
Subject: Announcing the MTEC Multi-Topic Solicitation

The Medical Technology Enterprise Consortium (MTEC) is excited to post this announcement for a **Request for Project Proposals (RPP) aimed to solicit prospective and current MTEC members for a broad range of medical technological solutions related to the seven Technology Focus Areas identified below.** Relevance to the healthcare needs of military Service members, Veterans, and beneficiaries is a key feature of this RPP.

The MTEC mission is to assist the U.S. Army Medical Research and Materiel Command (USAMRMC) by providing cutting-edge technologies and effective materiel life cycle management to transition medical solutions to industry that protect, treat, and optimize Warfighters' health and performance across the full spectrum of military operations. MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement (OTA), Agreement No. W81XWH-15-9-0001, with the U.S. Army Medical Research Acquisition Activity (USAMRAA). MTEC is currently recruiting a broad and diverse membership that includes representatives from large businesses, small businesses, "non-traditional" government contractors, academic research institutions and not-for-profit organizations.

Acquisition Approach

This RPP will be conducted using a two-staged approach, which is intended to streamline the initial proposal preparation time and effort. In Stage 1, prospective and current MTEC members are invited to submit White Papers using the format contained in this RPP against the seven Technology Focus Areas identified below. The Government will evaluate White Papers submitted and will select White Papers that best meet their current technology priorities. Offerors whose technology solution is selected for further consideration based on White Paper evaluation will be invited to submit a proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements. Prospective MTEC members submitting White Papers that are selected for further consideration will not receive a Stage 2 notification letter until they become a MTEC member. Rather, prospective members will be invited to become MTEC Members should they wish to continue to Stage 2. The Stage 2 process may vary depending on the Technology Focus Area and funding available. For example, some Stage 2 processes may require oral presentations, a commercial solutions offering (solutions brief), and/or full proposal submission using either the Full Project or Small Project Proposal Preparation guides.

Potential Funding Availability

The funding amount for this RPP is unspecified, and the number of awards is indeterminate and contingent upon funding availability. Any funding that is received by the USAMRMC and is appropriate for a research area described within this RPP may be utilized to fund proposals/applications. There are no specified funding limitations identified for a proposal submitted under this RPP. A budget should be commensurate with the nature and complexity of the proposed research.

Technology Focus Areas

Examples of specific areas of interest include, but are not limited to the following. These areas of interest are not listed in order of importance.

1) 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

2) 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; in 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
 - Act as resuscitation agents/therapeutics for treatment of shock and TBI to prevent secondary brain injury
 - Perform Evaluation of venous thrombosis chemoprophylaxis to prevent microthrombi and secondary brain injury in animal models of TBI
- o Advance designs for devices intended to diagnose concussion. These advances may include efforts to miniaturize, militarize, evaluate, and/or develop or enhance output/user interfaces. 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 resuscitative endovascular balloon occlusion of the aorta (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).
- Prototype medical simulation technologies, components, sub-systems and systems that will enable Medical Simulation Enterprise programs of records, 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 Joint Evacuation Training Simulation (JETS) and Point of Injury Training System (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 (FDA) 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.

All white paper 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. At a minimum, these projects must be at 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.

Other Information

MTEC is seeking input from **both MTEC members and non-members** via a project information paper to be considered by the panel. Project information papers will be shared with the panel under non-disclosure agreements. The MTEC may invite one or more of those who submit project information papers to participate in, or present to, the panel during their convening.

White papers are **due no later than September 29, 2017 at noon EDT**. MTEC membership is **NOT** required for the submission of a white paper in response to this MTEC RPP. Requirements of the White Paper can be found in the full RPP.

To view this solicitation, click [here](#).

Sincerely,

MTEC Project Team

