

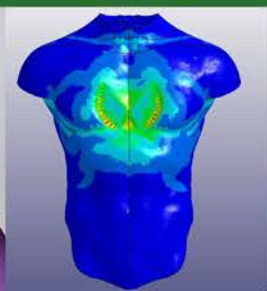
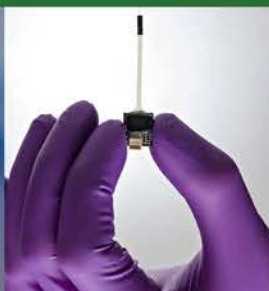


MTEC
Medical Technology
Enterprise Consortium

2019
ANNUAL REPORT



Protecting and Healing Those Who Serve





The past two decades have been hard on our men and women in uniform and our veterans.
Within their ranks there are

384,000 reasons to find ways to help people
struggling with traumatic brain injury

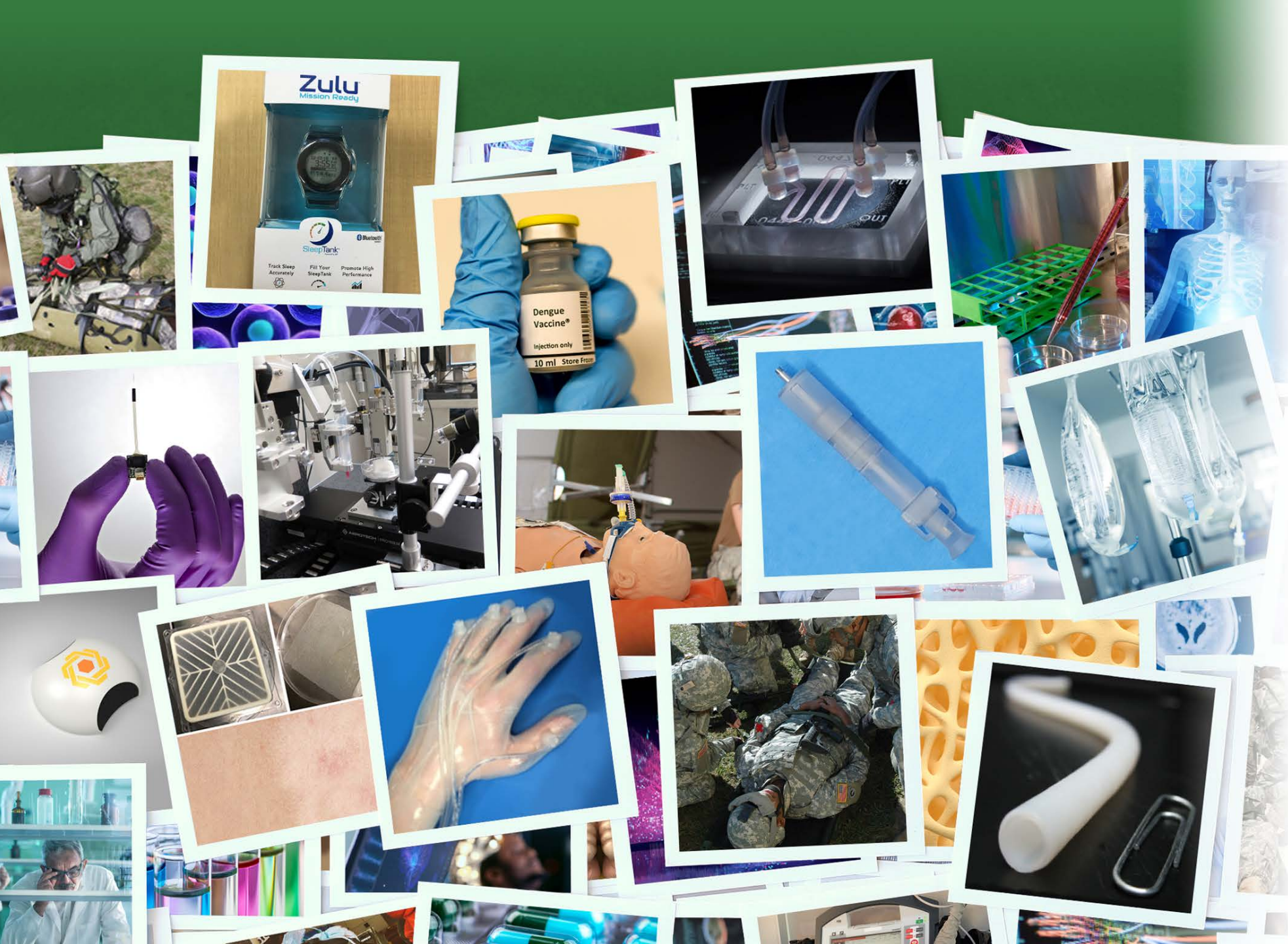
186,000 reasons to restore vision to those
who have suffered eye injuries

34,000 reasons to return full
functionality to injured hands

540,000 reasons to develop technology to ease the
effects of Post Traumatic Stress Disorder

52,824 reasons to continue working toward
more comfortable, effective prosthetics

Among the world-wide population, there are millions more reasons.
It's why we do what we do.



We are dedicated to protecting and healing those who serve.
We are scientists, technologists, and clinicians delivering high impact technologies.

Technologies for point of injury resuscitation treatments
and prolonged stabilization until evacuation

New treatments and diagnostics for acute
and long term mental health

Projects to advance the application of AI-enabled,
autonomous healthcare on the battlefield

New simulation technologies for medical training
in a myriad of environments

Projects to enable hospital based, clinical
rehabilitation on a large scale

Working together to advance and apply emerging medical science...
It's what we do.

