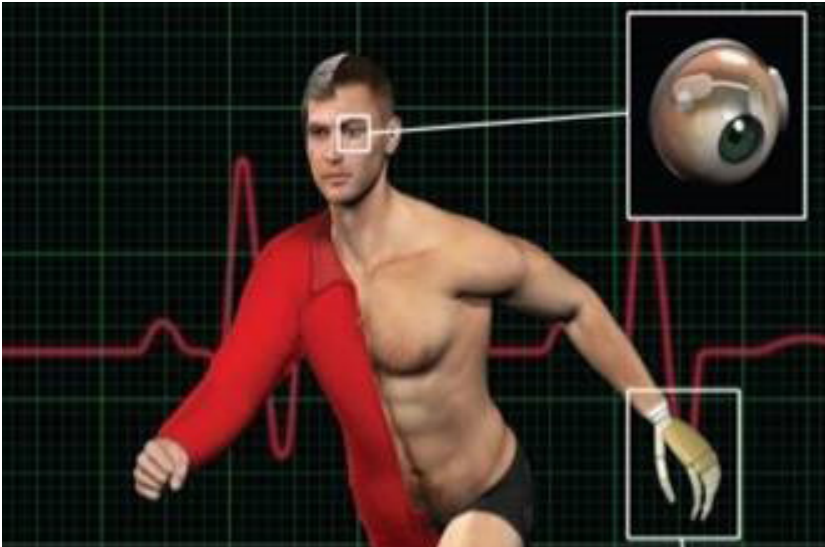


The ability of a telemedicine application to provide clinically proven, sleep therapies will significantly increase the capacity to better match a large and ever growing military population.

Clinical and Rehabilitative Medicine Research Program

The innovations in trauma care have saved more lives in combat than any previous engagement, but the results have left many warfighters with long term care needs and life-long disabilities. The Clinical and Rehabilitative Medicine Research Program takes on these challenges, especially the longer term care needs, to bring value and fulfillment back into servicemembers' lives. It focuses on innovations in restorative treatments and rehabilitative care to maximize function of wounded Service members in terms of duty, performance, and quality of life.

- Neuromusculoskeletal injury and sensory systems impairment
- Acute and chronic pain
- Regenerative medicine and composite tissue engineering
- Traumatic brain injury (TBI) rehabilitation
- Novel manufacturing technologies



