

2017 Annual Report

They serve selflessly. LET'S HELP HEAL THEM.

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OUR MISSION: To be the partner of choice for private industry, academic institutions, government agencies, and other research organizations seeking to accelerate the development of medical solutions that prevent and treat injuries and restore America's military and veterans to full health.

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 public-private collaboration among the United States Government, academic institutions, private industry, and philanthropic organizations. The organization facilitates faster transition from the laboratory to the patient, either on the battlefield or at the bedside, and then onward to the global community.

MTEC provides this public-private collaboration using a simplified contracting vehicle (the Other Transactions Agreement (OTA)), which enables Federal Sponsors to quickly and openly partner with academic, industrial, philanthropic, and investment organizations. The OTA tears down the walls that traditionally hinder public-private collaboration 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, and they partner to respond to Government-funded requests for proposals.

MTEC's team contributes to this acceleration. Experienced with Government funding, private industry finance, and implementation of military medicine and biomedical research, MTEC's executives and independent Board of Directors rapidly identify potential partnerships and manage those partnerships for efficient results and commercialization.

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MESSAGE FROM THE PRESIDENT

Dear Friends,

Thank you for your enthusiastic participation in MTEC! This has been a formative year in the life of our organization, and I am pleased to share our first Annual Report with you. We have made great strides since we were established in February 2016. MTEC saw significant growth in 2017, and I project that 2018 will be a year of great opportunity and continued success!

At MTEC, we never forget who we serve through our work—the Soldiers, Sailors, Airmen and women, and Marines in need of innovative technologies and methods to support military medical readiness, and improved clinical care and physiological function. We work with dedication and enthusiasm on their behalf. We are grateful to you, whose interest and support shape the future of MTEC and, most importantly, of those we serve.



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

As I reflect on our accomplishments over the past year, I am proud to share with you that we have:

- Diversified and expanded the number of solicited research topics from 1 medical technology focus area with 2 research topics in 2016 to 6 medical technology focus areas with 55 research topics in 2017;
- Expanded from 2 solicitations in our pilot year to 13 this year;
- Diversified our military sponsors from one to six organizations;
- Built a co-investment network of foundations, venture capitalists, and other investors to potentially supplement military funding;
- Grew our Board of Directors to include professionals from finance, investment, philanthropy, law, government affairs, research and development, and venture capital;
- Developed solicitation templates and contract methodologies that are tailored to support more efficient and agile acquisition strategies aligned to the needs of each military project and Sponsor;
- Increased consortium membership to over 150 organizations; and
- Initiated a Young Leaders Council of former military members to amplify MTEC's outreach.

I have challenged the MTEC staff to increase our productivity through learning from our experiences and by growing our existing relationships into sponsorships and memberships. We are striving to reduce time to award, thereby increasing the speed of prototype testing. To supplement our military funding, we are seeking significant non-Federal funding through our partnerships with foundations, venture capitalists, and other fundraising activities. This includes substantial growth of our individual donor program in 2018. We hope to double the number of biomedical technology providers—especially emerging firms—among our membership to bring forward more innovative solutions. Finally, we are working to increase our members' access to military and outside funding to accelerate the maturation of their own businesses. We are excited to work with you to conquer each of these challenges!

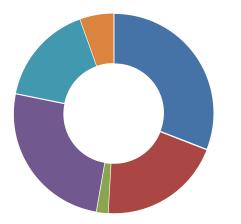
Thank you for accompanying us on this important journey. Together, we will write the future of MTEC.

My Best Regards, Dr. Lester Martinez Lopez

MEDICAL TECHNOLOGY FOCUS AREAS

(including all research topics solicited in 2017)

Distribution of Research Topics by Technology Focus Area Solicited in 2017



CLINICAL AND REHABILITATIVE MEDICINE

Innovation in definitive and rehabilitative care to reset wounded Service members in terms of duty, performance, and quality of life