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 is a public-private collaboration between the U.S. federal government (primarily DoD organizations) and the academic institutions, private companies, and non-profit organizations that make up MTEC's membership. This collaboration uses a simplified contracting vehicle (the Other Transaction Agreement (OTA)), which enables federal sponsors to quickly and openly partner with MTEC members in a more transparent manner. The OTA tears down the walls that traditionally restrict such

open transactions, enabling rapid and repeated interaction between government, private technology developers, and funding partners.

The consortium membership includes academic research centers, large industry leaders, small companies, as well as major medical research centers from around the world. MTEC reaches this community through multiple channels to seek out technologies that can enhance the military's performance on the battlefield. As single bidders or teamed proposers, our members have the opportunity to respond to government-funded requests for proposals within multiple research domains that are relevant to both military medicine and civilian medical needs.

We are dedicated to identifying emerging medical technologies and facilitating faster transition from the laboratory to the patient on the battlefield, at the bedside, and - ultimately - across the globe.

Through “technology pull” for specific clinical needs or “technology push” described in open concept white papers, the MTEC fosters a strong dialogue between the worldwide medical technology base and the military R&D community. Our flexible and tailorable solicitations use complexity, maturity, and cost factors to assist in channeling discussions and ultimate proposals that have higher acceptance rates by military evaluators. This value add service makes the MTEC a significant asset to both the military and industry clients.

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2019 - Making a Difference

What a year! MTEC has significantly expanded its DoD- outsourced prototyping activities, and an ever growing number of new technology providers have widened the spectrum of medical capabilities being explored. With a significant increase in available funding, MTEC’s membership has grown to offer innovative solutions to military medical needs. Work funded in our early awards is now reaching completion, and the first products are starting to transition to the clinic. It has been extremely satisfying to be a part of these efforts!

As MTEC looks forward to the new year, we anticipate further expansion into other military services and federal organizations and increased collaboration within the private sector.



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

Work funded in our early awards is now reaching completion, and the first products are starting to transition to the clinic.

A Special Thanks:

MTEC would like to express our appreciation to the military sponsors who demonstrate their faith in our ability to provide access to emerging technologies and providers who make the real work happen. Thank you so very much for your combined trust and participation!



Joint Program Committees 1, 2, 5, 6, 8



2019 Highlights:

- Expanded funding sponsors to include five Joint Program Committees (JPC-1, 2, 5, 6, 8), U.S. Army Medical Materiel Development Activity (USAMMDA), several military laboratories (U.S. Army Institute of Surgical Research (USAISR), Walter Reed Army Institute of Research (WRAIR)), Defense Health Agency (DHA), Naval Medical Research Center (NMRC), Office of Naval Research (ONR), Joint Operational Medicine Information Systems (JOMIS), and Congressional Special Interest (CSI) funding
- Added \$80M in new funding for a total program exceeding \$177M in contract ceiling
- Grew membership in 2019 to 336 active organizations (22% increase from 2018)
- Launched the “Open Concepts” Request for Information, which led to several new funding opportunities with targeted research topics, and will result in at least 15 new awards
- Monitored the first MTEC project to transition to the marketplace: BioBridge Global obtained U.S. Food and Drug Administration (FDA) approval for an adult human mesenchymal stem cell product useful for regenerative medicine therapies
- Developed strong alliances with BIO, Advamed, and MedTech Innovator to expand MTEC’s reach, resulting in an increase in membership and access to military-relevant technologies
- Implemented solutions to address lessons learned that will drive improvements in 2020:
 - Implemented several mechanisms to help members team and understand military requirements
 - Established collaborations with military project managers to drive milestone compliance
- Reduced research overhead costs to apply more funding to projects