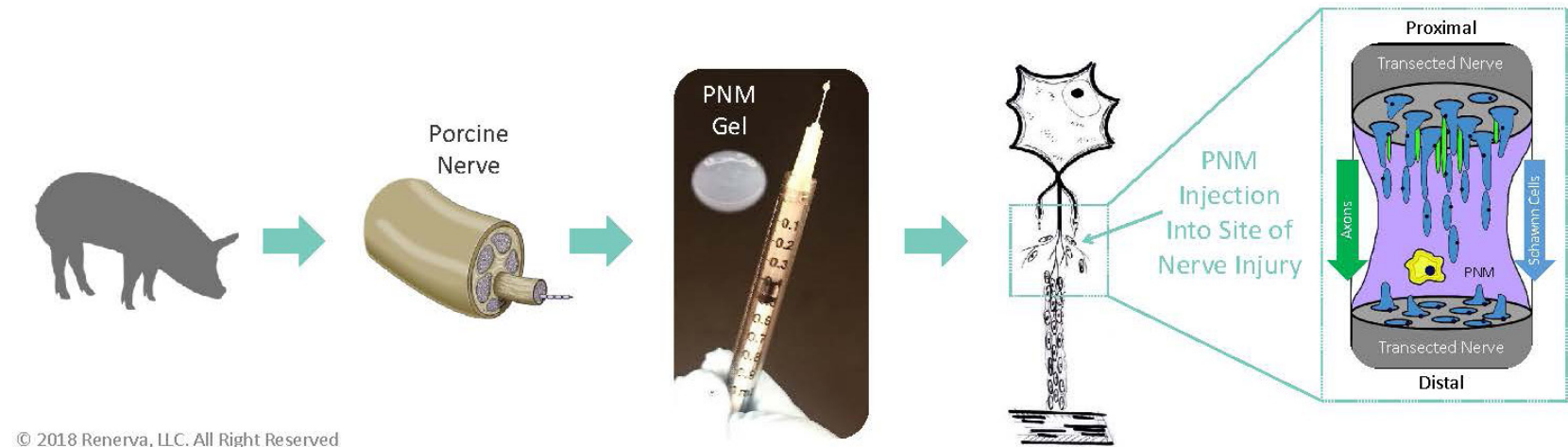
Recent Awards and Solicitations

Title	Awardee	Ceiling Value	Status
Prototype Solutions for Optic Nerve	Stanford University	\$ 3 M	Awarded
Prototype Solutions for Regenerative Peripheral Nerve	3 awards: Renerva; Nano Terra; Wake Forest University	\$ 7 M	Awarded
Volumetric Muscle Loss		\$ 2.5 M	Post selection cost analysis and final proposal discussion

Case Study: Peripheral Nerve Repair

Regenerative medicine technologies hold great promise for treating those who are severely injured, both military and civilians. Three new projects were awarded in 2018 to Renerva, LLC, Nano Terra, Inc., and Wake Forest University Health Sciences to develop innovative solutions to critical problems in nerve regeneration. For example, Renerva, LLC is developing an injectable gel derived from porcine (pig) nerves for the regeneration of human peripheral nerves. Its proposed mechanisms of action

include providing a scaffold for regeneration, fostering Schwann cell migration, increasing neurite extension, and providing anti-inflammatory function. This approach uses a biological engineering approach to restore the structure and function of damaged nerves by stimulating the patient's own body to heal itself, or "regenerate."



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Nerve function and the control over other tissues is a fundamental human need to perform daily life functions. When teamed with other regenerative areas such as skin, muscle, vascular restoration, the future will include less amputation and more regrowth.

Medical Simulation and Information Sciences

The Medical Simulation & Information Sciences Research Program (MSISRP) seeks to improve patient safety and quality of care through strategic over-the-horizon research; by transitioning more capable healthcare information and medical simulation technologies and systems; by addressing stakeholder driven priorities to bridge existing and future capability gaps in the MHS, and through proactive integration and implementation of emerging technologies into military healthcare relevant applications. The MSISRP explores the implications of models and technology for medical education and for the provision, management, and support of health services in the military.

- Combat casualty simulation; tools for medical education; health information technology infrastructure
- Enhanced autonomous and unmanned medical capabilities; medical robotics research
- Virtual health/telehealth and decision support tools for the combat medic

Recent Awards and Open Solicitations

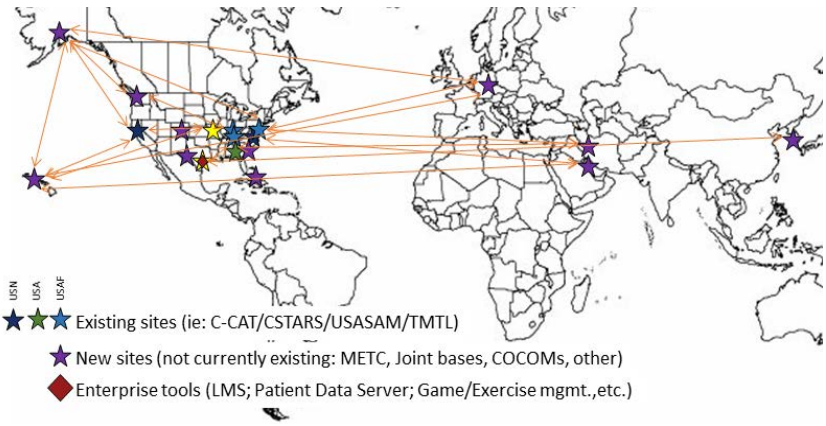
Title	Awardee	Ceiling Value	Status
Prototype Architecture for JETS	2 awards: IVIR & SIMQUIST	\$ 4 M	Awarded
MEDLOG Systems Upgrading	Arizona State University	\$ 2.4 M	Awarded
Assessment of Psychological & Physiological Effects of Virtual Reality	4 Awards to be made	\$ 2.5 M	Post cost analysis and final proposal discussion