- Muscle regeneration
- Bone regeneration and grafting
- Rebuilding skin after injury
- Regenerative medicine manufacturing
- Vision restoration
- Hearing restoration/repair
- Wound care (treatment of infection, bandages, dressings)
- Anti-infective therapies that prevent infection, reduce inflammation and pain sensation
- Permanent vascular repair
- Traumatic brain injury treatment
- Treatments of spinal cord injury
- Systemic peripherally-acting analgesics for severe acute pain
- Novel implanted or external interfaces that can acquire high fidelity physiological signals to drive advanced prosthetics or provide sensory/proprioceptive input
- Technologies to objectively assess neuromusculoskeletal rehabilitation across the spectrum of care
- Decellularization/recellularization scaffolding strategies
- 3D bioprinting and biofabrication of tissues and organs
- Artificial organ replacement

- Clinical & Rehabilitative Medicine
- Medical Simulation & Information Sciences
- Advanced Medical Technologies
- Combat Casualty Care
- Military Operational Medicine
- Infectious Disease

MEDICAL SIMULATION & INFORMATION SCIENCES

Exploration of the use of technology for medical training and for the provision, management, and support of health services in the military

- IT architecture for the Joint Evacuation and Transport Simulation (JETS) system
- Innovative defense medical logistics (i.e., shipping, inventory control)
- Models to predict the body's response to injury
- Medical device interoperability Precision medicine that uses genetic profiling or proteomics to identify improved clinical approaches for hospital-based care for both military and civilian medical needs
- Business practice-driven automated applications that improve clinical outcomes
- Virtual models for education and training
- Medical simulation technologies
- Holographic technologies
- Medical synthetic training environment prototypes
- Prototype medical simulation technologies, components, sub-systems and systems that will enable Medical Simulation Enterprise programs of records

INFECTIOUS DISEASE (ID)

Prevention, diagnosis, and treatment of ID encountered by service members during deployment and those that can significantly impact performance

- Dengue human infection model
- Combating antibiotic-resistant bacteria
- Systems biology approaches to antimicrobial resistance

COMBAT CASUALTY CARE

Development of medical interventions that can be used on the battlefield to reduce morbidity and mortality

- Cellular therapies for the treatment of hemorrhagic shock
- Extracorporeal life support devices
- Traumatic brain injury diagnosis
- Devices intended to diagnose concussion
- Technologies that provide prolonged field care
- Diagnostics that assist in directed care for personnel
- Hemostatic devices
- Point of injury wound care
- Wound dressings for prolonged field care
- Treatment of non-compressible hemorrhage
- Devices and techniques to extend the time for application of resuscitative endovascular balloon occlusion of aorta
- Pharmacological-based stabilization approaches
- Telehealth technologies and tools
- Stabilization of the craniomaxillofacial soft tissue envelope following acute injury

ADVANCED MEDICAL TECHNOLOGIES

Development of initiatives and products that will increase medical mobility while ensuring access to essential medical expertise and support, regardless of the operating environment

MILITARY OPERATIONAL MEDICINE

Development of effective countermeasures against stressors to maximize health, performance, and fitness

- Wearable physiological and performance sensors
- Experimental and computational platforms to characterize host responses to environmental health hazards
- Methods to detect, assess the risk of, or reduce the risk of musculoskeletal injury
- Pharmaceutical interventions to prevent hearing loss from exposure to hazardous noise
- Interventions to promote sleep, manage sleep/work cycles, and/or maintain cognitive performance
- Injury criteria and medical performance standards to protect against hearing loss, vestibular injury, and ocular facial injury
- Nutrition-based interventions
- Evidence-based tools that address a broad range of behavioral health issues
- Treatment of post-traumatic stress disorder (PTSD)





ONGOING FUNDED RESEARCH

MTEC has focused on building collaborations that contribute to top-notch biomedical research, development, and clinical studies related to our six medical technology focus areas. The number of solicitations released significantly increased from 2 in 2016 to 13 in 2017, resulting in an increase in research topic areas from 6 in 2016 to 55 in 2017. Additionally, the total number of awards increased from 8 to 20, including those in process and under negotiations, totaling \$52 million in available 2017 funds. This number includes \$11.5 million in private funding that was recruited into MTEC to supplement funding provided by the military.