MTEC's Goals for 2020

Enhance MTEC's relationship with the venture capital investor community

Initiate outreach to corporate development offices

Increase the diversity of Government funding sponsors

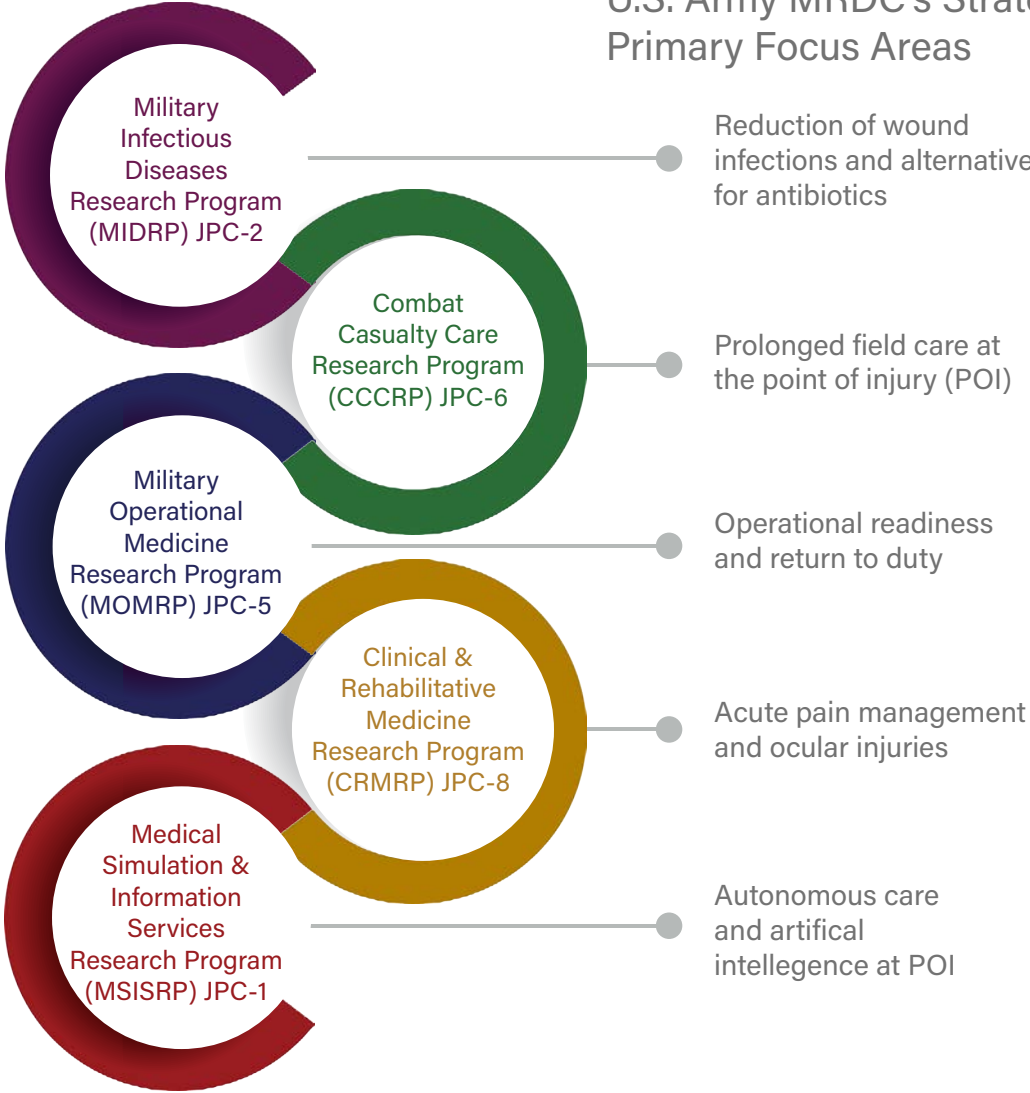


Concentrate outreach efforts on additional philanthropic funders

Implement a solicitation management software to streamline the solicitation-to-award schedule

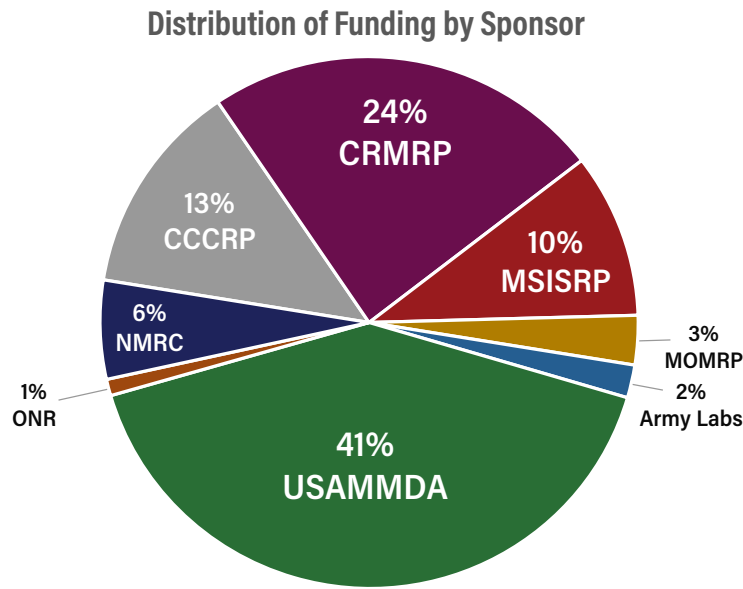
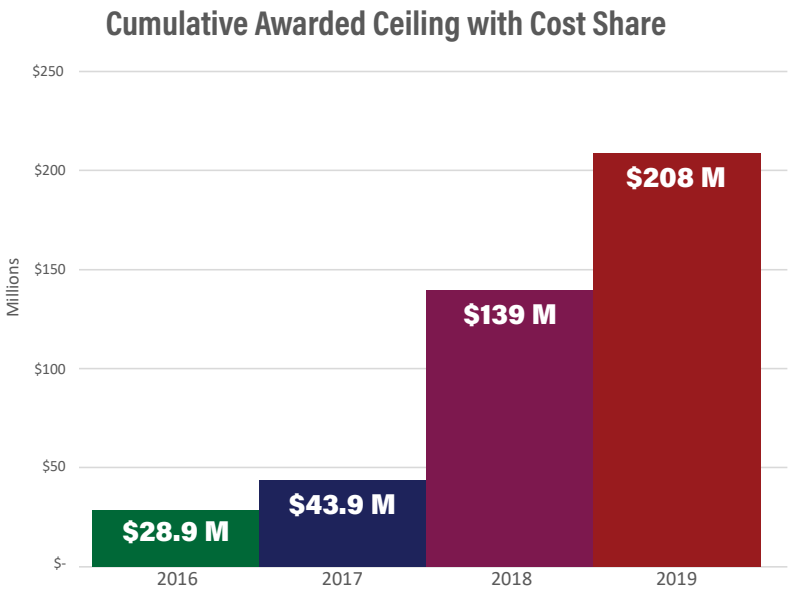
The U.S. Army Medical Research and Development Command (MRDC) has been MTEC's leading funding sponsor. For 2020, research and prototyping efforts will focus on the future operational environment to project and sustain soldier lethality to include renewed emphasis on the following priorities.

U.S. Army MRDC's Strategy for 2020 Primary Focus Areas



Funding Overview

MTEC experienced significant growth in funding, awards, and diversity in sponsorship in 2019. We expect this trend to continue in 2020, with approximately \$60M already identified for execution.