Case Study: Prototype Architecture for Joint Evacuation and Transport System

This large and multi-phased project endeavors to take disparate simulation models for training in support of the joint evacuation and transport system (treatment regimens for patients during their transport from point of injury to CONUS based facilities) and integrate them into a large multi-modal training infrastructure. These training modules include individual and team requirements and currently are limited by location and devices. The intent of the ultimate project is to weave all these modalities and locations into a syncopated assembly of entry points and devices that can support training anywhere, at any time, and at multi-levels of needs. The first phase provides for an architecture that is adaptive, broad and compliant to the military IT system and will capture these modalities into a common structure.

This project also set a precedent for the MTEC. It was the first project that was teamed after the fact, where two company’s individual proposals highlighted different strengths and weak-

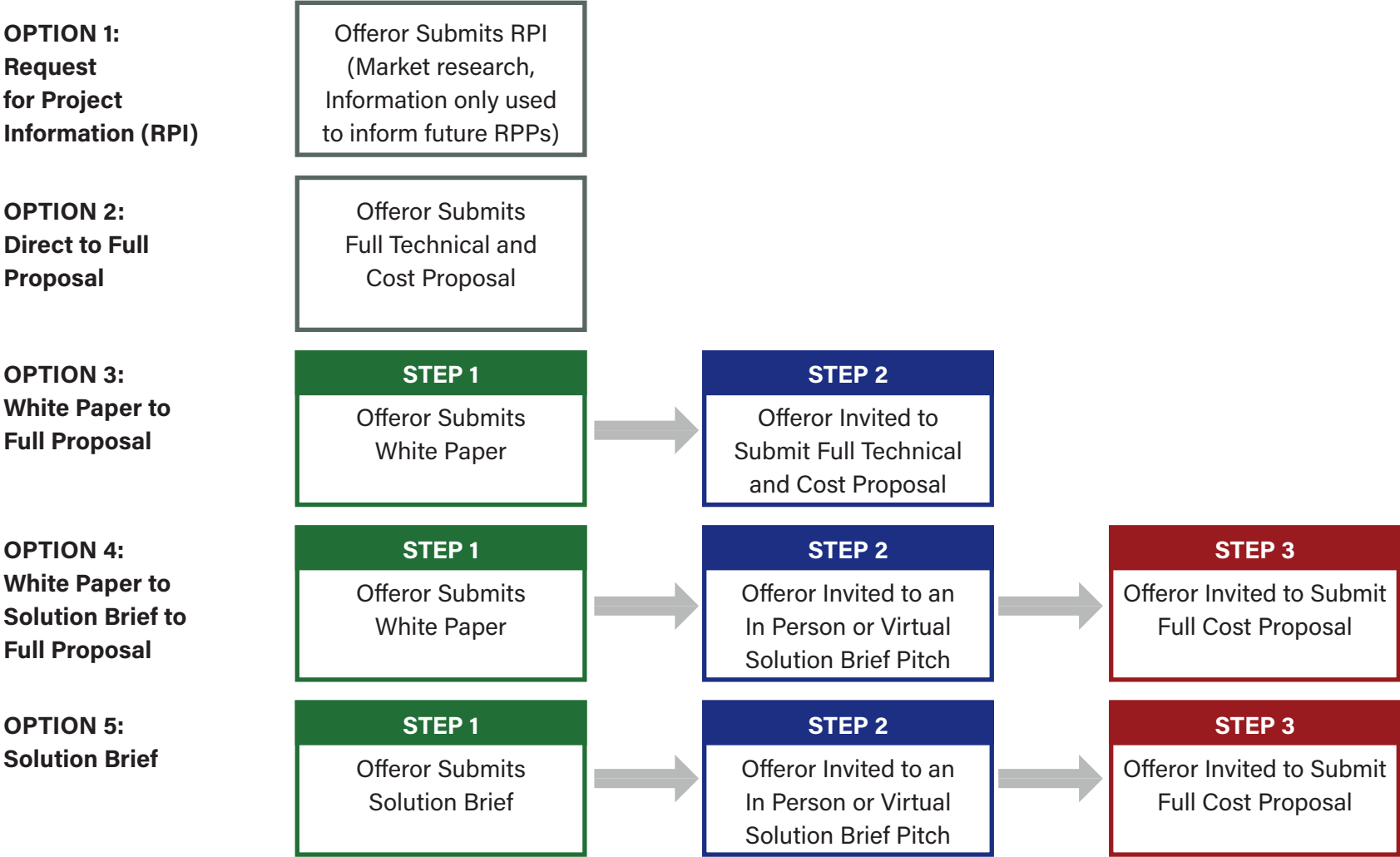
nesses, and through direction and discussion, they were able to team to bring forth a more complete proposal and subsequent capabilities to conduct the awarded work. Since this initial teamed project award, several other awards have been executed in different domains. This remains a huge plus for using the MTEC’s OTA processes.