Many exciting projects were awarded in 2017, some of which are highlighted below. The OTA has enabled MTEC to significantly reduce the timeline of traditional contracting methods (e.g., 4.5–12 months from solicitation to award instead of 12–24 months). We provide a summary of funded research in the table below. A complete list of the ongoing funded research is provided on page 9. The list includes all research activity funded in 2016 and 2017, and research solicitation activity that carried over from 2017 into 2018. Refer to the MTEC website (mtec-sc.org) for additional detail.

continued expansion projected for 2018.										
Number of:	2016	2017	2018 (Projected)							
Solicitations	2	13	10							
Research Topics	6	55	50							
Projects Selected (on contract or in process)	8	20	30							
Available Funds	\$32M	\$52M	\$85M							
Federal Funds	\$21M	\$40.5M	\$75M							
Private Funds	\$11M	\$11.5M	\$10M							
Consortium Members	87	154	225							

MTEC has successfully increased the number of research projects awarded and the availability of funds from 2016 to 2017, with continued expansion projected for 2018. **MULTI-TOPIC**: MTEC launched its first Multi-Topic Request for Project Proposals (RPP) in June 2017, which aimed to solicit white papers from prospective and current MTEC members. Although 40 specific areas of technical interest were included in the RPP, Offerors were invited to submit white papers on a broad range of medical technological solutions related to MTEC's six technology focus areas. White papers are currently under review by the military, and the Government will invite those Offerors selected for further consideration to submit a proposal in Stage 2. The Multi-Topic RPP mechanism operates as an "open door" between the MTEC community and the military, enabling the military to solicit solutions to specific problems, and the scientific community is able to either meet those specified needs or recommend a solution to a different medical need with military relevance.

JOINT EVACUATION AND TREATMENT SYSTEM (JETS): The development of a simulation architecture that allows users to access critical individual and team training on evacuation procedures and clinical protocols from multiple device entry points at any time and any location can significantly improve en route care for Warfighters. These critical skills are not reinforced in daily clinical care, and the capability to immerse individuals into valuable training scenarios on their own schedule can enhance the readiness of the deployable teams. Through MTEC, the military leveraged the flexibility of the OTA to form a new team from two separate companies to build a military-targeted simulation capability.

VASCULAR REPAIR: Vascular trauma to the extremities remains a major cause of morbidity and mortality among U.S. and allied Warfighters, and it has increased proportionately in recent conflicts. Optimal solutions would not only provide more durable repairs, but also reduce the need for autologous tissue (from the patient's own body) and decrease the number of surgical procedures required. Through an MTEC award, Humacyte, Inc. will complete several regulatory requirements in support of a submission to the Food and Drug Administration (FDA) for clearance to evaluate a novel human tissue engineered blood vessel (pictured below) in a trauma indication with military relevance. Previous Phase 2 clinical trials by Humacyte demonstrated the safety and efficacy of the engineered blood vessel for a renal/dialysis indication. This is a 'win-win' situation: Humacyte can expand its product use, and the military can leverage Humacyte's prior work to accelerate completion of a product with military relevance.





- Scientific and Biomedical Microsystems; Cambridge Neuro; Oxford University; University of Pennsylvania (developing a brain-machine interface composed of multiple individual penetrating silicon probe arrays, the size is pictured above relative to a coin)
- Arizona State University; Second Sight Medical Products, Inc.
- Massachusetts General Hospital; Bionic Eye Technologies, Inc.
- University of Maryland, Baltimore

VISION RESTORATION: Injuries related to the eye are among the most prevalent injuries that Warfighters sustain, accounting for 12–15% of all battlefield wounds. Early work has shown that stimulation of the brain can restore a level of vision to human patients. An image can be captured through camera-mounted glasses and forwarded to a computational device that translates stimuli to the brain through a microelectrode array implanted in the visual cortex. Though not a true aesthetic repair of the eye, the interim solution of a visual prosthesis provides basic sight functions, such as the ability to navigate, identify faces and objects critical to daily life, and read large print. MTEC made four awards totaling more than \$3.3 million that are focused on the development of a brain-machine interface, a major component of a visual prosthesis system (the list of Awardees is shown to the right). MTEC expects this to be an ongoing technology priority for the military. In 2018, MTEC's vision program will grow to include a new topic area—prototype technologies that restore, preserve, or regenerate the optic nerve damaged by traumatic eye injury.