Membership Growth

MTEC membership has continued to grow in 2019, increasing to 336 member organizations, 60% of which represent nontraditional defense contractors (NDCs). Academia and small businesses offer emerging innovations and new trends to the consortium. Large industry plays an important role in presenting opportunities for potential licensing agreements and acquisitions. Other members provide critical support services, such as regulatory consultants, contract research organizations (CROs), and contract development and manufacturing organizations (CDMOs). MTEC makes a conscientious effort to recruit members from all of these different organizations to create a well-rounded consortium.



Benefits of MTEC Membership:

- Provides a means for open and transparent communication between the government and technology providers to better understand the military needs
- Promotes teaming among offerors to provide the sponsor with more complete proposals that better meet technical requirements
- Facilitates the transition to long-term prototype agreements
- Provides access to other military contracting opportunities beyond MTEC
- Provides introductions to Fortune 500 companies, venture, and foundations as additional funding sources

Military Infectious Diseases

- OBJECTIVE: Prevent infectious disease threats to eliminate their impacts on operational readiness.**
- Specific areas of interest include:

 - Vaccines and drugs to prevent parasitic diseases (malaria)
 - Vaccines to prevent diarrheal diseases
- Vaccines to prevent viral diseases (dengue, hanta)
 - HIV countermeasures
 - Therapies to prevent and treat combat wound infections
 - Protection from disease-carrying arthropod vectors
 - Countermeasures against emerging infectious diseases

2019 Awards

Project Title	Prime Awardee(s)	Federal Ceiling Value	Cost Share	Sponsor*
Dual Activities of Novel Lipoxygenase Inhibitors to Combat Gram-Negative Pathogens and Sepsis	SRI International	\$999,939	\$0	WRAIR
Development of Personalized Bacteriophage Therapeutic for the Treatment of Bacterial Infections	Adaptive Phage Therapeutics	\$10,902,428	\$990,559	NMRC
Electroceutical Technology against Bacterial Drug Resistance	Indiana University	\$200,000	\$100,000	USAMRDC

2019 Solicitations Pending Award in 2020

Solicitation Title	Expected Number of Awards	Anticipated Federal Ceiling Value	Sponsor
Military Infectious Diseases – Prototype Innovation Program (MID-PIP)	4	\$10,000,000	USAMRDC

Combat Casualty Care

- OBJECTIVE: Reduce the mortality and morbidity associated with major combat related to trauma across the spectrum of care - from battlefield to CONUS-based hospitals.**
- Specific areas of interest include:

 - Hemorrhage control and resuscitation
- Traumatic brain injury care
 - Blood and blood products far forward
 - Burn injury and organ support
 - Tactical combat casualty care interventions
 - Extremity and maxillofacial trauma treatment
 - Prolonged field care

2019 Awards

Project Title	Prime Awardee(s)	Federal Ceiling Value	Cost Share	Sponsor
Oxygen Carrier for Use in Hemorrhagic Shock Resuscitation	Virtech Bio	\$6,948,432	\$913,487	USAMRDC
The Effects of Complete and Partial REBOA with Pharmacologic Treatment in Swine Models of Hemorrhagic Shock	University of Michigan	\$1,607,524	\$248,922	USAMRDC
BurRapid Epidural Drainage Attachment for Traumatic Brain Injury	Critical Innovations, LLC	\$998,799	\$225,302	USAMRDC
Rugged Real-Time Wearable Sensor for Assessment of Coagulopathy at Point of Injury	Aptitude Medical Systems, Inc.	\$2,499,759	\$0	USAMRDC
Circulating cfDNA Fragments for Detection and Diagnosis of Traumatic Brain Injury	Children’s Hospital of Philadelphia	\$2,191,389	\$369,350	USAMRDC
In-Field Detection of Acute Subdural Hematomas Requiring Urgent, Life-Saving Treatment in Severe TBI Patients	Kitware, Inc.	\$1,517,474	\$0	USAMRDC

2019 Solicitations Pending Award in 2020

Solicitation Title	Expected No. of Awards	Anticipated Federal Ceiling Value	Sponsor
Multi-Domain Life Saving Trauma Innovations (MuLTI)	3	\$5,700,000	USAMRDC
Hemorrhage Detection Technology	Minimum of 1	\$2,000,000	USAMMDA

Military Operational Medicine

OBJECTIVE: Develop countermeasures that address military-relevant stressors and prevent physical and psychological injuries during training and operations in order to maximize health, readiness, and performance.

Specific areas of interest include:

- Musculoskeletal injury
- Blunt, blast, and accelerative injury
- Behavioral health, wellness and resilience
- Psychiatry and clinical psychology disorders

- Health, readiness, and performance in austere environments
- Fatigue, cognitive health and performance
- Human operator health and performance in complex systems
- Environmental toxicant exposure
- Performance nutrition and weight balance
- Directed energy health hazards
- Biomedical aspects of human performance optimization and enhancement

2019 Awards and Solicitations

Project Title	Prime Awardee(s)	Federal Ceiling Value	Cost Share	Sponsor
Validation of Wearable Sleep and Fitness Monitor with the Sleep Tank Model	Institute for Behavior Resources	\$244,949	\$0	USAMRDC
Mobile Stress and Anger Management Tool (MSAT) Expansion and Evaluation	Design Interactive, Inc.	\$1,924,129	\$0	USAMRDC
LifeLens Physiologic Monitoring Platform – Ascent	LifeLens Technologies, LLC	\$2,996,970	\$0	USAMMDA
Optimizing the Scalability of Evidence-Based Behavioral Sleep Medicine Practices with iREST	Rehat LLC	\$1,222,973	\$0	USAMRDC
Integrated Tele-Sleep Mobile Platform Tele-Sleep Decision Assist Tool	University of Maryland, Baltimore	\$2,000,000	\$0	USAMRDC

Clinical and Rehabilitative Medicine

OBJECTIVE: Develop restorative treatments to maximize function of wounded Service members in terms of duty, performance, and quality of life.