The ability to access training simulations anywhere and at any time, whether single operator or team, provides an extremely powerful tool to enhance the ready status of military medical personnel to conduct their clinical and operational missions.

Solicitation Processes

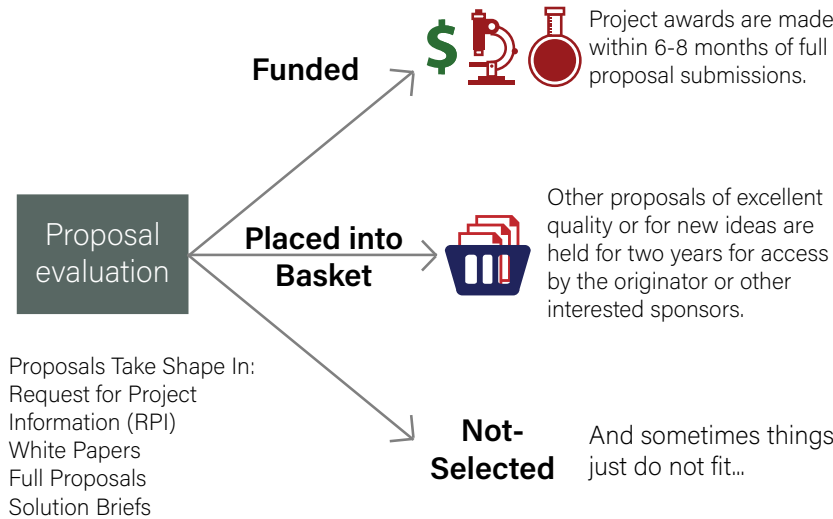
MTEC has developed tailored but formalized solicitation methods aligned to both funding sponsor desires as well as the complexity and maturity of the technologies being advertised for bid. Below is a depiction of the 5 methods in use.



MTEC's Basket Provision

The use of an “electronic basket” provides a means to maintain technically acceptable and reasonably priced proposals at a ready to award status for two years.

Any funding sponsor can access these proposals as funding becomes available without re-solicitation, thereby allowing the speedy and efficient use of future FY funding, expiring funds, or withheld appropriations.