PROTOTYPE ACCELERATION: This year, MTEC launched the Prototype Acceleration Award (PAA) mechanism, which focuses on advancing novel prototype technologies into the next major stage of development or next major milestone within a 12-month period of performance and for up to \$300,000. Examples of the next major stage of development/milestone include late animal testing and regulatory filing, manufacturing, next clinical trial, or regulatory approval. The Government selected six projects for award under the Prototype Acceleration Award mechanism this year. A list of the prime contractors and research topic areas are shown to the right.



- University of Texas at Arlington (dressing for hand wounds, pictured above)
- Ohio State University (bacterial drug resistance)
- Pulmotect, Inc. (prevention of pneumonia in damaged lung)
- SpherIngenics, Inc.(treatment of burns and ischemic wounds)
- Upside Biotechnologies Ltd.(treatment of severe burns)
- Wake Forest University (skin healing and regeneration)

Comprehensive List of Research Activity Initiated in 2016 and 2017, Including Carryover Activity into 2018

Solicitation No. Solicitation To	Collisitation Tonio	No. of Research	Year		Year awarded		ded	No. of	Total Funding	
	Solicitation Topic	Topics	2016	2017	2016	2017	2018	Awards	Federal	Private
16-01-REGEN	Regenerative Medicine Manufacturing	5	х		х			4	\$18 M	\$11 M
16-02-BMI	Vision Restoration	1	х			х		4	\$3.3 M	
17-01-DHIM	Dengue Human Infection Model	1		x			Х*	1*	\$3 M*	
17-02-PA	Prototype Acceleration	5		х		х		6	\$1.6 M	\$1.3 M
1/-03-01185	Cellular Therapy for the Treatment of Hemorrhagic Shock	1		x			х	1	\$2 M	\$1.5 M
17-05-PVR	Permanent vascular repair	1		х		х		1	0.65 M	\$3.6 M
17-07-1615	Prototype of Joint Evacuation and Transport Simulation	1		x			х	2	\$4 M	
17-08-Multi-Topic	Multi-Topic	44		x			Х*	>5*	>\$25 M*	>\$5 M*
17-09-ECLS	Extracorporeal Life Support Devices	1		х		х		1	\$1 M	
18-01-MEDLOG	Data Management Technologies and Industry Best Practices	1		x			Х*	1*	\$2.4 M	
18-04-I-PREDICT	Incapacitation Prediction for Readiness in Expeditionary Domains	1		x			Х*	2*	\$0.85 M	
Notes:										
00	ght blue color represent those solicitations v ents projections, not actual values	vhere awards are eit	her pen	ding or 1	the eval	uation	proces	s is curren	tly underwa	iy

UPCOMING RESEARCH TOPIC AREAS IN 2018

- Combating antibiotic-resistant bacteria (CARB)
- Systems biology approaches to infectious disease and combat trauma
- Treatment of traumatic brain injury (TBI)
- Treatment of post-traumatic stress disorder (PTSD)
- Treatment of spinal cord injury (SCI)
- Physiological monitoring/sensors

- Optic nerve regeneration
- In silico model of the human body to predict response to injury

- Telemedicine
- Autonomous and unmanned medical capabilities
- Peripheral nerve regeneration
- Cryopreserved platelets



Research topic areas for future solicitations can be developed to suit co-funding partnerships. The MTEC mechanism provides a process through which private funders work with public agencies to identify and co-fund areas of mutual interest.

SOLICITATION PROCESS – MULTIPLE CONTRACTING APPROACHES

MTEC has developed several proposal solicitation processes that promote a streamlined, interactive approach to acquisitions. Each acquisition is tailored according to the complexity of the research goals, the size of the efforts, and the maturity of the technologies. Rather than a one size fits all approach, MTEC has developed multiple contracting processes to meet the needs of the Government and our consortium. For example:

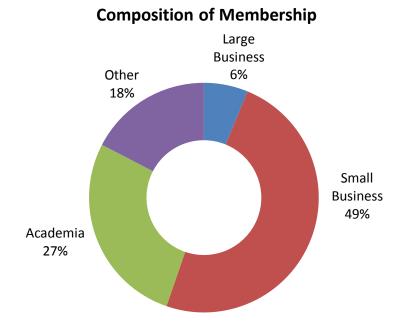
- Information Paper: A means to influence the Government's funding strategy and provide awareness of the "art of the possible" regarding specific military medical needs within the consortium's capabilities. Information papers explore technology approaches where a lack of current knowledge may exist.
- Direct to Full Proposal: Provides the fastest method to award where market research has validated strong technological maturity and a sufficient number of participant organizations offer solutions.
- White Paper to Full Proposal: Provides a means to identify approaches where a high level of confidence exists in the availability of technical solutions.
- Commercial Solutions Brief: An iterative approach for highly complex requirements that allows for frequent discussions with the Government to provide a better understanding of end goals without the requirement for Offerors to submit lengthy, detailed technical proposals.

In addition, the solicitation process developed by MTEC offers several advantages over standard Government contracting processes. For example:

- The OTA allows the Government to directly interact with potential Offerors to help Offerors more closely align proposals to the Government's medical needs.
- MTEC's management team can facilitate teaming among Consortium members in response to the Government's needs.
- Proposals are encouraged to include cost share to supplement Government funding.
- ✤ Faster timeline from solicitation release to date of award (4.5 12 months vs. 12 24 months).
- Basket provision allows source-selection-approved proposals to receive funding for 2 years.
- MTEC's outreach team can engage private funders (e.g., philanthropic, investor groups) to co-fund solicitations with the Government or directly fund from the basket.

CONSORTIUM MEMBERS

Our membership represents a wide range of organizations, including small and large businesses, academic research institutions, and not-for-profit organizations across all areas of military medicine. MTEC currently has over 150 member institutions from nine countries, which are poised to collaborate and contribute to innovative biomedical research and development. Fifty-three percent (53%) of member organizations are non-traditional defense contractors.



MTEC has implemented several strategies that provide value to consortium member organizations:

- Authorization to submit proposals in response to funding opportunities ;
- Access to the Federal market by small and emerging firms;
- Insight into the Government's medical needs;
- Ability to hear directly from the Government Sponsor on the solicitation, as well as to ask questions;
- Networking opportunities allowing organizations to form partnerships and learn from one another and government stakeholders at events, conferences, and forums;
- Information exchange with government attendees at MTEC membership meetings/MHSRS;
- Assistance with team formation through explanation of military needs, emphasis on commercialization end points, or post proposal evaluation discussions.

Joining MTEC is an easy process. Visit <u>https://mtec-sc.org/how-to-join-2/</u> for a step-by-step guide on how to join.

FUNDRAISING AND OUTREACH

Designed to develop the medical solutions that will protect, treat, and rehabilitate those who were put in harm's way in service to our Nation, MTEC brings hope and a better quality of life to our heroes.

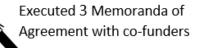
We are a nonprofit dedicated to veterans and those who serve. We believe that we owe it to our Warfighters and their future brothers and sisters in arms to develop and apply technologies that will preserve their lives, enhance their healing, and return the wounded to fully functioning lives. MTEC makes the wounded whole again by combining the resources of those who fund research and development with a best-in-class consortium of organizations to ensure rapid results.

We have the ability to partner with foundations, corporations, and individuals, teaming private dollars with government funding to accelerate promising medical research. Partnerships can be formed to sponsor a new research project, incrementally fund an existing initiative, award previous source selection-approved proposals, and grant out-of-cycle requests.

In 2017, MTEC



Received its FIRST philanthropic grant





Furthered co-funding conversations with 13 institutional prospects

Continued cultivation of 4 venture capital firms

In 2017, as part of our fundraising and outreach efforts, MTEC secured its first philanthropic grant from The Allergan Foundation, distributed its first broad-based appeal, and expanded promising co-funding conversations into the spinal cord injury, hearing, PTSD, TBI, and opioid addiction spaces.



The Allergan Foundation's Reception for Awardees.

From left to right: Gregory Brand, MTEC Outreach Member; Gwyn Grenrock, Executive Director of The Allergan Foundation; Skip Auch, MTEC Board Member; and Susan Stone, Foundation Board Member.