Specific areas of interest include:

- Treatment of Neuromusculoskeletal (NMS) injury
- Battlefield pain management
- Biomanufacturing of regenerative medicine therapies

2019 Awards and Solicitations

Project Title	Prime Awardee(s)	Federal Ceiling Value	Cost Share	Sponsor
Cardiosphere-Derived Cells for the Regeneration of Skeletal Muscle Following Traumatic Volumetric Muscle Loss	Cedars-Sinai Medical Center	\$1,930,033	\$0	USAMMDA
Enhanced Biologic Scaffold for Volumetric Muscle Loss	University of Pittsburgh	\$1,839,921	\$140,786	USAMMDA
Anti-Scar Treatment for Deep Partial Thickness Burns	Tesa Labtec GmbH	\$2,351,240	\$0	USAISR
A Novel Perfusion-Based, Scalable, and Single-Use Cell Expansion Bioreactor Advanced Development and Demonstration in a Clinical Cell Manufacturing Environment	Southwest Research Institute	\$2,948,354	\$0	USAMRDC
Development of a Universal Bioreactor Platform for Development Organization Regenerative Medicine Clinical Manufacturing	RegenMed	\$3,000,000	\$3,125,000	USAMRDC
Large-Scale Manufacturing of Extracellular Matrix (ECM) Hydrogels for Regenerative Medicine Applications	University of Pittsburgh	\$1,995,843	\$213,144	USAMRDC

Medical Simulation and Information Sciences

OBJECTIVE: *Improve patient safety and quality of care by transitioning more capable healthcare information and medical simulation technologies and systems, addressing stakeholder priorities to bridge existing and future capability gaps in the military health system, and proactively integrating and implementing emerging technologies into military healthcare relevant applications.*

Specific areas of interest include:

- Medical simulation (Joint Evacuation and Transport

Simulation (JETS), Point of Injury and Trauma Simulation (POINTS), Warfighter Performance, Resilience, Effectiveness, and Protection (WarPREP), Theater Hospital Operations Replication (THOR), Simulated Hospital Operations and Treatment System (SHOTS))

- Health information technology and informatics
- Medical capabilities to support dispersed operations
- Autonomous care and artificial intelligence at POI

2019 Awards

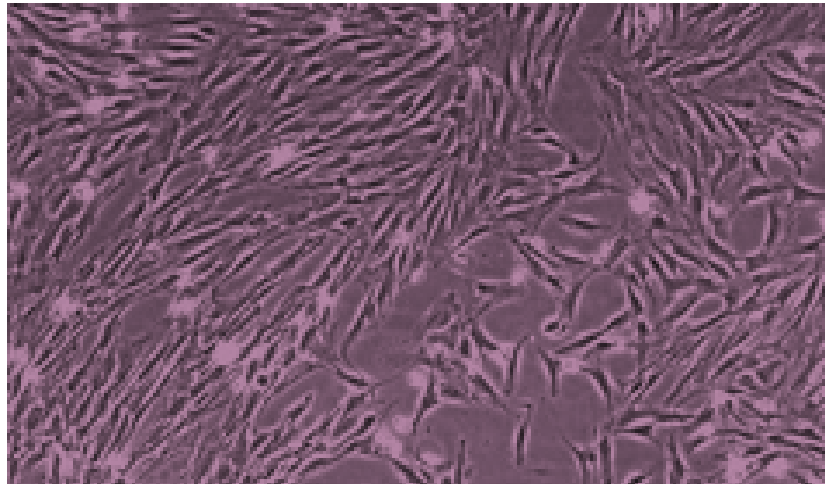
Project Title	Prime Awardee(s)	Federal Ceiling Value	Cost Share	Sponsor
Assessment of Psychological and Physiological Effects of Augmented Reality (APPEAR): Development of the Dual-Adaptation Protocol for Augmented Reality	Design Interactive, Inc.	\$1,249,999	\$0	USAMRDC
APPEAR: Augmented Reality Psychological Suitability Measures and Models	Design Interactive, Inc.	\$1,249,999	\$0	USAMRDC
APPEAR: Psychological	Chenega Healthcare Services, LLC	\$1,224,864	\$0	USAMRDC
A Realistic, Portable and Deployable Medical Patient Simulator Using Augmented Reality Technology for Mass Casualty Medical Response Training	Chenega Healthcare Services, LLC	\$749,653	\$0	USAMRDC
I-Predict Thorax Model Prototype Phase II	Southwest Research Institute	\$1,574,969	\$0	ONR
Burn Patient Transfer System (BPTS)	Chenega Healthcare Services, LLC	\$1,827,607	\$0	USAMRDC

Diversified Portfolio of Funding Sponsors

Although the U.S. Army Medical and Research Development Command’s Joint Program Committees are MTEC’s biggest funding sponsor, the portfolio of sponsors was well diversified in 2019.