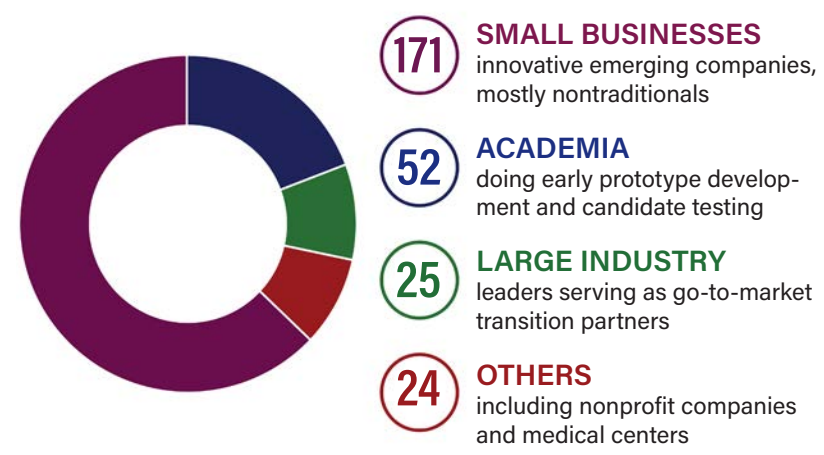
Highly efficient solicitation processes enable use of expiring funds, formation of strong project concepts and teams, and - most importantly - rapid access to innovation.

MTEC OTA Benefits

- The use of the basket saves time and is responsive to military needs and funding availability.
- The OTA often reaches award quicker than standard FAR based process, thereby reducing the risk of fund expiration.
- The “cost share in excess of requirement” evaluation factor can bring additional funding beyond the sponsor’s base funding.
- The discursive capability means fewer but more responsive proposals are generated.
- Post evaluation teaming is facilitated to bring segregated capabilities together in one proposal and project execution.

Membership

As demonstrated in early historical data, the membership for the MTEC has steadily climbed as the number of solicitations and areas of research have grown. Below you can see a breakout by category which validates one of the objectives of the MTEC: reaching out to small, emerging, high-tech companies to gain their participation early in the technology development process. These small, innovative companies now make up a sizable portion of our population. In addition, we are encouraging membership from a few large companies carefully placed within the therapeutic domains to foster mentor-protegee relations or pipeline potential. This includes such companies as Medtronic, Johnson and Johnson, Sanofi Pasteur, and Becton Dickinson.



MTEC’s membership ensures relevant conversations, capable project teams, robust competition, strong responses to RPPs, and high quality proposals aligned with military medical needs.



Technology and Company Outreach

Besides generating solicitations that are published in email, website, and federal directories, the MTEC is active with outside agencies that are helping to fill industry pipelines. A strong example of this is the MedTech Innovator group that maintains contact with over 1000 medical device companies and provides a means to recognize these entities as potential pipeline feeders to major industry players. In our case, we have now conducted a specific military pitch day that brings a number of companies in to brief on their capabilities and technologies directly to the military funding sponsors. In addition, through the application process, additional firms having potential military related prod-

ucts are identified as candidates that could also join the MTEC and gain from the OTA experience.

In addition, MTEC attends several large venues to reach out to potential members, including conferences such as the MHSRS, Advamed Med Tech Conference, and the large pharmaceutical BIO Conference.



MTEC conducts outreach to a focused community of technology innovators to bring the right mix of expertise and disciplines to prototype and research projects.



Fund Raising and Financial Outreach

The CY18 Multi-topic solicitation generated over 350 white papers for evaluation and disposition. From that one action, over 70 full proposals were requested that demonstrated military interest in new concepts identified in these papers. These white papers were forwarded to our co-investment circle for their consideration for potential joint or stand alone funding.

The goal of leveraging military funding with non-military funding to accelerate the development and marketing of medical solutions remains a high priority for the coming year.



Lessons learned: Though the interest from the venture community remains high, we have yet to complete a deal (though there are still some out in discussion). Generally, we found that we need to modify our information requests to provide greater details of value to the venture group and have them potentially engage a little earlier, maybe prior to the military evaluations. This remains an area of interest and dedicated work from the MTEC to make it real.