TO DONATE ONLINE, PLEASE VISIT: WWW.MTEC-SC.ORG

BOARD OF DIRECTORS

MTEC's Board of Directors is comprised of academic leaders and corporate executives with deep experience in medical technology development. As the governing body of MTEC, the Board of Directors oversees the organization's activities and ensures that it is meeting its mission. Dr. Lester Martinez Lopez, MPH, Major General (Ret.), U.S. Army, chairs the Board. The inaugural Board consisted of five members representing large medical device industry, large pharmaceutical industry, academia, and small industry. In July 2017, the Board was expanded to eight members to include representation from philanthropic organizations, for-profit new ventures, and the legal community. The members of MTEC's Board of Directors are:

- * Dr. Lester Martinez Lopez, MPH, Major General (Ret.), U.S. Army, President and Chairman, MTEC
- Mark D. Breyen, Senior Director, Global R&D, Non-Intensive Diabetes Technologies (Type 2), Medtronic Diabetes
- Dr. Kent Kester, FACP, FIDSA, FASTMH, Vice President and Head, Translational Science & Biomarkers, Sanofi Pasteur
- Theresa Peterson, Senior Executive of External Affairs and Advanced Technology Programs, General Electric*
- Gloria Matthews, DVM, PhD, DACVS, Senior Vice President of Research and Development, MiMedx Corporation*
- Str. Anthony Atala, MD, Director, Wake Forest Institute for Regenerative Medicine
- Leslie H. Sherman, *Managing Director and Co-Owner, Tircos, Inc.*
- Walter E. Auch, Jr., Founder, Auch Company, LLC
- Daniela Stricklin, PhD, MPH, Senior Science Advisor, Applied Research Associates, Inc.*
- Dr. Gautam S. Ghatnekar, PhD, President and CEO, FirstString Research
- Edward Steiner, Partner, Global Corporate Practice Group, Squire Patton Boggs (US) LLP



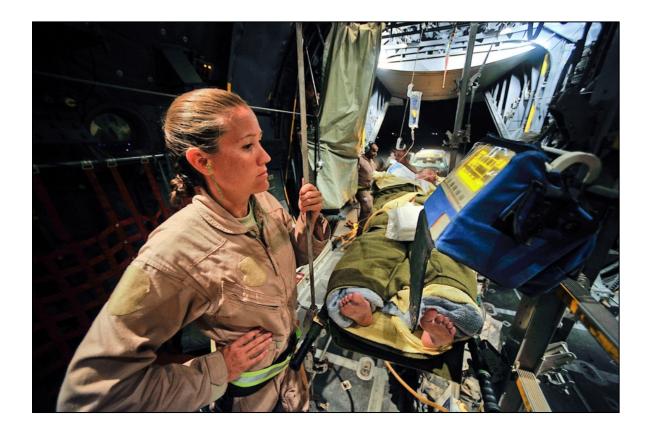
*Joined the MTEC Board on January 4, 2018

YOUNG LEADERS COUNCIL

The Young Leaders Council is composed of young veterans from across the country who are committed to MTEC's mission and to sharing this mission with others. As individuals who have seen the effects of injury on the battlefield—or have sustained injuries themselves—they know firsthand the importance of developing the medical solutions that will protect, treat, and rehabilitate our Nation's Warfighters. The Council seeks to lift awareness about MTEC – in general and among veterans – and to provide input into its messaging and communications efforts.

The current members of the Young Leaders Council are:

- Amanda Burrill, Lifestyle Personality and Freelance Writer and Former Naval Officer
- Joshua de Freitas, Senior Global Account Manager, Orthopedic and Soft Tissue Regenerative Materials Group, DSM Biomedical and Former Army Medical Evacuation (MEDEVAC) Officer
- Nicholas Graham, Engagement Manager, BLACKPANDA and Former Army Special Forces
- Myles Grantham, Director, Collegiate Access Program, Lead the Way Fund and Former Army Ranger
- Tim Lawton, Co-Founder, Frontier7 and Former Army Infantry Officer
- Colin Raymond, Group Facility Administrator, DaVita Kidney Care and Former Army Infantry Officer
- Nate Raymond, Senior Manager, Credera and Former Army Infantry Officer







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