2016	2017	2018	2019
Clinical & Rehabilitative Medicine Research Program (CRM RP)	Combat Casualty Care Research Program (CCCRP)	Clinical & Rehabilitative Medicine Research Program (CRM RP)	Combat Casualty Care Research Program (CCCRP)
	Clinical & Rehabilitative Medicine Research Program (CRM RP)	Medical Simulation & Information Sciences Research Program (MSISRP)	Clinical & Rehabilitative Medicine Research Program (CRM RP)
	Medical Simulation & Information Sciences Research Program (MSISRP)	Office of Naval Research (ONR)	U.S. Army Institute of Surgical Research (USAISR)
	Military Operational Medicine Research Program (MOMRP)	U.S. Army Medical Materiel Development Activity (USAMMDA)	Military Operational Medicine Research Program (MOMRP)
	U.S. Army Medical Materiel Development Activity (USAMMDA)		Naval Medical Research Center (NMRC)
			U.S. Army Medical Materiel Development Activity (USAMMDA)
			Walter Reed Army Institute of Research (WRAIR)

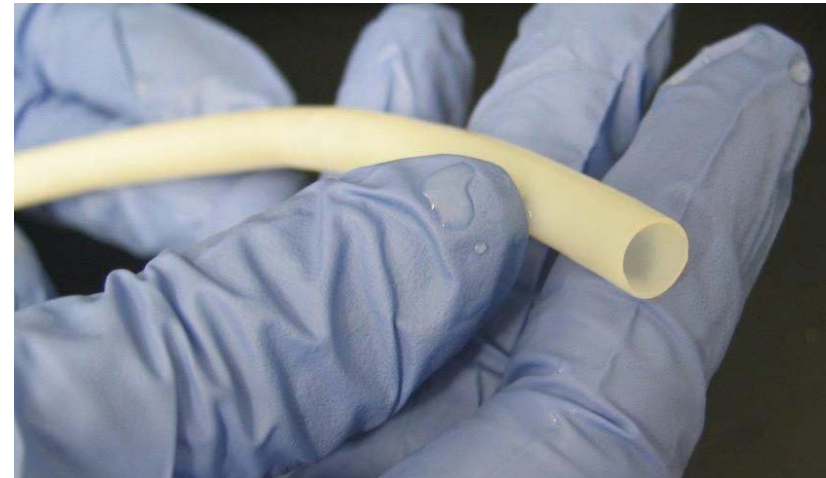
Research and Development Success Stories



Commercial Scale Up of Bone Marrow-Derived Mesenchymal Stem Cells (MSCs) for Regenerative Medicine
Project Team: BioBridge Global; Rooster Bio, Inc.; StemBioSys; US Army Institute of Surgical Research

Beyond enabling the development of new regenerative medicine, MTEC funding has been instrumental in providing this project team a springboard for new business in the United States, such as:

- Expanded service offerings geographically
- Routine support provided to academic researchers and small companies working through clinical trial preparations
- Development of new capabilities and support for cell manufacturing



Human Tissue Engineered Blood Vessels for Vascular Reconstruction in the Injured Warfighter
Project Team: Humacyte, Inc.

Humacyte has developed technology to bioengineer human acellular vessels (HAVs) that can be used to repair or replace damaged vasculature in warfighters and civilians. Humacyte's HAVs are now being clinically evaluated in patients experiencing blood vessel damage caused by blunt trauma, penetrating injuries, or other catastrophic events. MTEC funding has provided Humacyte an opportunity to partner with the military to navigate the uncharted regulatory pathway of innovative products to treat vascular injuries.



Manufacturing of a Negative Pressure Wound Therapy Dressing for Hand Wounds: ReHeal Glove
Project Team: University of Texas at Arlington, ReHeal LLC

The team at University of Texas, Arlington used MTEC funding provided through the prototype acceleration award to establish the manufacturing, assembly, sterilization, and packaging process for the ReHeal Glove. The award has successfully advanced the development of the ReHeal Glove to its next milestone, which enabled the team to successfully receive funding (2019) via the Congressionally Directed Medical Research Program (CDMRP) for early feasibility pilot trials in human subjects.