Philanthropic Donations

CY18 saw the start of true fund raising activities as we felt confident we could justify individuals entrusting their dollars into our portfolio of projects. We conducted several actions that better prepared us for this endeavor:

- Conducted a branding analysis which has led to the formation of a secondary entity “Lives Restored” with marketing material and website specifically being designed for more personal interest and donations
- Hiring two dedicated fund raisers with interest in social media and high net worth income targets
- Developed a budget for events to be enacted in CY19 to raise awareness and donations
- Combined Federal Campaign (CFC) approval and outreach during the CY18 fall campaign

Again, the goal is to identify specific projects that have high appeal to the general public that can generate dollars to accelerate the products to the clinic and human use.



Board of Directors

As a part of the bylaws of the MTEC, we rotate board members to provide for new blood and fresh ideas. In this past year, Dr. Tony Atala fulfilled his term as the representative of universities and non-profits. Dr. Atala was a major player on the board and in the initial establishment of the MTEC. We thank him for his support and service and wish him nothing but the best in the future while he continues to run the Wake Forest Institute of Regenerative Medicine. In his position, the MTEC was fortunate enough to place Dr. Pierre Noel of the Mayo Clinic.



Dr. Pierre Noel

is Director of the Mayo Clinic's Center for Military Medicine, which coordinates military-related practice, education, and research programs across the Mayo Clinic and provides medical services and education to active-duty service members and retirees. He is currently a physician in the Mayo Clinic's Department of Internal Medicine Division of Hematology and

Oncology, a Senior Visiting Fellow at the Brent Scowcroft Center on International Security, a Professor of Medicine at the Mayo Clinic College of Medicine and Science, and a primary consultant in protective medicine to the White House Medical Unit.

In addition, one of the at large positions came open due to the reassignment of Daniella Strickland who through her new employment could not continue to serve with us. Again we thank Dr. Strickland for her time, insights, and support over the past 12 months. In her position, Dr. Ron Poropatich was selected to join the board. We could not be happier, for Ron has a long history in Army medicine and R&D and maintains a strong acquaintance with many of the other members of the board.



Dr. Ron Poropatich

currently serves as the Director of the Center for Military Medicine Research (CMMR) and as a Professor of Medicine in the Pulmonary, Allergy and Critical Care Division at the University of Pittsburgh. Under Dr. Poropatich's leadership, the CMMR has developed a large DoD medical research portfolio and established the University of Pittsburgh as a key collaborative

research partner for the DoD. Since 2012, Dr. Poropatich has also acted as the Senior Advisor on Telemedicine for the University of Pittsburgh Medical Center, leveraging the use of virtual health solutions for this innovative leader in health care delivery.

2019 Strategic Plan

As the MTEC moves forward into CY19, we as an entity have gained both momentum and maturity in our efforts. Our brand is gaining traction in the halls of the military medical R&D community and within the medical technology domains of academia and industry. We are proud of the distance we have traveled, but we are also not complacent in where we have progressed to date. Therefore, we have developed a strategic plan for CY19 with a corresponding action plan of metrics and time frames. The details of this plan can be found on our website under our documents library, but below are the highlights of the areas in which we want to push to higher performance.

1. Improve outcomes for our sponsors – an outward face to the military and other governmental funding sponsors
2. Provide research and business opportunities for our Members – an outward face to our membership
3. Develop and encourage collaboration for success – a bridge between these two
4. Serve as a conduit for non-DoD funding – a face to the philanthropic world
5. Generate and maintain resources to fulfill the MTEC mission – an internal face to financial management



Membership Benefit

The MTEC provides direct access to government sponsors, networking opportunities with leading technology partners, and funded solicitations for leading research that aligns with military, governmental, and often civilian needs.

Stacey Lindbergh
MTEC Executive Director
execdirect@mtec-sc.org

Funding Sponsor Benefit

The government sponsor gains ready access to a consortium of broad and savvy technology providers with a means to hold discursive solicitation processes that lead to better proposals and better potential of success in their R&D efforts.

Lauren Palestrini
MTEC Director of Research
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Donation Benefit

Individuals and corporations can provide donations to much needed medical solutions that have an immediate clinical effect on our nation's warfighters but also to the greater US and world civilian populations.

Kim Cunningham
MTEC Director of Development
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