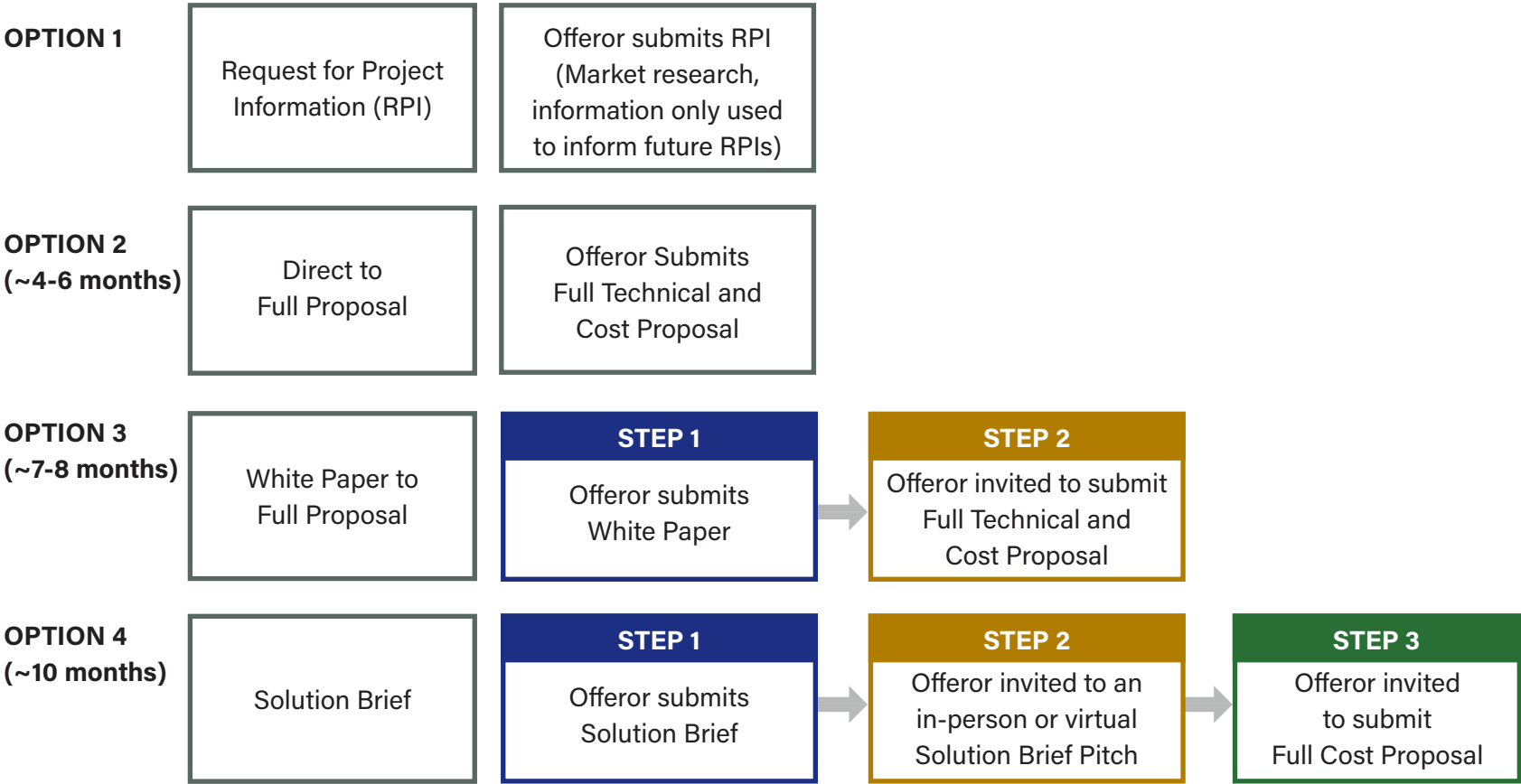


Fast Onset Abdominal Management (F.O.A.M.)™ Preclinical Studies
Project Team: Critical Innovations LLC

F.O.A.M.™ is designed to control severe intra-abdominal bleeding in critically ill trauma patients, when surgical intervention is not immediately available. MTEC funding has been instrumental in assisting Critical Innovations in propelling the device through key development milestones and closer to regulatory submission, where the program has achieved Breakthrough Device Designation from the Food and Drug Administration and has delivered very encouraging porcine study survival data. The device is now transitioning to large-scale manufacture.

Solicitation and Award Methodologies

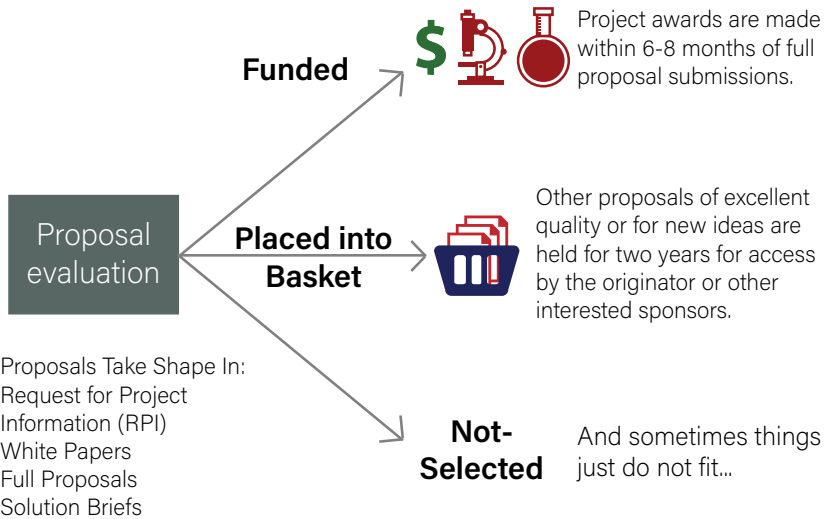
MTEC has developed tailored but formalized solicitation methods aligned to both funding sponsor desires as well as the complexity and maturity of the technologies being advertised for bid.



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.



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 the 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.
- Frequent, open communications between Government and industry helps map industry capabilities and trends to Government needs, leading to more responsive proposals.
- Post evaluation teaming is facilitated to bring segregated capabilities together in one proposal and project execution.

Technology and Company Outreach

An important facet of the MTEC mission is our ability to provide technology solutions that are responsive to the military's medical needs. In support of this goal, MTEC conducts outreach at several venues to recruit businesses and universities with military-relevant technologies. The outreach goals for 2020 include:

- Attend large medical conferences, such as BIO and ADVAMED Med Tech
- Present and/or exhibit at small and large conferences
- Participate in medical investment/venture conferences to foster collaborative opportunities with the investor community
- Conduct annual military "pitch days" through MedTech Innovator
- Attend military symposia (MHSRS), geography-centric events (SoCalBio), and research topic-specific meetings (annual vision research funders)
- Visit university campuses to explain the workings and benefits of military funding
- Interact with other funders (venture and foundations) to determine collaborative opportunities that overlap with military needs



Biotechnology
Industry
Organization



MTEC's membership integrates diverse organizations into cohesive teams that provide innovative medical solutions to both the military and the global community.

Feedback from Sponsors and Members

"Joining MTEC has been the best decision we have made in our first two years of our medical device launch. The MTEC staff has opened doors to connections and expertise that has truly been an enormous boost to our business that has helped define our path into 2020."

Tim Koehler, CEO. RAIN Scientific Inc.

"The MTEC OTA empowers member organizations of all sizes and academic institutions to work together with the Government to deliver advanced technologies and vital research to those who have sacrificed so much for our country."

Sara Langdon, Program Manager, USAMRMC

"The transparency, efficiency, and adaptability offered by MTEC and its outstanding team accelerate every step of the award process, from development to reporting."

Anne Germain, Ph.D., Co-Founder and CEO, Noctem, LLC

"MTEC has rapidly improved our ability to bring in innovative solutions and, where necessary, accelerate partnerships with the DoD. The OTA significantly enhances our ability to address critical Service member needs from medical R&D."

CDR Christopher Steele, Director & Joint Program Committee-5 Chair,
Military Operational Medicine Research Program, USAMRDC, Funding Sponsor

Board of Directors

MTEC's Board of Directors have decades of experience in both the military and medical domains who provide strategic oversight to the consortium. The Board includes several representatives from member organizations across MTEC's various segments, such as small business, large business, and academia. In addition, the Board includes three members with expertise in the areas of fundraising and financial management, legal technology transfer and acquisition, and military research. For profiles, visit: mtec-sc.org/board-members.

According to the MTEC Bylaws, the Board of Directors operates on a cycle where term limits are predetermined. We would like to thank Les Sherman, who represented the at-large member segment, for his service. Les has decades of experience producing medical devices for military use, and he provided MTEC with an invaluable "real world" perspective. He will be sorely missed! We wish him well on the ski slopes of Colorado, where he counts every day on the mountain a good day.

But as we say goodbye to one, we are excited to welcome our newest member – Dr. Andrew Omidvar.



Dr. Andrew Omidvar, MBA

Dr. Andrew Omidvar joined Philips as Vice President of Enterprise and Government R&D for Healthcare. He is responsible for shaping the long-term business strategy for Philips in the Federal Government Research & Development sector. Dr. Omidvar's experience and network will be beneficial to MTEC as he can help guide and align strategies to the stakeholder's mission and vision. He can also advance and guide innovations required for our service members to commercialization and bring industrial scale to military medical solutions. He has been instrumental in bridging gaps between requirements and R&D innovations to further support who needs them the most. Dr. Omidvar is a new addition to MTEC's Board of Directors because he has a clear vision and path from what could be to what can be.

Updates on the 2019 Strategic Plan

Goal 1: Improve Outcomes for Our Sponsors



- Proposal acceptance rate > 40%
- Diversity of funding sponsors increased
- User's manual published and military "OTA Workshop" conducted. BIDs (BAA Information Delivery System) delayed, but MTEC will pilot the program in Q1 2020

Goal 2: Provide Research and Business Opportunities for Our Members



- Strong relationship building between the military and our members
- Venture capital addendum in operation to enhance reviews by investor groups
- Educational webinars offered

Goal 3: Develop and Encourage Collaborations



- Over 70% of awards were made to teams
- MTEC's teaming software (collaboration database tool) and teaming newsletter are active

Goal 4: Serve as a Conduit for External Funding

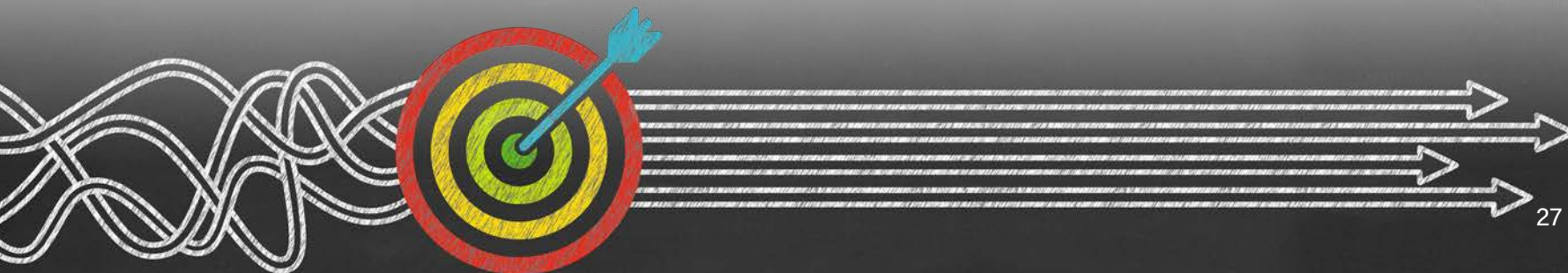


- Partnering with foundations and investors will be a priority in 2020
- Launched Lives Restored philanthropic campaign
- Actively revising our philanthropic approach, since initial efforts did not meet expectations

Goal 5: Generate and Maintain Resources to Fulfill MTEC Mission



- Growth in the number of awards has increased the resources available for MTEC operations
- Prudent budgets have maintained low operational costs (1.7%)
- Surplus generated additional research funding to be awarded in 2020



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.

Kathy Zolman
MTEC Director of Program Operations
kathy.zolman@ati.org

Funding Sponsor Benefit

The government sponsor gains ready access to a consortium of diverse, capable technology providers. Effective, streamlined solicitation processes lead to better proposals and better potential of success in R&D efforts.

Lauren Palestrini
MTEC Director of Research
lauren.palestrini@officer.mtec-sc.org

Philanthropic Benefit

Individuals and corporations can partner with MTEC to fund much needed medical research and development that may benefit our nation's warfighters, but also both Americans and global civilian populations.

Susan Raymond, Ph.D.
MTEC Director of Strategic Funding
sraymond@changingourworld.org

